



Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 483, 484, 488, 489, and 498

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RINs 0938-AU37 and 0938-AU32

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates the home health and home infusion therapy services payment rates for calendar year (CY) 2022 in accordance with existing statutory and regulatory requirements. This rule also finalizes recalibration of the case-mix weights and updates the functional impairment levels, and comorbidity adjustment subgroups while maintaining the current low utilization payment adjustment (LUPA) thresholds for CY 2022. Additionally, this rule finalizes a policy to utilize the physical therapy LUPA add-on factor to establish the occupational therapy add-on factor for the LUPA add-on payment amounts and makes conforming regulations text changes to reflect that allowed practitioners are able to establish and review the plan of care. It also finalizes proposed changes to the Home Health Quality Reporting Program (QRP) including finalizing proposed measure removals and adoptions, public reporting, and modification of effective dates. It also finalizes proposed modifications to the effective date for the reporting of measures and certain standardized patient assessment data in the Inpatient

Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP. In addition, this final rule codifies certain Medicare provider and supplier enrollment policies. It also makes permanent selected regulatory blanket waivers related to home health aide supervision that were issued to Medicare participating home health agencies during the COVID-19 public health emergency (PHE), and updates the home health conditions of participation regarding occupational therapists assessment completion to implement provisions of the Consolidated Appropriations Act, 2021 (CAA 2021). This final rule also finalizes proposals to expand the Home Health Value-Based Purchasing (HHVBP) Model and to end the original HHVBP Model one year early. Lastly, it establishes survey and enforcement requirements for hospice programs as set forth in the CAA 2021; and finalizes revisions to the infection control requirements for long-term care (LTC) facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as “nursing homes”) that will extend the mandatory COVID-19 reporting requirements beyond the current COVID-19 PHE until December 31, 2024.

DATES: These regulations are effective on January 1, 2022.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786-5229, for home health and home infusion therapy payment inquiries.

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

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

For more information about the Home Health Value-Based Purchasing Model, [https://share.cms.gov/center/CCSQ/CSG/DIQS/LTC/LTC COVID Reporting final rule/please](https://share.cms.gov/center/CCSQ/CSG/DIQS/LTC/LTC%20COVID%20Reporting%20final%20rule/please) visit the HHVBP Model Expansion webpage at <https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model>.

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

For information about the home health conditions of participation, contact Mary Rossi-Coajou at: mary.rossicoajou@cms.hhs.gov, James Cowher at james.cowher@cms.hhs.gov, or Jeannine Cramer at Jeannine.cramer@cms.hhs.gov.

For provider and supplier enrollment process inquiries: Frank Whelan, (410) 786-1302.

For information about the survey and enforcement requirements for hospice programs, send your inquiry via email to QSOG_Hospice@cms.hhs.gov.

For information about the LTC facility requirements for participation, contact Molly Anderson at: Molly.Anderson@cms.hhs.gov, Diane Corning at Diane.Corning@cms.hhs.gov, Kim Roche at Kim.Roche@cms.hhs.gov, or Alpha-Banu Wilson at Alphanu.Wilson@cms.hhs.gov.

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I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This final rule updates the payment rates for home health agencies (HHAs) for CY 2022, as required under section 1895(b) of the Social Security Act (the Act). This rule also finalizes recalibration of the case-mix weights under sections 1895(b)(4)(A)(i) and 1895(b)(4)(B) of the Act for 30-day periods of care in CY 2022 while maintaining the CY 2021 LUPA thresholds.

This final rule updates the CY 2022 fixed-dollar loss ratio (FDL) for outlier payments (outlier payments as a percentage of estimated total payments are not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act). Finally, this rule uses the physical therapy (PT) add-on factor to establish the occupational therapy (OT) LUPA add-on factor and finalizes conforming regulations text changes at § 409.43, ensuring the regulations reflect that allowed practitioners, in addition to physicians, may establish and periodically review the home health plan of care.

2. Home Health Value Based Purchasing (HHVBP) Model

In this rule, we expand the Home Health Value-Based Purchasing (HHVBP) Model to all Medicare-certified HHAs in the 50 States, Territories, and the District of Columbia beginning January 1, 2022 with CY 2022 as a pre-implementation year. We are finalizing that CY 2023 will be the first performance year and CY 2025 the first payment year, based on HHA performance in CY 2023. We are also finalizing our proposal to end the original HHVBP Model one year early for the HHAs in the nine original Model States, such that CY 2020 performance data would not be used to calculate a payment adjustment for CY 2022.

3. Home Health (HH) Quality Reporting Program (HH QRP), Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP

This rule finalizes proposals under the HH QRP, including removal of an Outcome and Assessment Information Set (OASIS)-based measure, the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure, under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This rule also finalizes our proposal to replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable measure, and also finalizes our proposal to begin public reporting of the Percent of Residents Experiencing One or More Major Falls with Injury measure and

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) measure beginning in April 2022. Finally, this rule finalizes proposed revisions to certain HH QRP reporting requirements.

This rule also finalizes similar compliance dates for certain IRF QRP and LTCH QRP requirements.

4. Changes to the Home Health Conditions of Participation

In this rule, we are finalizing our proposed changes to make permanent selected regulatory blanket waivers related to home health aide supervision that we extended to Medicare participating home health agencies during the COVID-19 PHE. Blanket waivers to Medicare requirements were issued to provide flexibilities to make sure beneficiaries continue to have access to the health care they need while reducing burden to HHAs. In addition, Division CC, section 115 of CAA 2021 requires the Secretary of Health and Human Services (the Secretary) to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy, and skilled nursing services are not initially on the plan of care. Therefore, we are finalizing our proposed changes: (1) to the home health aide supervision requirements; and (2) that allow occupational therapists to complete the initial and comprehensive assessments for patients.

5. Medicare Coverage of Home Infusion Therapy

This final rule updates the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act.

6. Provider and Supplier Enrollment Processes

In this final rule, we address a number of provisions regarding Medicare provider and supplier enrollment. Most of these provisions involve the finalization of the proposed codification of certain subregulatory policies. These policies related to: (1) the effective date of

billing privileges for certain provider and supplier types and certain provider enrollment transactions; and (2) the deactivation of a provider or supplier's billing privileges. We are also finalizing two regulatory clarifications related to HHA changes of ownership and HHA capitalization requirements.

7. Survey and Enforcement Requirements for Hospice Programs

In this final rule, we are finalizing changes to increase and improve transparency, oversight, and enforcement for hospice programs in addition to implementing the provisions of Division CC, section 407(b) of CAA 2021. We continue to review and revise our health and safety requirements and survey processes to ensure that they are effective in driving quality of care for hospice programs.

8. COVID-19 Reporting Requirements for Long Term Care Facilities

This final rule revises the infection control requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. By doing so, LTC facilities will be required to continue the COVID-19 reporting requirements published in the Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency interim final rule with comment period, published on May 8, 2020 (85 FR 27550) and the interim final rule, COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) Residents, Clients, published on May 13, 2021 (86 FR 26306). LTC facilities will be required to continue to report on a weekly basis to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN), suspected and confirmed COVID-19 infections, total deaths and COVID-19 deaths, personal protective equipment (PPE) and hand hygiene supplies, ventilator capacity and supplies, resident beds and census, access to COVID-19 testing, staffing shortages, therapeutics administered to residents for the treatment of COVID-19 requirements until December 31, 2024, with the possibility of reduced frequency of reporting and modified or limited data elements that are required in the future at the discretion of the Secretary. They will

also be required to report the COVID-19 vaccination status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events.

B. Summary of the Provisions of this Rule

1. Home Health Prospective Payment System (HH PPS)

In the CY 2022 proposed rule (86 FR 35874) we included discussions of preliminary Patient-Driven Groupings Model (PDGM) monitoring data and analyses on home health utilization; LUPAs; the distribution of the case-mix methodology as determined by clinical groupings, admission source and timing, functional status, and comorbidities; and therapy visits. Additionally, we provided preliminary analysis on HHA expenditures as reported on 2019 cost reports to estimate the difference between Medicare payments and HHAs' costs. We also provided a description and solicited comments on a potential repricing methodology for determining the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments. In section II.B.1. and 2. of this final rule, we provide a summary of comments on these topics.

In section II.B.3. of this rule, we are finalizing the recalibration of the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the CY 2021 LUPA thresholds for CY 2022.

In section II.B.4. of this rule, we update the home health wage index, and we also update the CY 2022 national, standardized 30-day period payment rates and the CY 2022 national per-visit payment amounts by the home health payment update percentage. The home health payment update percentage for CY 2022 is 2.6 percent. Additionally, this rule finalizes the FDL ratio at 0.40 for CY 2022, in order to ensure that aggregate outlier payments do not exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.B.4.c.(5). of this final rule, we finalize changes to utilize the physical therapy (PT) LUPA add-on factor to establish the OT add-on factor for the LUPA add-on payment

amounts with respect to the initial patient assessments newly permitted under Division CC, section 115 of CAA 2021 that revised § 484.55(a)(2) and (b)(3).

Section II.B.6. of this final rule finalizes conforming regulations text changes at § 409.43 to reflect new statutory provisions that allow practitioners in addition to physicians to establish and periodically review the home health plan of care. These changes are in accordance with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136, March 27, 2020).

2. Home Health Value Based Purchasing (HHVBP) Model

In section III.A. of this final rule, we are finalizing our proposal to expand the HHVBP Model to all Medicare-certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. However, we are designating CY 2022 as a pre-implementation year in response to a number of comments we received. CY 2023 will be the first performance year and CY 2025 the first payment year, with a maximum payment adjustment, upward or downward, of 5 percent. We are finalizing that the expanded Model would generally use benchmarks, achievement thresholds, and improvement thresholds based on CY 2019 data to assess achievement or improvement of HHA performance on applicable quality measures and that HHAs would compete nationally in their applicable size cohort, smaller-volume HHAs or larger-volume HHAs, as defined by the number of complete unique beneficiary episodes for each HHA in the year prior to the performance year. All HHAs certified to participate in the Medicare program prior to January 1, 2022, would be required to participate and would be eligible to receive an annual Total Performance Score based on their CY 2023 performance. We are finalizing the applicable measure set for the expanded Model, as well as policies related to the removal, modification, and suspension of quality measures, and the addition of new measures and the form, manner and timing of the OASIS-based, Home Health Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey-based, and claims-based measures submission in the applicable measure set beginning CY 2022 and subsequent years. We are also

finalizing our proposals for an appeals process, an extraordinary circumstances exception policy, and public reporting of annual performance data under the expanded Model.

In section III.B. of this final rule, we are finalizing our proposal to end the original HHVBP Model one year early. We are finalizing that we will not use CY 2020 performance data for the HHAs in the nine original Model States to apply payment adjustments for the CY 2022 payment year. We also are finalizing that we will not publicly report CY 2020 (performance year 5) annual performance data under the original HHVBP Model.

3. HH QRP

In section IV.C. of this final rule, we are finalizing the proposed updates to the HH QRP including: the removal of one OASIS-based measure, replacement of two claims-based measures with one claims-based quality measure; public reporting of two measures; revising the compliance date for certain reporting requirements for certain HH QRP reporting requirements; and summarizing comments received on our requests for information regarding digital quality measures and health equity.

4. Changes to the Home Health Conditions of Participation

In this section IV.D. of this rule, we finalize our proposal to make permanent selected regulatory blanket waivers related to home health aide supervision that we extended to Medicare-participating home health agencies during the COVID-19 PHE. In addition, we are revising our regulations to reflect Division CC, section 115 of CAA 2021. This provision requires CMS to permit an occupational therapist to conduct a home health initial assessment visit and complete a comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care, with either physical therapy or speech therapy, and when skilled nursing services are *not* initially in the plan of care.

We are finalizing proposed changes to the home health aide supervision requirements at § 484.80(h)(1) and (2) and conforming regulation text changes at § 484.55(a)(2) and (b)(3),

respectively, to allow occupational therapists to complete the initial and comprehensive assessments for patients in accordance with changes in the law.

We are also making a technical correction at § 484.50(d)(5).

5. Medicare Coverage of Home Infusion Therapy

In section V. of this final rule, we discuss the home infusion therapy services payment categories, as finalized in the CYs 2019 and 2020 HH PPS final rules with comment period (83 FR 56406, 84 FR 60611). Additionally, we discuss the home infusion therapy services payment adjustments including finalizing the proposal to update the geographic adjustment factors (GAFs) used for wage adjustment and finalizing the proposal to maintain the percentages finalized for the initial and subsequent visit policy. In this section we also discuss updates to the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act.

6. Provider and Supplier Enrollment Processes

In section VI. of this final rule, we addressed a number of provisions regarding Medicare provider and supplier enrollment. Most of these provisions involve the incorporation into 42 CFR part 424, subpart P, of certain sub-regulatory policies. These are addressed in section VI.B. of this final rule and include, for example, policies related to: (1) the effective date of billing privileges for certain provider and supplier types and the effective date of certain provider enrollment transactions; and (2) the deactivation of a provider's or supplier's billing privileges.

In addition, we finalized in section VI.C. of this final rule two regulatory clarifications related to HHA changes of ownership and HHA capitalization requirements.

7. Survey and Enforcement Requirements for Hospice Programs

In section VII. of this final rule, there are a number of provisions related to Division CC, section 407 of CAA 2021. These provisions enhance the hospice program survey process by requiring the use of multidisciplinary survey teams, prohibiting surveyor conflicts of interest, expanding CMS-based surveyor training to accrediting organizations (AOs), and requiring AOs

with CMS-approved hospice programs to begin use of the Form CMS-2567. Additionally, we are finalizing our proposed provisions to establish a hospice program complaint hotline. Lastly, the finalized provisions create the authority for imposing enforcement remedies for noncompliant hospice programs including the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. The Special Focus Program will be considered in future rulemaking.

Section 1865(a) of the Act provides that CMS may recognize and approve national AO Medicare accreditation programs which demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used by CMS to determine compliance with applicable requirements. When a CMS-approved AO program accredits a provider, CMS “deems” the provider to have complied with applicable Medicare conditions or requirements. The CAA 2021 provisions expanding requirements for AOs will apply to AOs with CMS-approved accreditation programs, and currently there are three such AOs: Accreditation Commission for Health Care (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). Half of all the Medicare-certified hospices have been deemed by these AOs.

We described and solicited comments on all aspects of the proposed survey and enforcement provisions for hospice programs.

8. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program

In section IX.A. of this final rule, we are finalizing our proposal to modify the compliance date for certain reporting requirements in the IRF QRP.

9. Long Term Care Hospital (LTCH) Quality Reporting Program

In section IX.B. of this final rule, we are finalizing our proposal to modify the compliance date for certain reporting requirements in the LTCH QRP.

10. COVID-19 Reporting Requirements for Long-Term Care (LTC) Facilities

In section X.C of this final rule, we finalize our COVID-19 reporting requirements with the following modifications:

- Reporting frequency is modified to no more than weekly, and may be reduced, at the discretion of the Secretary;
- The possibility of modified or limited data elements that are required in the future, contingent on the state of the pandemic and at the discretion of the Secretary.
- The addition of a sunset date of December 31, 2024, for all reporting requirements, with the exclusion of the reporting requirements at § 483.80(g)(1)(viii).

C. Summary of Costs, Transfers, and Benefits

TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2022 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated \$570 million (3.2 percent) in increased payments to HHAs in CY 2022.	To ensure home health payments are consistent with statutory payment authority for CY 2022.
HHVBP		The overall economic impact of the expanded HHVBP Model for CYs 2023 through 2027 is an estimated \$3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and skilled nursing facility (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.	
HH QRP	The total savings beginning in CY 2023 is an estimated \$2,762,277 based upon the removal of one OASIS-based measure, item M2016.		
Changes to the Home Health Conditions of Participation	We do not anticipate any costs or cost savings associated with our proposed Conditions of Participation provisions.		
Medicare Coverage of Home Infusion Therapy		The overall economic impact of the statutorily-required HIT payment rate updates is an estimated increase in payments to HIT suppliers of 5.1 percent (\$300,000) for CY 2022.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2022.
Provider and Supplier Enrollment Processes	We do not anticipate any costs or cost savings associated with our Medicare provider and supplier enrollment provisions.	The overall impact of our provider enrollment provisions will be a transfer of \$54,145,000 from providers/suppliers to the Federal Government. This will result from our provision prohibiting payment for services and items furnished by a deactivated provider or supplier.	
Survey and Enforcement Requirements for Hospice Programs	We estimate that the provisions that we present in the preamble of this final rule to implement Division CC, section 407 of CAA 2021 will result in an estimated cost of approximately \$5.5 million from FY 2021 through FY 2022.	We do not anticipate any transfers associated with our Medicare survey and enforcement requirements for hospice programs.	To ensure a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public.

Provision Description	Costs and Cost Savings	Transfers	Benefits
COVID-19 Reporting Requirements for Long Term Care Facilities	The total estimated continuing cost for the LTC reporting requirements finalized in this rule is \$2,171,571.		These changes will extend the benefits of COVID-19 reporting for LTC facilities beyond the PHE and will provide LTC facilities with more flexibility and eliminate unnecessary burden.

II. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. Statutory Background

Section 1895(b)(1) of the Act requires the Secretary to establish a Home Health Prospective Payment System (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.

In accordance with the statute, as amended by the Balanced Budget Act of 1997 (BBA), (Pub. L. 105–33, enacted August 5, 1997) we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. Section 4603(a) of the BBA allowed the Secretary to consider an appropriate unit of service and at such time, a 60-day unit of payment was established. 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). 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 41128,41214).

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 home health agencies (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.

Section 51001(a)(1)(B) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123) amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning 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 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.

Additionally, section 1895(b)(3)(A)(iv) of the Act 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 finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

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, section 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 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. 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. Current System for Payment of Home Health Services Beginning in CY 2020 and Subsequent Years

For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section

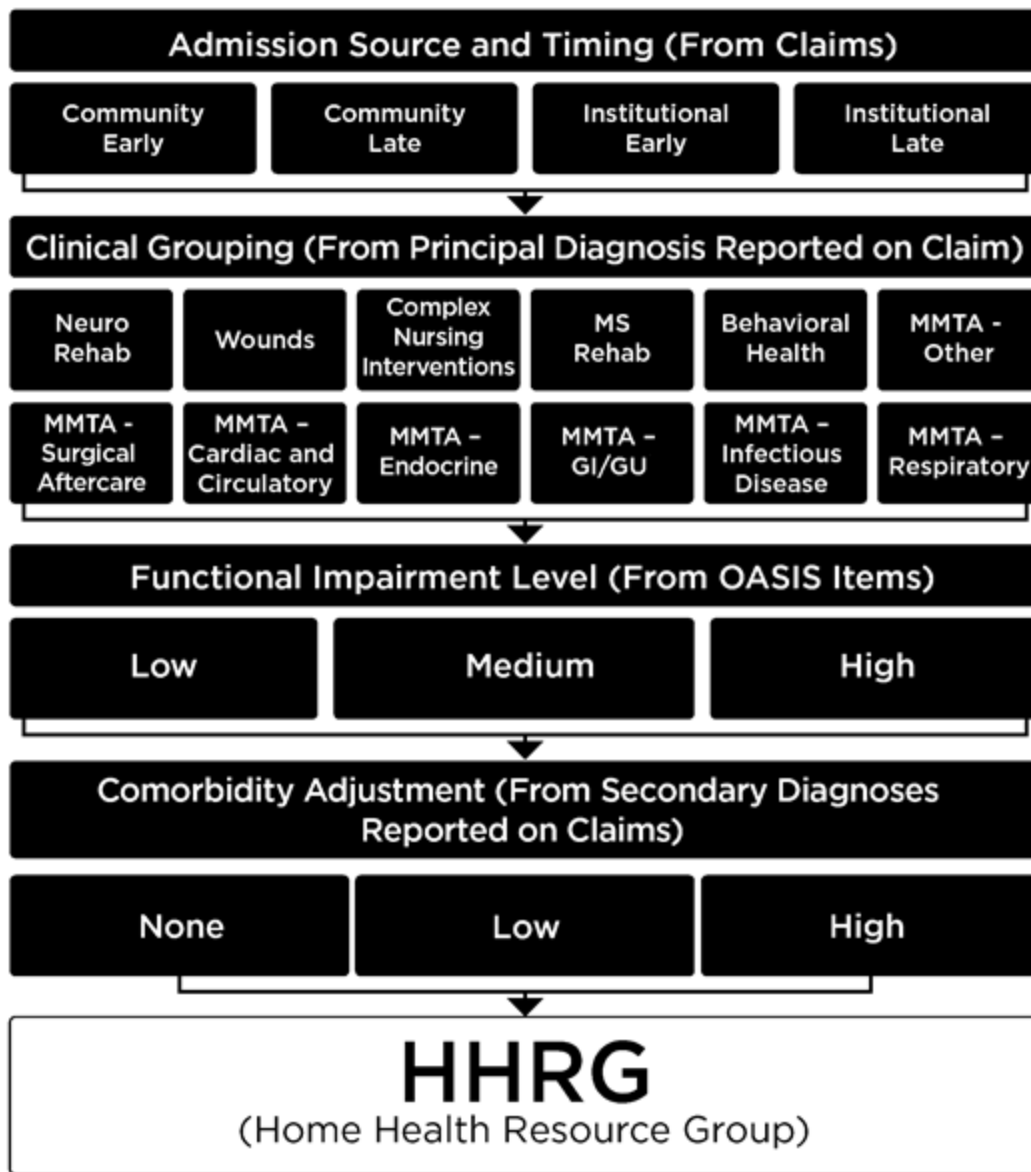
51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period payment rate includes payment for the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is now also part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service, as defined in section 1861(m) of the Act, is paid the fee schedule amount or is paid through the competitive bidding program and such payment is not included in the national, standardized 30-day period payment amount.

To better align payment with patient care needs and to better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE2000 available at <https://www.cms.gov/regulations-and-guidance/guidance/transmittals2020-transmittals/se20005>. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) assessment instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in Figure 1. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA)

threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment (PEP). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this 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 (admission source, timing clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. A detailed description of each of the case-mix variables under the PDGM have been described previously, and we refer readers to the CY 2021 HH PPS final rule (85 FR 70303,70305).

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



B. Provisions of the Final Rule

1. PDGM Monitoring

The PDGM made several changes to the HH PPS, including replacing 60-day episodes of care with 30-day periods of care, removing therapy volume from directly determining payment, and developing 432 case-mix adjusted payment groups in place of the previous 153 groups. In the CY 2022 HH PPS proposed rule (86 FR 35880), we provided preliminary data analyses on the PDGM including: overall home health utilization, clinical groupings and comorbidities, admission source and timing, functional impairment levels, and therapy visits. We also provided data analysis on the 2019 HHA Medicare cost reports. We solicited comments on the preliminary

PDGM data and cost analyses, along with other factors CMS should be monitoring. These comments and our responses are summarized in this section of the rule.

Comment: Many commenters viewed the overall decrease in utilization as more likely related to the COVID-19 PHE, rather than the implementation of the PDGM. One industry association stated that the COVID-19 PHE brought extensive changes in patient mix, home health patient census, significant practice changes and changes in admission source referrals. Commenters also stated because of the COVID-19 PHE, patients were often unwilling to allow home health clinicians into their homes to receive needed care. Commenters also indicated that half of HHAs provided services to actively infected COVID-19 patients. We received several comments regarding the increase of LUPAs in CY 2020. Commenters remarked that the increase of LUPAs is more attributable to pandemic-related factors rather than HHAs taking advantage of the PDGM. Commenters also stated that the use of telehealth for the provision of home health visits contributed to the increase in LUPAs in CY 2020 because of safety concerns and patient refusal to allow for in-person visits. Other commenters stated because telehealth services are not reported as home health visits, utilization of home health services is not fully captured. Additionally, several commenters recommended that CMS examine CY 2020 data at a more granular level due to the COVID-19 PHE, including, but not limited to, geographical differences and seasonal trends.

Response: CMS appreciates all of the comments received regarding CY 2020 utilization trends and the impact of the COVID-19 PHE on the provision of home health services. We acknowledge commenter statements and concerns as to how the COVID-19 PHE affected the types of home health patients served and how HHAs had to adjust care practices in response. We also understand that the COVID-19 PHE has presented unique challenges for all providers who have had to develop and institute new protocols and processes to ensure the health and safety of home health staff and beneficiaries. CMS instituted maximum flexibilities and

implemented waivers to assist providers in navigating the COVID-19 PHE and to safeguard the continued provision of Medicare home health services.¹

In the CY 2021 HH PPS final rule (85 FR 70298), CMS finalized changes to § 409.43(a) as implemented in the March, 2020 COVID–19 interim final rule with comment (IFC) (85 FR 19230), to allow the use of telecommunications technology more broadly, even outside of the COVID-19 PHE. If HHAs use telecommunications technology in the provision of home health care, the regulations state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment, in accordance with section 1895(e)(1)(A) of the Act. Such changes were made to provide flexibility in the provision of care during the COVID-19 PHE and beyond as we recognize telecommunication services, at times, may be in the best interest of the patient and support the overall care of beneficiaries. However, since the law does not consider services furnished via a telecommunications system a home visit, these encounters, while allowed, are not included in utilization analysis.

We also understand the interest in monitoring the impact of the COVID-19 PHE on home health services. While we continue to conduct analyses on home health utilization and other metrics, including the effects of COVID-19, we note that the PHE is ongoing and as such, patterns and trends may change over time. We will continue to examine the effects of the ongoing COVID-19 PHE on home health utilization and will determine when and how best to provide this information. We note that CMS does publish COVID-19 data and statistics, which provides information on how the COVID-19 PHE is affecting the Medicare population and aims

¹ Coronavirus waivers & flexibilities. <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.

to better inform individual and public policy healthcare decisions to address the impact of COVID-19.²

Comment: Several commenters requested additional detailed analyses of the impact of the PDGM on home health utilization. Some examples of suggested additional analyses included demographic data, social determinants of health, Program for Evaluating Payment Patterns Electronic Report (PEPPER reports), and HHA provider types, such as profit versus non-profit. A commenter recommended that CMS should supplement its analysis of utilization data with additional data and monitoring tools, such as survey data. Another commenter supports CMS' plans to assess the relationship of the OASIS GG items to resource use and their correlation to the current OASIS M1800-1860 items that address functional status. We received several comments stating that the level of data provided in the proposed rule did not reflect whether the home health services furnished were appropriate. Commenters also suggested that CMS examine patient outcomes and patient experiences in future rulemaking. Other commenters raised concerns about HHA admission practices. Commenters expressed concern that some HHAs exclude eligible beneficiaries with longer-term, chronic conditions, prematurely discharge patients, "cherry-pick" patients to admit to home health, and decrease necessary home health aide services. Several commenters requested that CMS continue to closely review and monitor therapy utilization data under the PDGM to evaluate for unintended consequences, and if appropriate implement safeguards as needed. Specifically, commenters stated that the removal of therapy thresholds for payment have resulted in decreases in therapy utilization, termination of therapy staff, and increased use of algorithms, rather than clinical judgment, to determine the appropriate number of therapy visits.

Response: We thank commenters for the additional suggestions for more detailed analyses on home health utilization and other relevant trends and will consider such suggestions

² Preliminary Medicare COVID-19 Data Snapshot. <https://www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot>

for future analyses. We appreciate the concerns by commenters regarding potential aberrant practices and quality of care issues. As we continue to analyze home health utilization, we will monitor for any emerging trends that may warrant any program integrity actions.

Regarding the concerns related to the removal of therapy thresholds, beginning in CY 2020, section 1895(b)(4)(B)(ii) of the Act, as added by section 51001 of the Bipartisan Budget Act of 2018 (BBA 2018) eliminated the use of therapy thresholds in calculating payments for CY 2020 and subsequent years. However, as with analysis of overall home health utilization, we will continue to monitor the provision of therapy visits, including by subspecialty. We remind commenters that all home health services, including therapy, must be provided in accordance with the Conditions of Participation at 42 CFR 484.60. Specifically, the individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training. Services must be furnished in accordance with accepted standards of practice.

Comment: We received several comments regarding our analysis on the CY 2019 Medicare home health cost reports. Specifically, commenters expressed concerns over the accuracy of cost report data. Commenters stated that the home health agency cost report data may not adequately reflect the home health industries' costs as providers vary in complexity, sophistication, size and resources.

Response: We appreciate the commenters' feedback on the CY 2019 cost report analysis provided in the proposed rule. We recognize that with the COVID-19 PHE, the CY 2019 data on the Medicare cost reports may not reflect the most recent changes such as increased telecommunications technology costs, increased PPE costs, and hazard pay. As we stated in the CY 2022 HH PPS proposed rule (86 FR 35884), when the CY 2020 cost reports become

available, we will update the estimated 30-day period of care costs in CY 2020 in future rulemaking.

2. Comment Solicitation on the Annual Determination of the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Payment Expenditures under the HH PPS

In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized the use of three behavior assumptions in order to calculate a 30-day budget-neutral payment amount for CY 2020 as required by section 1895(b)(3)(A)(iv) of the Act. These included the clinical coding, the comorbidity, and the LUPA behavior assumptions. In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we finalized a -4.36 percent behavior assumption adjustment in order to calculate a national, standardized 30-day base payment rate, assuming that these behaviors would happen half as frequently during the first year of implementation of the PDGM and 30-day unit of payment. Section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures beginning with 2020 and ending with 2026. In the CY 2020 final rule with comment period (84 FR 60513), we stated that we interpret actual behavior changes to encompass both behavior changes that were previously outlined, as assumed by CMS, and other behavior changes not identified at the time that the budget neutral 30-day payment for CY 2020 was determined. In the CY 2022 proposed rule (86 FR 35889), we solicited comments on a possible methodology where we would use actual CY 2020 30-day period claims data to simulate 60-day episodes to determine what CY 2020 payments would have been under the 153-group case-mix system and 60-day unit of payment. We also solicited comments on any potential alternative methods for determining the difference between assumed and actual behavior changes on estimated aggregate expenditures. We received comments on the methodology described in the proposed rule, comments regarding potential alternative methods,

and comments on the previously finalized behavior assumptions which are summarized in this section of the rule.

Comment: We received several comments stating that an independent analysis of the actual versus assumed behavior changes show that CMS' assumptions on two of the three previously finalized behavior assumptions were inaccurate. These commenters stated that CMS overestimated the clinical group assumption and the LUPA assumption. These commenters stated that the magnitude of coding the highest paying clinical diagnosis was overstated and the actual change in coding practices did not manifest as CMS assumed. Commenters also stated that there was a significant increase in the frequency of LUPA periods of care, indicating that the LUPA assumption also was overestimated. That is, commenters stated that HHAs did not make 1-2 extra visits to meet or exceed the LUPA threshold to receive a full, case-mix adjusted 30-day period payment. Commenters recommended that we remove these behavior assumptions and the -4.36 percent payment adjustment for rate setting in CY 2022. Other comments stated that not only should the -4.36 percent adjustment be removed, but that we should further increase the 30-day payment in CY 2022.

A few commenters stated CMS does not have the authority to institute budget neutrality adjustments beyond those related to behavior changes. In addition, a few commenters stated we must utilize a PDGM budget neutrality methodology that is solely focused on assumed behavior changes that were incorporated into the original 2020 rate setting.

Many commenters noted, as projected, the reported comorbidity levels have increased. Some commenters state this change may be because HHAs are now comprehensively recording these secondary diagnoses on home health claims, thereby more accurately reflecting patient acuity. However, other commenters disagreed and believe there is a change in aggregate patient acuity due to the COVID-19 PHE. Several commenters stated that there have been noted increases in the functional impairment level. Many stated that an increase of patients into the high functional impairment category and a decrease in the low functional impairment category

could be a direct result of the COVID-19 PHE, because HHAs had to accept higher acuity and more functionally impaired patients while elective surgeries were canceled and decreased the utilization in patients with lower functional impairment scores. The majority of commenters were supportive of foregoing any payment adjustment in CY 2022 based on the difference between assumed versus actual behavior change.

Response: We appreciate the commenters feedback and would like to remind commenters that section 1895(b)(3)(a)(iv) of the Act required CMS to make behavioral assumptions when calculating the budget-neutral 30-day payment rate. Section 1895(b)(3)(D) of the Act also requires CMS to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures beginning with CY 2020 and ending with CY 2026. Therefore, we cannot simply remove a behavior change assumption; rather, we are required by law to annually determine the effects of behavior change on estimated aggregate expenditures. Furthermore, we stated in the CY 2019 HH PPS final rule with comment period (53 FR 56455), the CY 2020 HH PPS final rule with comment period (84 FR 60513), and the CY 2022 HH PPS proposed rule (86 FR 35890), that we interpret actual behavior changes to encompass both behavior changes that were previously outlined, as assumed by CMS, and other behavior changes not identified at the time that the budget neutral 30-day payment amount for CY 2020 was determined.

The law gives CMS the discretion to make temporary and permanent payment adjustments at a time and in a manner determined, by the Secretary, to be appropriate. As such, we did not propose any adjustment to the national, standardized 30-day payment rate in the CY 2022 HH PPS proposed rule based on any behavior assumptions. The law requires that we make any temporary and permanent payment adjustment based on the difference between assumed versus actual behavior change on estimated aggregate expenditures through notice and comment rulemaking.

Given some of the comments stating that CMS overestimated the behavior change, we wish to remind commenters that the CYs 2020 and 2021 LDS files included two separate datasets; one uses claims with a “full” behavior assumption applied, using the initial proposed -8.389 percent adjustment, and the other uses claims with a “no” behavior assumption applied (no adjustment for changes in behavior). As stated previously in the CY 2020 HH PPS final rule with comment period (84 FR 60512), CMS applied the three behavioral assumptions to only half of the 30-day periods of care, randomly selected. The -4.36 percent behavior adjustment is not included in the CYs 2020 and 2021 LDS files given the 30-day periods to which the assumptions were applied were done so randomly. Therefore, any independent analysis conducted would need to include application of the behavior assumptions to only half of the 30-day periods in the LDS files.

Comment: The majority of commenters disagreed with the methodology set out in the proposed rule. Their concerns related to: the exclusions we applied to the data when simulating 60-day episodes claims from 30-day periods; the impact of the COVID-19 PHE; the lack of comparability between case-mix models (for example, the assertion that a case-mix of 1.0 is not the same across two systems); and the removal of payment incentives for therapy visits leading to a decline in therapy services furnished in CY 2020. Many commenters offered an alternative approach to compare CY 2018 60-day episodes converted to 30-day periods used for CY 2020 rate setting to actual CY 2020 30-day periods. Commenters stated such approach would more accurately determine the differences between assumed versus actual behavior changes on estimated aggregate expenditures, would be less biased, would eliminate the need to model other changes that occurred due to the implementation of the PDGM, and would avoid the impact of the COVID-19 PHE on therapy utilization. A few commenters also recommended to incorporate some analysis of evaluating “real” and “nominal” changes in the average case-mix weight.

However, MedPAC supported the method presented in the proposed rule for computing the budget-neutral amount stating the method was reasonable and would satisfy the requirement

to reconcile payments based on the differences between assumed versus actual behavior change on estimated aggregate expenditures, as required by section 1895(a)(3)(D) of the Act.

Response: We appreciate the commenters' comprehensive review of the methodology described in the CY 2022 HH PPS proposed rule. We will consider all alternative approaches as we continue to develop and refine a methodology for annually determining the difference between assumed versus actual behavior changes on estimated aggregate expenditures. As stated previously, the methodology and any associated payment adjustment based on the difference between assumed versus actual behavior change on estimated aggregate expenditures will be made through future notice and comment rulemaking.

3. CY 2022 PDGM LUPA Thresholds and PDGM Case-Mix Weights

a. CY 2022 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds would be set at the 10th percentile 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. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care is be paid the full 30-day period case-mix adjusted payment amount (subject to any PEP or outlier adjustments). If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the CY 2022 per-visit payment amounts as described in section III. of this final rule. 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.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group would be reevaluated every

year based on the most current utilization data available at the time of rulemaking. However, CY 2020 was the first year of the new case-mix adjustment methodology and we stated in the CY 2021 final rule (85 FR 70305, 70306) we would maintain the LUPA thresholds that were finalized and shown in Table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. At that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

We have received anecdotal feedback from stakeholders that in CY 2020, HHAs billed more LUPAs because patients requested fewer in-person visits due the COVID-19 PHE. As discussed further in this section of this rule, we proposed to update the case-mix weights for CY 2022 using CY 2020 data as there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups. CMS believes that the COVID-19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID-19 PHE on the calculation of the case-mix weight would be minimized since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that would control for the impacts of the COVID-19 PHE. We note that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. If we had proposed to set the LUPA thresholds using CY 2020 data and then set the LUPA thresholds again for CY 2023 using data from CY 2021, it is likely that there would be an increase in these thresholds due to the lower number of visits that occurred in CY 2020. Therefore, to mitigate any potential future and significant short-term variability in the

LUPA thresholds due to the COVID-19 PHE, we proposed to maintain the LUPA thresholds finalized and displayed in Table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes. We believe that maintaining the LUPA thresholds for CY 2022 was the best approach because it mitigates potential fluctuations in the thresholds caused by visit patterns changing from what we observed in CY 2020 potentially due to the COVID-19 PHE. The public comments on our proposal to maintain the CY 2021 LUPA thresholds for CY 2022 payment purposes and our responses are summarized in this section of the rule.

Comment: Some commenters expressed their support for the policy to maintain the CY 2020 LUPA thresholds for CY 2022 in order to mitigate potential fluctuations in the thresholds caused by changing visit patterns in CY 2020 potentially due to the COVID-19 PHE. One commenter recommended that CMS allow telehealth visits to be counted toward meeting LUPA thresholds. This commenter stated that in situations where virtual care visits can be equally as efficacious as an in-person meeting, and CMS should allow these visits to count within this payment framework.

Response: We thank the commenters for their support. As noted previously, the goal of maintaining the LUPA thresholds for CY 2022 is to mitigate any potential fluctuations in the thresholds resulting from any changes in visit patterns resulting from the COVID-19 PHE. While we understand that there are ways in which technology can be further utilized to improve patient care, better leverage advanced practice clinicians, and improve outcomes while potentially making the provision of home health care more efficient, we remind stakeholders that under current law, services furnished via a telecommunications system cannot be considered a home health visit for purposes of eligibility or payment. Section 1895(e)(1)(A) of the Act prohibits payment for services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care.

Final Decision: We are finalizing the proposal to maintain the LUPA thresholds for CY 2022. The LUPA thresholds for CY 2022 are located on the HHA Center webpage.³

b. CY 2022 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization; that is, responses to OASIS items M1800-M1860 and M1032. A home health period of care receives points based on each of the responses associated with these functional OASIS items, which are then converted into a table of points corresponding to increased resource use. The sum of all of these points results in a functional score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the higher the response is associated with increased resource use. The sum of all of these points results in a functional impairment score which is used to group home health periods into one of three functional impairment levels with similar resource use. The three functional impairment levels of low, medium, and high were designed so that approximately 1/3 of home health periods from each of the clinical groups fall within each level. Home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2022, we proposed to use CY 2020 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS proposed rule (82 FR 35320) and the Home Health Groupings Model (HHGM) technical report from December 2016⁴ provide a more detailed explanation as to the construction of these functional impairment levels using the OASIS items. We proposed to use this same methodology previously finalized to

³ Home Health Agency Center webpage. <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>.

⁴ Overview of the Home Health Groupings Model Technical Report. November 2016. <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

update the functional impairment levels for CY 2022. The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2022 are listed in Tables 2 and 3, respectively.

TABLE 2: OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2020

	Responses	Points (2020)	Percent of Periods in 2020 with this Response Category
M1800: Grooming	0 or 1	0	33.8%
	2 or 3	3	66.2%
M1810: Current Ability to Dress Upper Body	0 or 1	0	28.8%
	2 or 3	6	71.2%
M1820: Current Ability to Dress Lower Body	0 or 1	0	13.7%
	2	5	63.3%
	3	12	23.0%
M1830: Bathing	0 or 1	0	3.5%
	2	1	13.4%
	3 or 4	9	51.4%
	5 or 6	17	31.7%
M1840: Toilet Transferring	0 or 1	0	63.7%
	2, 3 or 4	5	36.3%
M1850: Transferring	0	0	2.0%
	1	3	24.4%
	2, 3, 4 or 5	7	73.6%
M1860: Ambulation/Locomotion	0 or 1	0	4.5%
	2	7	16.8%
	3	6	61.2%
	4, 5 or 6	19	17.5%
M1032: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	70.1%
	Four or more items marked (Excluding responses 8, 9 or 10)	12	29.9%

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the Chronic Conditions Data Warehouse (CCW) July 12, 2021.

TABLE 3: THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2020

Clinical Group	Level of Impairment	Points (2020)
MMTA – Other	Low	0-33
	Medium	34-48
	High	49+
Behavioral Health	Low	0-32
	Medium	33-48
	High	49+
Complex Nursing Interventions	Low	0-36
	Medium	37-56
	High	57+
Musculoskeletal Rehabilitation	Low	0-35
	Medium	36-48
	High	49+
Neuro Rehabilitation	Low	0-36
	Medium	37-55
	High	56+
Wound	Low	0-36
	Medium	37-54
	High	55+
MMTA - Surgical Aftercare	Low	0-34
	Medium	35-45
	High	46+
MMTA - Cardiac and Circulatory	Low	0-32
	Medium	33-47
	High	48+
MMTA – Endocrine	Low	0-30
	Medium	31-44
	High	45+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-36
	Medium	37-51
	High	52+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-33
	Medium	34-48
	High	49+
MMTA – Respiratory	Low	0-36
	Medium	37-48

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021.

The following is a summary of the comments received and our responses to comments on the proposal to update the functional points and the functional impairment levels by clinical group.

Comment: MedPAC was supportive of the proposal to update the functional points and functional impairment levels for CY 2022 and recommended that CMS to continue to update the functional categories in this manner in future payment years. MedPAC stated that the re-weighting CMS proposed for CY 2022 would reset the payment categories based on 2020 data, so that periods will again be evenly distributed across the three functional payment categories. MedPAC believes that maintaining this distribution helps to ensure the accuracy of Medicare payments.

Response: We thank the Commission for its support.

Final Decision: We are finalizing the proposal to update the functional points and functional impairment levels for CY 2022.

c. CY 2022 Comorbidity Subgroups

Thirty-day periods of care 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 diagnosis subgroups have at least as high as the median resource use and are reported in more than 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 receives no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we stated that we would continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements so that payments align with the actual costs of providing care. For CY 2022, we proposed to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2020 home health data.

For CY 2022, we proposed to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups and 85 high comorbidity adjustment interaction subgroups. To generate the final comorbidity subgroups, we used CY 2020 home health claims data with linked OASIS data (as of July 12, 2021). The tables later in this section have been revised to reflect the results using the updated data. The final comorbidity subgroups include 20 low comorbidity adjustment subgroups as identified in Table 4 and 87 high comorbidity subgroups as identified in Table 5.

TABLE 4: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2022

Low Comorbidity Subgroup	Subgroup Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
Circulatory 9	Other Venous Embolism and Thrombosis
Circulatory 10	Varicose Veins and Lymphedema
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Musculoskeletal 1	Lupus
Musculoskeletal 2	Rheumatoid Arthritis

Neoplasms 1	Malignant Neoplasms of Lip, Oral Cavity and Pharynx, includes Head and Neck Cancers
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Neurological 10	Diabetes with Neuropathy
Neurological 11	Diabetic Retinopathy and Macular Edema
Respiratory 9	Respiratory Failure and Atelectasis
Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site

TABLE 5: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2022

Comorbidity Subgroup Interaction	Comorbidity Group	Subgroup Description	Comorbidity Group	Subgroup Description
1	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
2	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
4	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
5	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
6	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
7	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
8	Cerebral 1	Occlusion/Stenosis of Pre-cerebral/Cerebral Arteries without Cerebral Infarction	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
9	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with Neuropathy
10	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 2	Hemolytic, Aplastic, and Other Anemias
11	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure

12	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
16	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
17	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
18	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
19	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
20	Circulatory 10	Varicose Veins and Lymphedema	Heart 9	Valve Disorders
21	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 3	Joint Pain
22	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
23	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
24	Circulatory 10	Varicose Veins and Lymphedema	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
25	Circulatory 10	Varicose Veins and Lymphedema	Heart 12	Other Heart Diseases
26	Circulatory 10	Varicose Veins and Lymphedema	Neurological 10	Diabetes with Neuropathy
27	Circulatory 10	Varicose Veins and Lymphedema	Heart 11	Heart Failure
28	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
29	Circulatory 10	Varicose Veins and Lymphedema	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
30	Circulatory 10	Varicose Veins and Lymphedema	Neurological 11	Diabetic Retinopathy and Macular Edema
31	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
32	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
33	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
35	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
36	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
37	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease

38	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
39	Circulatory 9	Other Venous Embolism and Thrombosis	Neurological 10	Diabetes with Neuropathy
40	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
41	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes Graft-Versus-Host-Disease
42	Endocrine 1	Hypothyroidism	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
43	Endocrine 1	Hypothyroidism	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
44	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
45	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
46	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes Graft-Versus-Host-Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes Graft-Versus-Host-Disease	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
48	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
49	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
50	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
51	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
52	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
53	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
54	Heart 11	Heart Failure	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
55	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
56	Heart 11	Heart Failure	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
57	Heart 12	Other Heart Diseases	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
58	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
59	Heart 9	Valve Disorders	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
60	Infectious 1	C-diff, MRSA, E-coli, Sepsis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
61	Infectious 1	C-diff, MRSA, E-coli, Sepsis	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site

62	Musculoskeletal 2	Rheumatoid Arthritis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
63	Musculoskeletal 3	Joint Pain	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
64	Musculoskeletal 3	Joint Pain	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
65	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
66	Musculoskeletal 4	Lumbar Spinal Stenosis	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
67	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
68	Neurological 10	Diabetes with Neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
69	Neurological 10	Diabetes with Neuropathy	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
70	Neurological 10	Diabetes with Neuropathy	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
71	Neurological 11	Diabetic Retinopathy and Macular Edema	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
72	Neurological 4	Alzheimer's Disease and Related Dementias	Respiratory 9	Respiratory Failure and Atelectasis
73	Neurological 4	Alzheimer's Disease and Related Dementias	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
74	Neurological 4	Alzheimer's Disease and Related Dementias	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
75	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
76	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
77	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
78	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
79	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
80	Renal 1	Chronic Kidney Disease and End Stage Renal Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
81	Renal 1	Chronic Kidney Disease and End Stage Renal Disease	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
82	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
83	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
84	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site
85	Respiratory 9	Respiratory Failure and Atelectasis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers

86	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers
87	Skin 3	Diseases of Arteries, Arterioles and Capillaries with Ulceration and Non-Pressure Chronic Ulcers	Skin 4	Stages Two through Four and Unstageable Pressure Ulcers by Site

In this section of the rule is a summary of the comments received and our response to those comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment subgroups for CY 2022.

Comment: A commenter requested that CMS reassign diseases and disorders, as well as specific ICD-10 CM diagnosis codes, to different clinical groups or comorbidity subgroups to align with codes representing either similar conditions or similar clinical manifestations. The commenter requested the following reassignments:

- 1) Reassign dementia codes currently listed in the Behavioral Health clinical group to the Neuro Rehabilitation clinical group, due to the clinical similarities of Alzheimer’s Disease and dementia, and to mirror the current classification of dementia within the neurological comorbidity subgroup
- 2) Add musculoskeletal pain, M25.5XX codes to the Musculoskeletal Rehabilitation (MS-Rehab) clinical group when listed as a primary diagnosis, as 14 of 17 M25.5XX codes are included in the Musculoskeletal 3 comorbidity subgroup;
- 3) Add the “specified by organism” sepsis codes A40.0 through A40.9 and A41.01 through A41.89 to the Infectious 1 comorbidity subgroup to align with current coding practices including A41.9 sepsis unspecified;
- 4) Assign leukemia in relapse diagnosis subgroup codes, C92.4X, C92.5X, C92.6X, C92.AX to the Neoplasm 22 comorbidity subgroup, consistent with similar leukemia codes included in this comorbidity subgroup;
- 5) Reassign the diagnosis subgroup diabetes with mononeuropathy codes, EXX.41, and the diagnosis subgroup diabetes with autonomic (poly)neuropathy, EXX.43, codes to the Neurological 10 comorbidity subgroup, as neuropathy is a neurological condition

and the Neurological 10 comorbidity subgroup already contains diabetic polyneuropathy codes;

- 6) Review the Neurological 11 comorbidity subgroup for a potential error since almost all the codes are related to vision issues except for the neuropathy diagnosis subgroup G62 codes. In addition, the commenter noted other types of hereditary and idiopathic neuropathy diagnosis subgroup G60 codes and inflammatory neuropathy diagnosis subgroup G61 codes are not assigned to a comorbidity subgroup when listed as a secondary diagnosis. The commenter requested reassigning the neuropathy diagnosis subgroup codes G60, G61, and G62 to the Neurological 10 comorbidity subgroup, which currently includes diabetic neuropathy;
- 7) Assign rheumatic tricuspid valve disease diagnosis codes I08 to the Heart 9 comorbidity subgroup to align with other nonrheumatic valve disorders.

Response: We appreciate the commenter’s review of these codes and suggested reassignments. As we stated in the CY 2020 final rule with comment period (84 FR 60510), and as described in the technical report “Overview of the Home Health Groupings Model”,⁵ the home health-specific comorbidity list is based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries. We used this process to develop categories of conditions that identify clinically relevant relationships associated with increased resource use. We understand the magnitude of clinical conditions and comorbidities, and the interactions that exist between them, in the Medicare home health population; however, we remind commenters that only those subgroups of diagnoses that represent more than 0.1 percent of periods of care and that have at least as high as the median resource use will receive a low comorbidity adjustment. We describe this method for determining statistical significance in the CY 2020 final rule with comment period (84 FR 60510). This is based on the knowledge that the

⁵ Overview of the Home Health Groupings Model. November 18, 2016. <https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf>.

average number of comorbidities in the aggregate becomes the standard within that population for the purpose of payment. However, because we still expect HHAs to report all secondary diagnoses that affect care planning, there will be comorbidity subgroups included in the home health-specific list that don't meet the criteria to receive an adjustment.

We reviewed each of the requested coding changes to determine if the reassignment to a certain clinical group or comorbidity subgroup was warranted.

1. Request for Dementia Codes to be Reassigned from the Behavioral Health Clinical Group to the Neuro Rehabilitation Clinical Group

We determined there are only two dementia codes listed in the Behavioral Health clinical group with a Neurological 3 comorbidity subgroup; both of which are unspecified dementia codes. Because the commenter stated that reclassifying the dementia codes to a different clinical group would align with the current comorbidity subgroup Neurological 3, we expanded our review to include all ICD-10 CM diagnosis codes in the Neurological 3 comorbidity subgroup. Table 6 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 6: COMORBIDITY SUBGROUP NEUROLOGICAL_3 ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
F02.80	Dementia in other diseases classified elsewhere without behavioral disturbance	N/A	Neurological_3
F02.81	Dementia in other diseases classified elsewhere with behavioral disturbance	N/A	Neurological_3
F03.90	Unspecified dementia without behavioral disturbance	Behavioral Health	Neurological_3
F03.91	Unspecified dementia with behavioral disturbance	Behavioral Health	Neurological_3
F04	Amnesic disorder due to known physiological condition	N/A	Neurological_3
F05	Delirium due to known physiological condition	N/A	Neurological_3
F06.1	Catatonic disorder due to known physiological condition	N/A	Neurological_3
F06.8	Other specified mental disorders due to known physiological condition	N/A	Neurological_3

Our clinical advisors determined that because the two dementia codes (F03.90 and F03.91) listed in the Behavioral Health clinical group are unspecified and the etiology is unknown, they are clinically appropriate to be in the Behavioral Health clinical group and would not warrant a change in clinical group assignment. Upon review of the comorbidity subgroup

codes in Table 6, we determined that these codes are more appropriate in a behavioral health comorbidity subgroup. Additionally, assigning these codes to the Behavioral 4 comorbidity subgroup does not result in a change in the comorbidity adjustment for these codes.

2. Request for Musculoskeletal Pain diagnosis subgroup, M25.5X codes to be reassigned to Musculoskeletal Rehab clinical group

We reviewed the ICD-10 CM diagnoses codes M25.5XX indicating musculoskeletal pain. Table 7 lists these codes, their description, their current assigned clinical group and current assigned comorbidity subgroup.

TABLE 7: MUSCULOSKELETAL PAIN ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
M25.50	Pain in unspecified joint	N/A	No group
M25.511	Pain in right shoulder	N/A	Musculoskeletal 3
M25.512	Pain in left shoulder	N/A	Musculoskeletal 3
M25.519	Pain in unspecified shoulder	N/A	No group
M25.521	Pain in right elbow	N/A	Musculoskeletal 3
M25.522	Pain in left elbow	N/A	Musculoskeletal 3
M25.529	Pain in unspecified elbow	N/A	No group
M25.531	Pain in right wrist	N/A	Musculoskeletal 3
M25.532	Pain in left wrist	N/A	Musculoskeletal 3
M25.539	Pain in unspecified wrist	N/A	No group
M25.541	Pain in joints of right hand	N/A	Musculoskeletal 3
M25.542	Pain in joints of left hand	N/A	Musculoskeletal 3
M25.549	Pain in joints of unspecified hand	N/A	No group
M25.551	Pain in right hip	N/A	Musculoskeletal 3
M25.552	Pain in left hip	N/A	Musculoskeletal 3
M25.559	Pain in unspecified hip	N/A	No group
M25.561	Pain in right knee	N/A	Musculoskeletal 3
M25.562	Pain in left knee	N/A	Musculoskeletal 3
M25.569	Pain in unspecified knee	N/A	No group
M25.571	Pain in right ankle and joints of right foot	N/A	Musculoskeletal 3
M25.572	Pain in left ankle and joints of left foot	N/A	Musculoskeletal 3
M25.579	Pain in unspecified ankle and joints of unspecified foot	N/A	No group
M25.59	Pain in other specified joint	N/A	No group

Our clinical advisors reviewed the ICD-10 CM diagnoses codes M25.5XX for musculoskeletal pain and have determined that these codes lack the specificity to clearly support a rationale for skilled services. In the CY 2019 HH PPS final rule with comment period (83 FR 56473), we stated that many of the codes that indicate pain or contractures as the primary diagnosis, for example M54.5 (low back pain) or M62.422 (contracture of muscle, right hand), although site specific, do not indicate the cause of the pain or contracture. We stated that we would expect a more definitive diagnosis indicating the cause of the pain or contracture, as the

reason for the skilled care, in order to appropriately group the home health period. While we believe that codes that describe signs and symptoms (as opposed to diagnoses) are not appropriate as principal diagnosis codes for grouping home health periods into clinical groups, we recognize that pain can significantly impact the patient’s recovery and plan of care. Therefore, when musculoskeletal pain with a specific location is indicated as a secondary diagnosis, we believe these codes are appropriate to remain in the Musculoskeletal 3 comorbidity subgroup. We disagree with the comment that the ICD-10 CM diagnoses codes M25.5XX should be reassigned to the MS-Rehab clinical group.

3. Request for Sepsis, Specified by Organism codes to be assigned to the Infectious 1 comorbidity subgroup

We reviewed sepsis, specified by organism, codes A40.0 through A40.9 and A41.01 through A41.89. Table 8 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 8: SEPSIS SPECIFIED BY ORGANISM ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
A40.0	Sepsis due to streptococcus, group A	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.1	Sepsis due to streptococcus, group B	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.3	Sepsis due to Streptococcus pneumoniae	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.8	Other streptococcal sepsis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A40.9	Streptococcal sepsis, unspecified	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.01	Sepsis due to Methicillin susceptible Staphylococcus aureus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.02	Sepsis due to Methicillin resistant Staphylococcus aureus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.1	Sepsis due to other specified staphylococcus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.2	Sepsis due to unspecified staphylococcus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.3	Sepsis due to Hemophilus influenzae	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group

A41.4	Sepsis due to anaerobes	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.50	Gram-negative sepsis, unspecified	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.51	Sepsis due to Escherichia coli [E. coli]	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.52	Sepsis due to Pseudomonas	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.53	Sepsis due to Serratia	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.59	Other Gram-negative sepsis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.81	Sepsis due to Enterococcus	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
A41.89	Other specified sepsis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group

Our clinical advisors reviewed the ICD-10-CM codes A40.0 through A40.9 and A41.01 through A41.89 and concur that clinically these codes are appropriate for inclusion in the Infectious 1 comorbidity subgroup when listed as a secondary diagnosis. We remind readers that ICD-10 CM codes A40.0 through A40.9 and A41.01 through A41.89 require the etiology code to be coded as primary, when applicable. When we reassigned the codes listed in Table 8 to Infectious 1, there was no change to the comorbidity adjustment for these codes (for example, no change in payment).

5. Request for Leukemia in Relapse codes to be reassigned to the Neoplasm 22 comorbidity subgroup

We reviewed the ICD-10 CM codes indicating leukemia or histiocytosis with no comorbidity subgroup when listed as a secondary diagnosis. Table 9 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 9: LEUKEMIA AND HISTIOCYTOSIS ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
C92.02	Acute myeloblastic leukemia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.42	Acute promyelocytic leukemia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.52	Acute myelomonocytic leukemia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C92.62	Acute myeloid leukemia with	MMTA - Infectious Disease, Neoplasms, and	No Group

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
	11q23-abnormality in relapse	Blood-Forming Diseases	
C92.A2	Acute myeloid leukemia w multilineage dysplasia, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.40	Acute panmyelosis w myelofibrosis not achieve remission	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.41	Acute panmyelosis with myelofibrosis, in remission	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.42	Acute panmyelosis with myelofibrosis, in relapse	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C94.6	Myelodysplastic disease, not classified	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group
C96.6	Unifocal Langerhans-cell histiocytosis	MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	No Group

Our clinical advisors reviewed the leukemia and histiocytosis codes listed in Table 9 and concur that these codes are appropriate for inclusion in the Neoplasm 22 comorbidity subgroup when listed as a secondary diagnosis code. When we reassigned the codes listed in Table 9 to Neoplasm 22, there was no change to the comorbidity adjustment for these codes (for example, no change in payment).

5. Request for Subgroup of Diabetes with Mononeuropathy and Autonomic (Poly) Neuropathy be reassigned to the Neurological 10 comorbidity subgroup

We reviewed the ICD-10 CM diagnosis codes, diabetes with mononeuropathy, EXX.41, and diabetes with autonomic (poly)neuropathy, EXX.43. Table 10 lists these codes, their description, their current assigned clinical group, and current assigned comorbidity subgroup.

TABLE 10: DIABETES WITH MONONEUROPATHY OR AUTONOMIC (POLY)NEUROPATHY ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
E08.41	Diabetes mellitus due to underlying condition with diabetic mononeuropathy	N/A	Endocrine 2
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy	N/A	Endocrine 2
E09.41	Drug or chemical induced diabetes mellitus with neurological complications with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 2
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 2
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 3
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 3
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 3
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	MMTA – Endocrine	Endocrine 3
E13.41	Other specified diabetes mellitus with diabetic mononeuropathy	MMTA – Endocrine	Endocrine 3
E13.43	Other specified diabetes mellitus with diabetic autonomic	MMTA – Endocrine	Endocrine 3

Our clinical advisors first reviewed all of the current ICD-10 CM diagnoses currently listed in the Neurological 10 comorbidity subgroup. We determined that all of the codes listed in the Neurological 10 comorbidity subgroup are specific to diabetic unspecified neuropathy or diabetic polyneuropathy. The ICD-10 CM diagnosis codes EXX.41, diabetes with mononeuropathy, are different from diabetes with unspecified neuropathy or diabetic polyneuropathy in terms of clinical effects on the body system as a whole. Therefore, we disagree that the ICD-10 CM diagnosis codes EXX.41 should be reassigned to the Neurological 10 comorbidity subgroup. However, our clinical advisors agree that ICD-10 CM diagnosis subgroup EXX.43, diabetes with autonomic (poly)neuropathy, should be reassigned to the Neurological 10 comorbidity subgroup. The Endocrine 2 and Endocrine 3 comorbidity subgroups currently receive no comorbidity adjustment; whereas the Neurological 10 comorbidity subgroup currently receives a low comorbidity adjustment. Reassignment of the ICD-10 CM diagnosis subgroup EXX.43, diabetes with autonomic (poly)neuropathy, to Neurological 10 results in these codes receiving a low comorbidity adjustment when listed as a secondary diagnosis.

6. Request for neuropathy diagnosis subgroup G60, G61, and G62 codes to be reassigned to the Neurological 10 comorbidity subgroup

We reviewed the Neurological 11 comorbidity subgroup and concur with the commenter that almost all of the ICD-10 CM diagnosis codes listed are primarily related to eye diseases and disorders (for example, retinopathy and macular degeneration). As the commenter also noted that there are other types of hereditary, idiopathic, and inflammatory neuropathies with no neurological comorbidity subgroup assigned, we reviewed the diagnosis subgroup G codes indicating a specified neuropathy (mono or poly) or unspecified polyneuropathy. Table 11 lists these codes, their description, their current assigned clinical group, and comorbidity subgroup.

TABLE 10: OTHER SPECIFIED NEUROPATHY (MONO OR POLY) OR UNSPECIFIED POLYNEUROPATHY ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
G13.0	Paraneoplastic neuromyopathy and neuropathy	N/A	No Group
G58.0	Intercostal neuropathy	N/A	No Group
G60.0	Hereditary motor and sensory neuropathy	Neurological Rehab	No Group
G60.2	Neuropathy in association with hereditary ataxia	Neurological Rehab	No Group
G60.3	Idiopathic progressive neuropathy	Neurological Rehab	No Group
G60.8	Other hereditary and idiopathic neuropathies	Neurological Rehab	No Group
G60.9	Hereditary and idiopathic neuropathy, unspecified	Neurological Rehab	No Group
G61.1	Serum neuropathy	Neurological Rehab	No Group
G61.82	Multifocal motor neuropathy	Neurological Rehab	No Group
G62.0	Drug-induced polyneuropathy	Neurological Rehab	Neurological 11
G62.1	Alcoholic polyneuropathy	Neurological Rehab	Neurological 11
G62.2	Polyneuropathy due to other toxic agents	N/A	Neurological 11
G62.81	Critical illness polyneuropathy	Neurological Rehab	Neurological 11
G62.82	Radiation-induced polyneuropathy	Neurological Rehab	Neurological 11
G62.89	Other specified polyneuropathies	Neurological Rehab	Neurological 11
G62.9	Polyneuropathy, unspecified	N/A	Neurological 11
G90.09	Other idiopathic peripheral autonomic neuropathy	Neurological Rehab	No Group
G99.0	Autonomic neuropathy in diseases classified elsewhere	N/A	No Group

We determined that all of the codes listed in the Neurological 10 comorbidity subgroup are specific to diabetic unspecified neuropathy or diabetic polyneuropathy and therefore disagree that the neuropathy diagnosis subgroup G60, G61, and G62 codes should be reassigned. Our clinical advisors reviewed all the current neurological comorbidity subgroups and determined that the Neurological 11 comorbidity subgroup clinically remains the most appropriate comorbidity subgroup for codes G60, G61, and G62. However, we may consider additional neurological comorbidity subgroups in the future and, if appropriate, will reassign ICD-10 CM diagnosis codes if needed.

7. Request for Rheumatic Tricuspid Valve Disease diagnoses subgroup, I08.- codes to be assigned to the Heart 9 comorbidity subgroup

We reviewed the ICD-10 CM diagnosis subgroup I08.X, related to rheumatic disorders involving valves. Table 12 lists these codes, their description, their current assigned clinical group, and comorbidity subgroup.

TABLE 12: RHEUMATIC DISORDERS ICD-10 CM DIAGNOSIS CODES

ICD-10-CM Code	Code Description	Clinical Group Name	Comorbidity Subgroup
I08.0	Rheumatic disorders of both mitral and aortic valves	MMTA - Cardiac and Circulatory	No Group
I08.1	Rheumatic disorders of both mitral and tricuspid valves	MMTA - Cardiac and Circulatory	No Group
I08.2	Rheumatic disorders of both aortic and tricuspid valves	MMTA - Cardiac and Circulatory	No Group
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid	MMTA - Cardiac and	No Group

	valves	Circulatory	
I08.8	Other rheumatic multiple valve diseases	MMTA - Cardiac and Circulatory	No Group
I08.9	Rheumatic multiple valve disease, unspecified	MMTA - Cardiac and Circulatory	No Group

Our clinical advisors agree that these codes are clinically appropriate for inclusion in the Heart 9 comorbidity subgroup when listed as a secondary diagnosis. When we reassigned the codes listed in Table 12 to Heart 9, there was no change to the comorbidity adjustment for these codes (for example, no change in payment).

Final Decision: After reviewing the requested diseases and disorders for a clinical group or comorbidity subgroup reassignment, we are finalizing the reassignments of the following ICD-10 CM diagnosis codes: The ICD-10 CM diagnosis codes in the Neurological 3 comorbidity subgroup will be reassigned to the Behavioral 4 comorbidity subgroup; Sepsis, specified by organism, ICD-10 CM codes A40.0 through A40.9 and A41.01 through A41.89 will be assigned to the Infectious 1 comorbidity subgroup (note that while these codes will now be a part of the Infectious 1 comorbidity subgroup, we remind stakeholders that category A40 “streptococcal sepsis” and category A41 “other sepsis” have a code first note. If both the principal and secondary diagnoses are from category A40 and A41, there will not be a comorbidity adjustment, as both are listed from the same diagnosis subchapter); Leukemia in relapse and histiocytosis ICD-10 CM diagnosis codes will be assigned to the Neoplasm 22 comorbidity subgroup; The EXX.43 ICD-10 CM diagnosis codes will be reassigned to the Neurological 10 comorbidity subgroup; The I08.X ICD-10 CM diagnosis codes will be assigned to the Heart 9 comorbidity subgroup. Table 13 in this section of the rule shows the final ICD-10 CM diagnosis code comorbidity subgroup reassignments. We did not reassign any clinical group for any ICD-10 CM diagnosis code. The final CY 2022 Clinical Group and Comorbidity Adjustment Diagnosis List is posted on the HHA Center webpage.⁶

TABLE 13: FINAL ICD-10 CM DIAGNOSIS CODES COMORBIDITY SUBGROUP

⁶ HHA Center webpage: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>.

REASSIGNMENTS

ICD-10-CM Codes	Current "Old" Comorbidity Subgroup	Reassigned "Final" Comorbidity Subgroup
F02.80, F02.81, F03.90, F03.91, F04, F05, F06.1, F06.8	Neurological 3	Behavioral 4
A40.0, A40.1, A40.3, A40.8, A40.9 A41.01 through A41.53, A41.59, A41.81, A41.89	No Group	Infectious 1
C92.02, C92.42, C92.52, C92.62, C92.A2, C94.40 through C94.42, C94.6, C96.5, C96.6	No Group	Neoplasm 22
E08.41, E09.41	Endocrine 2	Endocrine 2 (no change)
E08.43, E09.43	Endocrine 2	Neurological 10
E10.41, E11.41, E13.41	Endocrine 3	Endocrine 3 (no change)
E10.43, E11.43, E13.43	Endocrine 3	Neurological 10
G60, G61, and G62 subgroups	Neurological 11	Neurological 11 (no change)
I08.0 through I08.3, I08.8, I08.9	No Group	Heart 9
M25.50, M25.519, M25.529, M25.539, M25.549, M25.559, M25.569, M25.579, M25.59	No Group	No Group (no change)
M25.511, M25.512, M25.521, M25.522, M25.531, M25.532, M25.541, M25.542, M25.551, M25.552, M25.561, M25.562, M25.571, M25.572	Musculoskeletal 3	Musculoskeletal 3 (no change)

d. CY 2022 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called home health resource groups (HHRGs). In the CY 2019 HH PPS final rule with comment period (83 FR 56515), we finalized a policy to annually recalibrate the PDGM case-mix weights using a fixed effects model with the most recent and complete utilization data available at the time of annual rulemaking. Annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. To generate the proposed recalibrated CY 2022 case-mix weights, we used CY 2020 home health claims data with linked OASIS data (as of March 30, 2021). To generate the final recalibrated CY 2022 case-mix weights, we used CY 2020 home health claims data with linked OASIS data (as of July 12, 2021). These data are the most current and complete data available at this time. The tables later in this section have been revised to reflect the results using the updated data.

In the CY 2022 HH PPS proposed rule (86 FR 35874), we stated that we believe that recalibrating the case-mix weights using data from CY 2020 would be more reflective of PDGM

utilization and patient resource use than case-mix weights that were set using simulated claims data of 60-day episodes grouped under the old system. Using data from CY 2020 would begin to shift case-mix weights derived from data with 60-day episodes grouped under the old system to data from actual 30-day periods under the PDGM.

The claims data provide 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 following steps:

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 refer readers to Table 13 for further information on the OASIS items used for the functional impairment level under the PDGM. We measure resource use with the cost-per-minute + NRS approach that uses information from 2019 home health cost reports. We use 2019 home health cost report data because it is the most complete data available at the time of rulemaking. Other variables in the regression model include the 30-day period's admission source, clinical group, and 30-day period timing. We also include HHA 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: 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 0.05 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 0.05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: Hold the LUPA thresholds at their current thresholds as described previously in the proposed rule.

Step 4: 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 14 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

**TABLE 14: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT
DIVIDED BY AVERAGE RESOURCE USE
(LUPA THRESHOLDS HELD)**

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
MMTA - Other - Medium Functional	\$168.35	1.1%	0.1169
MMTA - Other - High Functional	\$323.27	0.9%	0.2245
MMTA - Surgical Aftercare - Low Functional	-\$88.46	1.2%	-0.0614
MMTA - Surgical Aftercare - Medium Functional	\$133.25	1.2%	0.0925
MMTA - Surgical Aftercare - High Functional	\$369.37	1.1%	0.2565
MMTA - Cardiac and Circulatory - Low Functional	-\$52.38	6.4%	-0.0364
MMTA - Cardiac and Circulatory - Medium Functional	\$122.40	6.4%	0.0850
MMTA - Cardiac and Circulatory - High Functional	\$282.64	6.5%	0.1963
MMTA - Endocrine - Low Functional	\$279.06	2.4%	0.1938
MMTA - Endocrine - Medium Functional	\$448.54	2.4%	0.3115
MMTA - Endocrine - High Functional	\$554.37	2.4%	0.3850
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-\$78.08	1.8%	-0.0542
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	\$122.71	1.3%	0.0852
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	\$253.62	1.5%	0.1761
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-\$51.16	1.6%	-0.0355
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	\$123.72	1.7%	0.0859
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	\$313.29	1.5%	0.2175
MMTA - Respiratory - Low Functional	-\$44.10	3.3%	-0.0306
MMTA - Respiratory - Medium Functional	\$121.07	2.0%	0.0841
MMTA - Respiratory - High Functional	\$275.31	2.5%	0.1912
Behavioral Health - Low Functional	-\$123.45	0.8%	-0.0857
Behavioral Health - Medium Functional	\$98.91	0.8%	0.0687
Behavioral Health - High Functional	\$230.10	0.7%	0.1598
Complex - Low Functional	-\$111.18	1.2%	-0.0772
Complex - Medium Functional	\$91.71	0.9%	0.0637
Complex - High Functional	\$48.10	1.0%	0.0334
MS Rehab - Low Functional	\$99.47	6.5%	0.0691
MS Rehab - Medium Functional	\$247.69	6.9%	0.1720
MS Rehab - High Functional	\$480.42	6.1%	0.3336
Neuro - Low Functional	\$255.82	3.5%	0.1776
Neuro - Medium Functional	\$446.01	3.5%	0.3097
Neuro - High Functional	\$625.61	3.5%	0.4344
Wound - Low Functional	\$423.16	5.6%	0.2938

Wound - Medium Functional	\$594.79	4.0%	0.4130
Wound - High Functional	\$774.05	4.7%	0.5375
Admission Source with Timing (Community Early is excluded)			
Community - Late	-\$566.96	62.8%	-0.3937
Institutional - Early	\$306.83	19.5%	0.2131
Institutional - Late	\$171.47	6.1%	0.1191
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	\$92.66	48.8%	0.0643
Comorbidity Adjustment - Has at least one interaction from interaction list	\$316.28	14.7%	0.2196
Constant	\$1,368.54		
Average Resource Use	\$1,440.10		
Number of 30-day Periods	7,590,683		
Adjusted R Squared	0.3290		

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021.

The case-mix weights finalized for CY 2022 are listed in Table 15 and is posted on the HHA Center webpage.⁷

TABLE 15—CASE-MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.1101	4
1FC21	Behavioral Health - High	Early - Community	1	1.1744	4
1FC31	Behavioral Health - High	Early - Community	2	1.3297	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.3232	4
2FC21	Behavioral Health - High	Early - Institutional	1	1.3875	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.5428	4
3FC11	Behavioral Health - High	Late - Community	0	0.7164	2
3FC21	Behavioral Health - High	Late - Community	1	0.7807	2
3FC31	Behavioral Health - High	Late - Community	2	0.9360	3
4FC11	Behavioral Health - High	Late - Institutional	0	1.2292	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2935	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4488	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8646	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9289	4
1FA31	Behavioral Health - Low	Early - Community	2	1.0842	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0777	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1420	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2973	3
3FA11	Behavioral Health - Low	Late - Community	0	0.4709	2

⁷ HHA Center Webpage: <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3FA21	Behavioral Health - Low	Late - Community	1	0.5352	2
3FA31	Behavioral Health - Low	Late - Community	2	0.6905	2
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9837	2
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0480	2
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2033	2
1FB11	Behavioral Health - Medium	Early - Community	0	1.0190	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0833	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2386	5
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2321	4
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2964	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4517	3
3FB11	Behavioral Health - Medium	Late - Community	0	0.6253	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.6896	2
3FB31	Behavioral Health - Medium	Late - Community	2	0.8449	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1381	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.2024	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3577	3
1DC11	Complex - High	Early - Community	0	0.9837	3
1DC21	Complex - High	Early - Community	1	1.0481	2
1DC31	Complex - High	Early - Community	2	1.2033	2
2DC11	Complex - High	Early - Institutional	0	1.1968	4
2DC21	Complex - High	Early - Institutional	1	1.2611	4
2DC31	Complex - High	Early - Institutional	2	1.4164	4
3DC11	Complex - High	Late - Community	0	0.5900	2
3DC21	Complex - High	Late - Community	1	0.6544	2
3DC31	Complex - High	Late - Community	2	0.8096	2
4DC11	Complex - High	Late - Institutional	0	1.1028	3
4DC21	Complex - High	Late - Institutional	1	1.1671	3
4DC31	Complex - High	Late - Institutional	2	1.3224	3
1DA11	Complex - Low	Early - Community	0	0.8731	3
1DA21	Complex - Low	Early - Community	1	0.9374	3
1DA31	Complex - Low	Early - Community	2	1.0927	2
2DA11	Complex - Low	Early - Institutional	0	1.0862	3
2DA21	Complex - Low	Early - Institutional	1	1.1505	3
2DA31	Complex - Low	Early - Institutional	2	1.3058	3
3DA11	Complex - Low	Late - Community	0	0.4794	2
3DA21	Complex - Low	Late - Community	1	0.5438	2
3DA31	Complex - Low	Late - Community	2	0.6990	2
4DA11	Complex - Low	Late - Institutional	0	0.9922	2
4DA21	Complex - Low	Late - Institutional	1	1.0565	2
4DA31	Complex - Low	Late - Institutional	2	1.2118	2
1DB11	Complex - Medium	Early - Community	0	1.0140	3
1DB21	Complex - Medium	Early - Community	1	1.0783	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1DB31	Complex - Medium	Early - Community	2	1.2336	2
2DB11	Complex - Medium	Early - Institutional	0	1.2271	4
2DB21	Complex - Medium	Early - Institutional	1	1.2914	4
2DB31	Complex - Medium	Early - Institutional	2	1.4467	4
3DB11	Complex - Medium	Late - Community	0	0.6203	2
3DB21	Complex - Medium	Late - Community	1	0.6846	2
3DB31	Complex - Medium	Late - Community	2	0.8399	2
4DB11	Complex - Medium	Late - Institutional	0	1.1331	3
4DB21	Complex - Medium	Late - Institutional	1	1.1974	3
4DB31	Complex - Medium	Late - Institutional	2	1.3527	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1466	5
1HC21	MMTA - Cardiac - High	Early - Community	1	1.2109	5
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3662	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3596	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.4240	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5793	5
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7529	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8172	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9725	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2656	4
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3300	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4853	4
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9139	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9783	4
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1336	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1270	4
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1913	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3466	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5202	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.5846	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7399	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0330	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0974	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2526	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.0353	5
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0996	5
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.2549	5
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2484	5
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.3127	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4680	5
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6416	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7059	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8612	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1544	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.2187	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3740	4
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3353	5
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3996	5
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5549	5
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5483	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.6127	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7680	4
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9416	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0059	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1612	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4543	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5187	3
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6740	3
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1441	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2084	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3637	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.3572	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4215	3
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.5768	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.7504	2
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.8147	2
3IA31	MMTA - Endocrine - Low	Late - Community	2	0.9700	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.2632	3
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3275	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.4828	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2618	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3261	5
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4814	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4748	5
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5392	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6945	5
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.8681	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9324	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.0877	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3808	3
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4452	3
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.6005	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1264	4
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1908	3
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3461	3
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3395	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.4038	4
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5591	4
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7327	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.7971	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9524	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2455	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.3098	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4651	4
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8961	3
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9604	3
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1157	3
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1092	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1735	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3288	4
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5024	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.5667	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7220	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0152	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0795	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2348	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0355	4
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0999	4
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2551	4
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2486	4
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.3129	4
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4682	4
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6418	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7062	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8615	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1546	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.2189	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3742	4
1KC11	MMTA - Infectious - High	Early - Community	0	1.1679	3
1KC21	MMTA - Infectious - High	Early - Community	1	1.2322	3
1KC31	MMTA - Infectious - High	Early - Community	2	1.3875	3
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3809	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4453	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.6005	4
3KC11	MMTA - Infectious - High	Late - Community	0	0.7742	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8385	2
3KC31	MMTA - Infectious - High	Late - Community	2	0.9938	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2869	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3513	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.5066	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9148	3
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9791	3
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1344	3
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1278	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1922	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3475	4
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5211	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.5854	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7407	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0339	2
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.0982	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2535	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0362	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.1006	3
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2558	4
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2493	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.3136	4
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4689	4
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6425	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7069	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8622	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1553	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2196	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3749	4
1AC11	MMTA - Other - High	Early - Community	0	1.1748	4
1AC21	MMTA - Other - High	Early - Community	1	1.2391	4
1AC31	MMTA - Other - High	Early - Community	2	1.3944	4
2AC11	MMTA - Other - High	Early - Institutional	0	1.3879	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.4522	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.6075	5
3AC11	MMTA - Other - High	Late - Community	0	0.7811	2
3AC21	MMTA - Other - High	Late - Community	1	0.8454	2
3AC31	MMTA - Other - High	Late - Community	2	1.0007	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2939	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.3582	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.5135	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9503	4
1AA21	MMTA - Other - Low	Early - Community	1	1.0147	4
1AA31	MMTA - Other - Low	Early - Community	2	1.1699	4
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1634	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.2277	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3830	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Final Recalibrated Weight for 2022	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3AA11	MMTA - Other - Low	Late - Community	0	0.5566	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6210	2
3AA31	MMTA - Other - Low	Late - Community	2	0.7762	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0694	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1337	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2890	3
1AB11	MMTA - Other - Medium	Early - Community	0	1.0672	5
1AB21	MMTA - Other - Medium	Early - Community	1	1.1316	5
1AB31	MMTA - Other - Medium	Early - Community	2	1.2868	4
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2803	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.3446	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4999	5
3AB11	MMTA - Other - Medium	Late - Community	0	0.6735	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7379	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8931	3
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1863	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2506	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.4059	4
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1415	4
1LC21	MMTA - Respiratory - High	Early - Community	1	1.2058	4
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3611	4
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3546	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.4189	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5742	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7478	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8121	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9674	3
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2606	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3249	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4802	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9197	4
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9840	4
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1393	4
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1327	4
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1971	4
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3524	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5260	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.5903	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7456	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0388	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.1031	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2584	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0344	4

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1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0987	5
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2540	5
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2474	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.3118	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4671	5
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6407	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7050	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8603	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1535	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2178	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3731	4
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.2068	4
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2711	5
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.4264	4
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.4199	5
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4842	5
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.6395	5
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.8131	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8774	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0327	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.3259	4
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3902	4
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.5455	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8889	3
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9532	3
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1085	4
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1019	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1663	4
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3216	4
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.4952	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.5595	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7148	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0080	3
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.0723	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2276	4
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0428	4
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.1072	4
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2625	5
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2559	4
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.3202	5
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4755	5
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6491	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7135	2

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3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8688	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1619	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2262	4
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3815	4
1EC11	MS Rehab - High	Early - Community	0	1.2839	5
1EC21	MS Rehab - High	Early - Community	1	1.3483	5
1EC31	MS Rehab - High	Early - Community	2	1.5035	5
2EC11	MS Rehab - High	Early - Institutional	0	1.4970	6
2EC21	MS Rehab - High	Early - Institutional	1	1.5613	6
2EC31	MS Rehab - High	Early - Institutional	2	1.7166	6
3EC11	MS Rehab - High	Late - Community	0	0.8902	2
3EC21	MS Rehab - High	Late - Community	1	0.9546	2
3EC31	MS Rehab - High	Late - Community	2	1.1098	3
4EC11	MS Rehab - High	Late - Institutional	0	1.4030	4
4EC21	MS Rehab - High	Late - Institutional	1	1.4673	4
4EC31	MS Rehab - High	Late - Institutional	2	1.6226	5
1EA11	MS Rehab - Low	Early - Community	0	1.0194	5
1EA21	MS Rehab - Low	Early - Community	1	1.0837	5
1EA31	MS Rehab - Low	Early - Community	2	1.2390	5
2EA11	MS Rehab - Low	Early - Institutional	0	1.2324	5
2EA21	MS Rehab - Low	Early - Institutional	1	1.2968	5
2EA31	MS Rehab - Low	Early - Institutional	2	1.4521	5
3EA11	MS Rehab - Low	Late - Community	0	0.6257	2
3EA21	MS Rehab - Low	Late - Community	1	0.6900	2
3EA31	MS Rehab - Low	Late - Community	2	0.8453	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.1385	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.2028	3
4EA31	MS Rehab - Low	Late - Institutional	2	1.3581	4
1EB11	MS Rehab - Medium	Early - Community	0	1.1223	5
1EB21	MS Rehab - Medium	Early - Community	1	1.1867	5
1EB31	MS Rehab - Medium	Early - Community	2	1.3419	5
2EB11	MS Rehab - Medium	Early - Institutional	0	1.3354	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.3997	6
2EB31	MS Rehab - Medium	Early - Institutional	2	1.5550	6
3EB11	MS Rehab - Medium	Late - Community	0	0.7286	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7930	2
3EB31	MS Rehab - Medium	Late - Community	2	0.9482	3
4EB11	MS Rehab - Medium	Late - Institutional	0	1.2414	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.3057	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.4610	4
1BC11	Neuro - High	Early - Community	0	1.3847	5
1BC21	Neuro - High	Early - Community	1	1.4491	5
1BC31	Neuro - High	Early - Community	2	1.6044	5

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2BC11	Neuro - High	Early - Institutional	0	1.5978	5
2BC21	Neuro - High	Early - Institutional	1	1.6621	5
2BC31	Neuro - High	Early - Institutional	2	1.8174	5
3BC11	Neuro - High	Late - Community	0	0.9910	2
3BC21	Neuro - High	Late - Community	1	1.0554	3
3BC31	Neuro - High	Late - Community	2	1.2107	3
4BC11	Neuro - High	Late - Institutional	0	1.5038	4
4BC21	Neuro - High	Late - Institutional	1	1.5681	4
4BC31	Neuro - High	Late - Institutional	2	1.7234	4
1BA11	Neuro - Low	Early - Community	0	1.1280	5
1BA21	Neuro - Low	Early - Community	1	1.1923	5
1BA31	Neuro - Low	Early - Community	2	1.3476	4
2BA11	Neuro - Low	Early - Institutional	0	1.3410	5
2BA21	Neuro - Low	Early - Institutional	1	1.4054	5
2BA31	Neuro - Low	Early - Institutional	2	1.5606	5
3BA11	Neuro - Low	Late - Community	0	0.7343	2
3BA21	Neuro - Low	Late - Community	1	0.7986	2
3BA31	Neuro - Low	Late - Community	2	0.9539	2
4BA11	Neuro - Low	Late - Institutional	0	1.2470	3
4BA21	Neuro - Low	Late - Institutional	1	1.3114	4
4BA31	Neuro - Low	Late - Institutional	2	1.4666	4
1BB11	Neuro - Medium	Early - Community	0	1.2600	5
1BB21	Neuro - Medium	Early - Community	1	1.3244	5
1BB31	Neuro - Medium	Early - Community	2	1.4796	5
2BB11	Neuro - Medium	Early - Institutional	0	1.4731	6
2BB21	Neuro - Medium	Early - Institutional	1	1.5374	6
2BB31	Neuro - Medium	Early - Institutional	2	1.6927	6
3BB11	Neuro - Medium	Late - Community	0	0.8663	2
3BB21	Neuro - Medium	Late - Community	1	0.9307	2
3BB31	Neuro - Medium	Late - Community	2	1.0860	3
4BB11	Neuro - Medium	Late - Institutional	0	1.3791	4
4BB21	Neuro - Medium	Late - Institutional	1	1.4434	4
4BB31	Neuro - Medium	Late - Institutional	2	1.5987	5
1CC11	Wound - High	Early - Community	0	1.4878	5
1CC21	Wound - High	Early - Community	1	1.5521	5
1CC31	Wound - High	Early - Community	2	1.7074	5
2CC11	Wound - High	Early - Institutional	0	1.7009	5
2CC21	Wound - High	Early - Institutional	1	1.7652	5
2CC31	Wound - High	Early - Institutional	2	1.9205	5
3CC11	Wound - High	Late - Community	0	1.0941	3
3CC21	Wound - High	Late - Community	1	1.1585	3
3CC31	Wound - High	Late - Community	2	1.3137	3
4CC11	Wound - High	Late - Institutional	0	1.6069	4

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4CC21	Wound - High	Late - Institutional	1	1.6712	4
4CC31	Wound - High	Late - Institutional	2	1.8265	4
1CA11	Wound - Low	Early - Community	0	1.2442	5
1CA21	Wound - Low	Early - Community	1	1.3085	4
1CA31	Wound - Low	Early - Community	2	1.4638	4
2CA11	Wound - Low	Early - Institutional	0	1.4572	4
2CA21	Wound - Low	Early - Institutional	1	1.5216	4
2CA31	Wound - Low	Early - Institutional	2	1.6768	4
3CA11	Wound - Low	Late - Community	0	0.8505	2
3CA21	Wound - Low	Late - Community	1	0.9148	3
3CA31	Wound - Low	Late - Community	2	1.0701	3
4CA11	Wound - Low	Late - Institutional	0	1.3632	3
4CA21	Wound - Low	Late - Institutional	1	1.4276	3
4CA31	Wound - Low	Late - Institutional	2	1.5829	3
1CB11	Wound - Medium	Early - Community	0	1.3633	5
1CB21	Wound - Medium	Early - Community	1	1.4277	5
1CB31	Wound - Medium	Early - Community	2	1.5830	5
2CB11	Wound - Medium	Early - Institutional	0	1.5764	5
2CB21	Wound - Medium	Early - Institutional	1	1.6407	5
2CB31	Wound - Medium	Early - Institutional	2	1.7960	5
3CB11	Wound - Medium	Late - Community	0	0.9696	3
3CB21	Wound - Medium	Late - Community	1	1.0340	3
3CB31	Wound - Medium	Late - Community	2	1.1893	3
4CB11	Wound - Medium	Late - Institutional	0	1.4824	4
4CB21	Wound - Medium	Late - Institutional	1	1.5467	4
4CB31	Wound - Medium	Late - Institutional	2	1.7020	4

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW July 12, 2021.

To ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the CY 2022 national, standardized 30-day period payment rate. Typically, the case-mix weight budget neutrality factor is calculated using the most recent, complete home health claims data available. However, due to the COVID-19 PHE, we looked at using the previous calendar year's home health claims data (CY 2019) to determine if there were significant differences between utilizing CY 2019 and CY 2020 claims data. We noted that CY 2020 is the first year of actual PDGM utilization data, therefore, if we were to use CY 2019 data due to the COVID-19 PHE we would need to simulate 30-day periods from 60-day episodes under the old system. We believe that using CY 2020

utilization data is more appropriate than using CY 2019 utilization data because it is actual PDGM utilization data. The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2022 PDGM case-mix weights (developed using CY 2020 home health claims data) are applied to CY 2020 utilization (claims) data are equal to total payments when CY 2021 PDGM case-mix weights (developed using CY 2018 home health claims data) are applied to CY 2020 utilization data. This produces a case-mix budget neutrality factor for CY 2022 of 1.0396. For reasons described previously, CY 2020 utilization data was used to calculate the case-mix weight budget neutrality factor because it is the most recent complete data we have at the time of this rulemaking.

We invited comments on the CY 2022 proposed case-mix weights and proposed case-mix weight budget neutrality factor and comments are summarized later in this section.

Comment: MedPAC supports CMS' proposal to use CY 2020 data to recalibrate the PDGM case-mix weights for CY 2022.

Response: We thank MedPAC for its support.

Comment: Many commenters were generally opposed to the proposal to recalibrate the PDGM case-mix weights for CY 2022. These commenters expressed concerns about the influence of the COVID-19 PHE on the types of patients receiving home health care, and the use of CY 2020 data. These commenters believe that CY 2020 utilization will likely not be representative of utilization patterns in CY 2022. One commenter stated that the trends seen in 2020 and 2021 will not hold permanently, and therefore data from these periods would be skewed if used in modifying the PDGM rate structure or case-mix weight recalibration. Another commenter cautioned against the use of CY 2020 data for recalibration and stated that the COVID-19 PHE directly led to shifts in referral sources, and increases in the severity of cases. One commenter expressed concern by what they describe as "the inconsistency in the usage of CY 2020 data, when both case-mix weights and LUPAs rates are dependent upon utilization and care patterns." Another commenter stated that while annual recalibration of case-mix weights is

generally appropriate to ensure that that case-mix weights reflect recent trends in utilization and resource, the COVID-19 PHE has had significant effects on home health utilization and overall case-mix severity in CY 2020. Several commenters recommended that CMS maintain the structure and design of the PDGM for CY 2022.

Response: We acknowledge commenter statements and concerns as to how the COVID-19 PHE affected home health utilization in CY 2020 as well as potential impact to CY 2021 utilization. However, we continue to believe that it is important to base the PDGM case-mix weights on actual PDGM utilization data and patient resource and shift away from the use of data prior to the implementation of the PDGM, where utilization was influenced by different incentives, such as the therapy thresholds used in case-mix adjustment prior to the PDGM. As stated in the CY 2022 HH PPS proposed rule (86 FR 35892), there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups. CMS believes that the COVID-19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID-19 PHE on the calculation of the case-mix weight would be minimized since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight). Finally, we note that if we chose not to recalibrate for CY 2022, it would be the third calendar year without an update to the case-mix weights. We believe that prolonging recalibration could lead to more significant variation in the case-mix weights than what is observed using CY 2020 utilization data.

Comment: One commenter expressed concern with the frequency of case-mix weight recalibration. This commenter believes that CMS should not recalibrate the case-mix weights for CY 2022 because annual changes are too frequent. This commenter recommended that CMS change the frequency of recalibration from annually to no more often than every three years.

Response: We thank the commenter for the recommendation. In the CY 2019 HH PPS final rule, we finalized our proposal to annually recalibrate the PDGM case-mix weights (83 FR 56515) to reflect the most recent utilization data available at the time of rulemaking. We stated that 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. Any changes to the frequency of the recalibration of the case-mix weights would need to be proposed through notice and comment rulemaking.

Final Decision: We are finalizing the recalibration of the HH PPS case-mix weights as proposed for CY 2022. We are also finalizing the proposal to implement the changes to the PDGM case-mix weights in a budget neutral manner by applying a case-mix budget neutrality factor to the CY 2022 national, standardized 30-day period payment rate. As stated previously, the final case-mix budget neutrality factor for CY 2022 will be 1.0396.

4. CY 2022 Home Health Payment Rate Updates

a. CY 2022 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for home health 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 with comment period (83 FR 56425), we finalized a rebasing of the home health market basket to reflect 2016 cost report data. As such, based on the rebased 2016-based home health market basket, we finalized our policy that the labor share is 76.1 percent and the non-labor 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 with comment period (83 FR 56425,56436).

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 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 changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please visit <http://www.bls.gov/mfp>, to obtain the BLS historical published MFP data.

The home health update percentage for CY 2022 is based on the estimated home health market basket update, specified at section 1895(b)(3)(B)(iii) of the Act. In the CY 2022 HH PPS proposed rule, we proposed a market basket update of 2.4 percent (based on IHS Global Inc.'s first-quarter 2021 forecast with historical data through fourth-quarter 2020) (86 FR 35909). The CY 2022 proposed home health market basket update of 2.4 percent was then reduced by a productivity adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148), of 0.6 percentage point for CY 2022. In effect, the proposed home health payment update percentage for CY 2022 was a 1.8 percent increase. 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 2022, the proposed home health payment update was -0.2 percent (1.8 percent minus 2 percentage points). We also proposed that if more recent data became available after the publication of the proposed rule and

before the publication of the final rule (for example, more recent estimates of the home health market basket update and productivity adjustment), we would use such data, if appropriate, to determine the home health payment update percentage for CY 2022 in the final rule (86 FR 35909).

Comment: Several commenters had concerns with the market basket update factor. The commenters noted that the HH PPS market basket update factor has recently declined from 3.0 percent in CY 2019 to 2.4 percent in CY 2022. They stated this is likely because the market basket price indices do not reflect the pandemic-driven inflation in large part because the market basket composite index is determined on a 4-quarter rolling average basis and reflect general cost changes across the healthcare industry—failing to account for home health specific price changes on a real-time and industry specific basis.

They also stated that the COVID-19 PHE in CY 2020 has in some part affected the supply of and demand for certain inputs, including home health labor leading to a general increase in labor and other input prices. For example, the pandemic intensified staffing shortages for HHAs as home health workers left their jobs due to fear of exposure to the virus. As such, HHAs had to raise wages to attract adequate staff. Additionally, the commenters stated that the CMS HH PPS market basket price indexes and cost weight categories may not capture increased telehealth and personal protective equipment (PPE) costs that HHAs faced as a result of the pandemic. The commenters provided an example of data from a Partnership for Quality Home Healthcare (PQHH) member HHA that suggested that in March and April of CY 2020, average pricing for masks and gowns approximately increased 8 and 6 times, respectively.

The commenters also noted that in CY 2020, some portion of home health visits were shifted to telehealth during the COVID-19 PHE. The commenters stated that HHAs can report costs of telehealth on the HHA cost report, but incompletely, which implies that cost weights and price proxies in CY 2020 and future years fail to accurately account for telehealth use.

One commenter also constructed an estimated market basket index using results from the 2021 PQHH Labor Cost Survey related to the three largest components of the market basket index (wages and salaries, benefits, and administrative and general expenses). Based on this analysis, the commenter determined that the home health specific market basket update factor should have increased by approximately 1.1 percentage points between CY 2019 and CY 2020 and by approximately 1.2 percentage points between CY 2020 and CY 2021. The commenter noted that these results were in stark contrast to CMS HH PPS market basket update factors that decreased by 0.1 percentage point between CY 2019 and CY 2020, and further by 0.6 percentage point between CY 2020 to CY 2021.

The commenter noted that CMS' indicated in the CY 2021 final rule that the lower update (2.3 percent) for CY 2021 was "primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets were expected to be significantly impacted during the recession that started in February 2020 and throughout the anticipated recovery." In contrast, their results showed that HHA wages grew at a slightly higher rate between 2019 and 2021, although underlying data shows that therapy professions primarily those in urban areas experienced a decline in wage growth in 2020. In addition, the commenter stated that the significant increase in benefits costs and administrative, general, and other costs seem to influence a large part of their increase in the estimated market basket constructed from the survey data. The commenter noted that these results reflect that the COVID-19 pandemic in 2020 likely resulted in price inflation for most HHA inputs as opposed to a recession and highlight the need for CMS to consider using price proxies that accurately reflect trends in the home health industry.

Response: We appreciate the comment and the commenter's analysis of home health agency costs. The 2016-based home health market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services

purchased in the base period. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured.

Any increase in costs as a result of the COVID-19 PHE (to the extent they differ from the price increase of the 2016-based home health market basket) would not be reflected in the market basket update factor. Changes in costs would be reflected when the market basket cost weights are updated to incorporate more recent home health agency cost data.

The current HHA market basket cost weights are based on Medicare cost report data from 2016. Typically, a market basket is rebased every four to five years. However, we continually monitor the cost weights in the market baskets to ensure they are reflecting the mix of inputs used in providing services. We do not yet have cost report data available to determine the impact of the COVID-19 PHE on HHA cost structures. When the data becomes available, we will review the 2020 Medicare cost report data to evaluate the impact of the COVID-19 PHE as well as implementation of the PDGM and determine whether a rebasing of the market basket cost weights is appropriate. Any future rebasing or revising of the HHA market basket will be proposed and subject to public comments in future rulemaking.

We disagree with the commenter that the price proxies used in the HHA market basket do not accurately reflect trends in the home health industry. The price proxies used in the market basket represent the price indices that correspond with the relevant cost categories (which were determined using HHA Medicare cost report data and Bureau of Economic Analysis Benchmark Input-Output data for NAICS 621600, Home Health Care Services), capturing the overall inflation of these products or services. Specifically, the aggregate compensation price proxy reflects the occupational composition of the home health industry (healthcare and nonhealthcare) published by the BLS Office of Occupational Employment Statistics. About 25 percent of the home health market basket is proxied by the Employment Cost Index (ECI) for Wages and Salaries and ECI for Benefits for civilian hospital workers, reflecting the price increases for compensation for skilled healthcare workers that are also employed by HHAs. Another 27

percent of the home health market basket is proxied by the ECI for Wages and Salaries and ECI for Benefits for healthcare social assistance workers, reflecting the price increases for compensation for overall healthcare workers such as home health aides and nursing aides. A description of the detailed methodology used to develop the 2016-based HHA market basket can be found in the CY 2019 final rule (83 FR 56427).

For this final rule, based on IHS Global Inc.'s (IGI's) third quarter 2021 forecast, the CY 2022 increase in the 2016-based home health market basket is 3.1 percent (compared to the proposed rule of 2.4 percent), which is primarily due to forecasted higher compensation prices. The revised higher forecast for compensation prices for CY 2022 reflects the recent faster historical trends, lower projected labor-force participation, and higher anticipated overall inflation as compared to IGI's first quarter 2021 forecast.

We understand the commenter's concern for adequate price increase and payment for Medicare services. As noted in the previous comment by the Medicare Payment Advisory Commission, Medicare margins are estimated to be roughly 15 percent in 2019. In addition, we would note that the increase in the home health market basket used for the HHS PPS (that is based on a forecast) over the CY 2010 to CY 2020 time period has exceeded the resulting actual increase in the home health market basket by an average of 0.5 percentage point each year.

Comment: Several commenters supported CMS' proposal to increase aggregate payments in CY 2022 by 1.8 percent; however, they stated that due to the increased demand on the home health industry as a result of the COVID-19 PHE as well as the lack of coverage for home health services delivered remotely, they strongly encouraged CMS to implement a larger increase.

The commenters stated that annual increases to the home health payment rates have not kept pace with recent increases in home health providers' staffing and other costs, and that CMS should consider rising labor costs in particular when finalizing rates for CY 2022. They noted that patients are safest at home during a pandemic, and home health providers risk their own

safety to ensure that these patients continue to receive quality care with minimum exposure.

Therefore, they believed HHAs should be adequately reimbursed.

Several commenters recommended that CMS establish a process and methodology to modify home health agency payment systems and rates during a PHE to address new costs triggered by the COVID-19 PHE or unpredicted limitations in payment models. They stated that CMS modified both the market basket increase and productivity adjustment in other sectors in final rules that take effect on October 1, 2021; however, they believe neither those changes in other sectors, nor the proposed 2022 rate adjustment in home health services adequately accounts for the increased costs of care in 2021 that are highly likely to continue in 2022.

The commenters stated that foremost among the cost increases not adequately represented in the market basket increase are personal protective equipment and other infection control costs. They stated that the market basket index reflects increases in the cost of goods and labor, but it does not address new costs or volume increases in the use of such items as PPE. While the end of the COVID-19 PHE is unfortunately not known, commenters stated that they believe it is reasonable and fair to conclude that the use of PPE will be maintained at levels comparable to 2020 throughout 2021 and into 2022. As such, the commenters stated that the increased cost of care, as experienced in 2020-2021, as it relates to PPE will continue in 2022. They stated that CMS could include a PPE cost add-on to the 2022 payment episodic and per visit payment rates. The commenters stated that conceptually, an add-on has been used in Medicare home health services previously to reflect the administrative costs of OASIS and other administrative activities for LUPA-only patient care.

Response: We appreciate the commenters' support for the use of the productivity-adjusted market basket to annually update HH PPS payments. As proposed, we are using the latest available data to determine the CY 2022 home health market basket update and productivity adjustment for this final rule.

We recognize the unique challenges and market conditions as a result of the COVID-19 PHE, but based on the data available we continue to believe that the home health market basket adequately captures changes in prices associated with providing home health services. As described in the CY 2019 Home Health PPS final rule with comment period (83 FR 56427), the cost weights were calculated using the 2016 Medicare cost report data, which is provided directly by freestanding home health agencies. The price proxies used in the market basket reflect a projection of the expected price pressures for each category of expenses.

We contract with IHS Global Inc. (IGI) to purchase their quarterly forecasts of the price proxies that are used in the market baskets and multifactor productivity (MFP) that is used to determine the productivity adjustment, to ensure independence of the projections. Consistent with our proposal to use more recent data as they become available, for this final rule we have incorporated more current historical data and revised forecasts provided by IGI that factor in expected price and wage pressures. By incorporating the most recent estimates available of the market basket update and productivity adjustment, we believe these data reflect the best available projection of input price inflation faced by HHAs for CY 2022, adjusted for economy-wide productivity, which is required by statute.

We understand the commenters' concerns that the COVID-19 PHE had unexpected effects on operating costs for healthcare providers, including additional expenses related to PPE costs and services furnished remotely, for which HHAs are not paid directly. Section 1895(e)(1)(A) of the Act prohibits payment for home health services furnished via a telecommunications system, if such services substitute for in-person home health services ordered as part of a plan of care. These remote services also cannot be considered a home health visit for purposes of eligibility or payment; however, we do acknowledge the importance of these services during a PHE and beyond. In the CY 2021 final rule (85 FR 70323), we modified the language at § 409.46(e) allowing a broader use of telecommunications technology to be reported as allowable administrative costs on the home health cost report, recognizing that these services

have the potential to improve efficiencies, expand the reach of healthcare providers, allow more specialized care in the home, and allow HHAs to see more patients or to communicate with patients more often.

We disagree that the market basket methodology should be modified from the current methodology to account for the incorporation of costs during this or future PHEs. The market baskets account for changes in provider input expenses in two ways: (1) through the base year cost weights; and (2) through the projected price pressures for each cost category as measured by each of the price proxies.

As previously explained, the CMS market baskets are Laspeyres-type price indexes where relative cost weights are established for a base year. The major cost weights for the home health market basket are currently based on the reported expenses for the universe of home health agencies for 2016 on the Medicare Cost Report, and we periodically rebase the cost weights for each of the CMS market baskets to update the relative cost shares. Generally, these base year weights are updated within a five-year timeframe during a rebasing and revising of the market basket; this allows for the market baskets to reflect changes in the spending patterns of providers across the various cost categories. We have found that these cost weights typically do not change substantially from year to year. The Medicare Cost Report data are available with a time lag (for example, the most recent complete data available for home health agencies would reflect 2019 experience). We did not propose to rebase or revise the HHA market basket for CY 2022; however, as stated previously, we plan to review the 2020 Medicare cost report data when they become available to determine whether the distribution of costs faced by HHAs is different when compare to prior years. Any future rebasing or revising of the HHA market basket will be proposed and subject to public comments in future rulemaking.

Consistent with our proposal to use more recent data, the HHA CY 2022 market basket increase factor is 2.6 percent (3.1 percent market basket update reduced by 0.5 percentage point

productivity adjustment) reflecting IGI's 2021 third quarter forecast. The proposed HHA CY 2022 market basket increase factor based on IGI's 2021 first quarter forecast was 1.8 percent.

Comment: MedPAC recognized that CMS must provide the statutorily mandated payment update, but they stated that this increase is not warranted based on their analysis of payment adequacy. In their March 2021 report to the Congress, the Commission found positive access, quality, and financial indicators for the sector, with margins of 15.8 percent for freestanding HHAs in 2019. Though consistent with statute, they believe that a payment update of 1.8 percent will keep payments higher than necessary for adequate access to quality care. They noted that the Commission recommended that the Congress reduce the 2021 Medicare base payment rate for HHAs by 5 percent for the 2021 payment year.

Response: We appreciate MedPAC's concern regarding the payment increase for HHAs; however, we do not have the statutory authority to implement its recommendation.

Final Decision: As proposed, we are finalizing our policy to use more recent data to determine the home health payment update percentage for CY 2022 in this final rule. Based on IHS Global Inc.'s third-quarter 2021 forecast with historical data through second-quarter 2021, the home health market basket update is 3.1 percent. The CY 2022 home health market basket update of 3.1 percent is then reduced by a productivity adjustment of 0.5 percentage point for CY 2022. For HHAs that submit the required quality data for CY 2022, the home health payment update is a 2.6 percent increase. For HHAs that do not submit the required quality data for CY 2022, the home health payment update is 0.6 percent (2.6 percent minus 2 percentage points).

b. CY 2022 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 home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied

to home payments. We proposed to continue this practice for CY 2022, as we continue to believe that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS.

In the CY 2021 HH PPS final rule (85 FR 70298), we finalized the proposal to adopt the revised Office of Management and Budget (OMB) delineations with a 5 percent cap on wage index decreases, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 only and no cap would be applied to wage index decreases for the second year (CY 2022). Therefore, we proposed to use the FY 2022 pre-floor, pre-reclassified hospital wage index with no 5 percent cap on decreases as the CY 2022 wage adjustment to the labor portion of the HH PPS rates. For CY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018 (FY 2018 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 2022 HH PPS wage index, we proposed 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 proposed 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 proposed to continue to use the most recent wage index previously available for that area. The

most recent wage index previously available for rural Puerto Rico is 0.4047. 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 2022, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). The CY 2022 wage index value for Hinesville, GA is 0.8539.

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 66085,66087), we adopted OMB's 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 2022 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8738. Bulletin No. 17-01 is available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf>.

On April 10, 2018 OMB issued OMB Bulletin No. 18-03 which superseded the August 15, 2017 OMB Bulletin No. 17-01. On September 14, 2018, OMB issued OMB Bulletin No. 18-04 which superseded the April 10, 2018 OMB Bulletin No. 18-03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18-04 may be obtained at: <https://www.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-metropolitan-statistical-areas.pdf>.

On March 6, 2020, OMB issued Bulletin No. 20-01, which provided updates to and superseded OMB Bulletin No. 18-04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20-01 provided detailed information on the update to statistical areas since

September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to <https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>.) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. In the CY 2021 HH PPS final rule (85 FR 70298) we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20-01 in future rulemaking. After reviewing OMB Bulletin No. 20-01, we have determined that the changes in Bulletin 20-01 encompassed delineation changes that would not affect the Medicare wage index for CY 2022. Specifically, the updates consisted of changes to NECTA delineations and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in the CY 2021 HH PPS final rule (85 FR 70298) we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, while we proposed to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific wage index updates would not be necessary for CY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any geographic areas for purposes of the wage index calculation for CY 2022.

We received several comments on the CY 2022 home health wage index proposals. A summary of these comments and our responses are as follows:

Comment: A few commenters recommended overarching changes to the home health wage index including the creation of a home health specific wage index, allowing home health agencies to appeal their wage index values or utilize geographic reclassification, and establishing a home health floor of 0.80 similar to the hospice floor.

Response: While we thank the commenters for their recommendations, these comments are outside the scope of the proposed rule. Any changes to the way we adjust home health payments to account for geographic wage differences, beyond the wage index proposals discussed in the CY 2022 HH PPS proposed rule (86 FR 35874), would have to go through notice and comment rulemaking. While CMS and other stakeholders have explored potential alternatives to using OMB's statistical area definitions, CMS continues to explore potential alternatives to explore alternatives to using OMB's delineations but we continue to believe that in the absence of home health specific wage data, using the pre-floor, pre-reclassified hospital wage data is appropriate and reasonable for home health payments. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification. The reclassification provision found in section 1886(d)(10) of the Act is specific to hospital inpatient prospective payment system (IPPS) hospitals only.

Additionally, the application of the hospice floor is specific to hospices and does not apply to HHAs. The hospice floor was developed through a negotiated rulemaking advisory committee, under the process established by the Negotiated Rulemaking Act of 1990 (Pub. L. 101-648). Committee members included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; consumer groups; and a government representative. The Committee reached consensus on a methodology that resulted in the hospice wage index. Because the reclassification provision applies only to hospitals, and the hospice floor applies only to hospices, we continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the home health payment rates. This position is longstanding and consistent with other Medicare payment systems (for example, SNF PPS, IRF PPS, and Hospice).

Comment: A commenter stated that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting home health costs, particularly in States like New York which has

among the nation's highest labor costs now greatly exacerbated by the States' implementation of a phased in \$15 per hour minimum wage hike, the balance of which is unfunded by Medicare".

Response: Regarding minimum wage standards, we note that such increases would be reflected in future data used to create the hospital wage index to the extent that these changes to State minimum wage standards are reflected in increased wages to hospital staff.

Comment: A few commenters recommended that CMS reconsider its decision to apply the new OMB geographic designations for CBSAs in the annual wage index update. Specifically, commenters had concerns with wages index decreases for counties in New Jersey that moved from the New York City Metropolitan CBSA and now make up the newly created New Brunswick-Lakewood, NJ, CBSA as well as Franklin County, Massachusetts, that moved from rural to urban status.

Response: We remind commenters that the revised OMB delineations were finalized in the CY 2021 HH PPS final rule (85 FR 70306). Additionally, we continue to believe it is important for the home health wage index to use the latest OMB delineations available in order to maintain an accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We note that the wage-index value is applied to home health payments are based on where the individual is receiving home health services and not the location of the home health agency. For example, if a home health agency in New Jersey is servicing a patient in the New York City Metropolitan CBSA, the wage index for New York City would apply to the payment.

Comment: A few commenters stated that providers should be protected against substantial payment reductions due to dramatic reductions in wage index values from 1 year to the next and recommended that CMS maintain the 5 percent cap that was put in place for CY 2021. A commenter recommended that CMS should implement a 2 percent cap on wage index decreases for CY 2022. Other commenters recommended that CMS adopt a transition policy for

home health providers that mirrors the 5-percent cap on annual wage index reductions included in the FY 2022 IPPS/LTCH PPS final rule.

Response: We appreciate the suggestions for improving the HH PPS wage index. We did not propose changes to the HH PPS wage index methodology for CY 2022, and therefore we are not finalizing any changes to that methodology in this final rule. However, we will take these comments into consideration to potentially inform future rulemaking.

Comment: A commenter stated that rural areas are disproportionately affected by what the commenter artificially reduced rural hospital wage indices. This commenter believes that in areas with lower population densities, travel costs are increased because of the time and mileage involved in traveling from patient to patient to provide services, and the current method of adjusting labor costs using the hospital wage index does not accurately account for increased travel costs and lost productivity in serving rural areas.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the added cost of traveling from one patient to the next. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas.

Final Decision: After considering the comments received in response to the CY 2022 HH PPS proposed rule, we are finalizing our proposal to continue to use the pre-floor, pre-reclassified hospital inpatient wage index with no 5 percent cap on wage index decreases as the wage adjustment to the labor portion of the HH PPS rates. For CY 2022, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2017 and before October 1, 2018 (FY 2018 cost report data).

The final CY 2022 HH PPS wage index is available on the CMS website at:

<https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center>.

c. CY 2022 Annual Payment Update

(1) Background

The 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 HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020.

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 with comment period (83 FR 56435), we finalized rebasing the home health market basket to reflect 2016 Medicare cost report data. We also finalized a revision to the labor share to reflect the 2016-based home health market basket compensation (Wages and Salaries plus Benefits) cost weight. We finalized our policy that for CY 2019 and subsequent years, the labor share would be 76.1 percent and the non-labor share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2022:

- Multiply the national, standardized 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 30-day period payment amount, 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 home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health 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.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

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

- A LUPA is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A 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.

(2) CY 2022 National, Standardized 30-Day Period Payment Amount

In the CY 2022 HH PPS proposed rule (86 FR 35880), CMS provided preliminary monitoring data for the first year of the PDGM and presented a repricing method to determine the differences between assumed and actual behavior changes and the impact of such on estimated aggregate expenditures. For CY 2022, we did not propose to make any additional

permanent or temporary adjustments to the national, standardized 30-day period payment in accordance with section 1895(b)(3)(D) of the Act.

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 2022 national, standardized 30-day period payment rate, we apply a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor and the home health payment update percentage discussed in section III.C.2. of this final rule. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we apply a case-mix weights budget neutrality factor to the CY 2021 national, standardized 30-day period payment rate. The final case-mix weights budget neutrality factor for CY 2022 is 1.0396.

Additionally, we also apply a wage index budget neutrality to ensure that wage index updates and revisions are implemented in a budget neutral manner. Typically, the wage index budget neutrality factor is calculated using the most recent, complete home health claims data available. However, due to the COVID-19 PHE, we looked at using the previous calendar year's home health claims data (CY 2019) to determine if there were significant differences between utilizing 2019 and 2020 claims data. Our analysis showed that there is only a small difference between the wage index budget neutrality factors calculated using CY 2019 and CY 2020 home health claims data. Therefore, we decided to continue our practice of using the most recent and complete home health claims data available; that is why we used CY 2020 claims data for the CY 2022 payment rate updates.

To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day periods using the CY 2022 wage index so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2021 wage index and the CY 2021 national standardized 30-day period payment rate adjusted by the case-mix

weights recalibration neutrality factor. Then, by dividing the payment rate for non-LUPA 30-day periods using the CY 2022 wage index by the payment rate for non-LUPA 30-day periods using the CY 2021 wage index, we obtain a wage index budget neutrality factor of 1.0019. We then apply the wage index budget neutrality factor of 1.0019 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the CY 2022 home health payment update percentage of 2.6 percent. The CY 2022 national, standardized 30-day period payment rate is calculated in Table 16.

TABLE 16: CY 2022 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2021 National Standardized 30-Day Period Payment	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY2022 HH Payment Update	CY 2022 National, Standardized 30-Day Period Payment
\$1,901.12	1.0396	1.0019	1.026	\$2,031.64

The CY 2022 national, standardized 30-day period payment rate for an HHA that does not submit the required quality data is updated by the CY 2022 home health payment update of 2.6 percent minus 2 percentage points and is shown in Table 17.

TABLE 17: CY 2022 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2021 National Standardized 30-Day Period Payment	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update Minus 2 Percentage Points	CY 2022 National, Standardized 30-Day Period Payment
\$1,901.12	1.0396	1.0019	1.006	\$1,992.04

(3) CY 2022 National Per-Visit Rates for 30-day Periods of Care

The national per-visit rates are used to pay LUPAs and to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health 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 2022 national per-visit rates, we started with the CY 2021 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 30-day periods of care using the CY 2022 wage index and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2021 wage index. By dividing the payment rates for LUPA 30-day periods of care using the CY 2022 wage index by the payment rates for LUPA 30-day periods of care using the CY 2021 wage index, we obtained a wage index budget neutrality factor of 1.0019. We apply the wage index budget neutrality factor in order to calculate the CY 2022 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 2022 home health payment update percentage of 2.6 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 2022 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2022 home health payment update percentage of 2.6 percent and are shown in Table 18.

TABLE 18: CY 2022 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2021 Per-Visit Payment Amount	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update	CY 2022 Per-Visit Amount
Home Health Aide	\$69.11	X 1.0019	X 1.026	\$71.04
Medical Social Services	\$244.64	X 1.0019	X 1.026	\$251.48
Occupational Therapy	\$167.98	X 1.0019	X 1.026	\$172.67
Physical Therapy	\$166.83	X 1.0019	X 1.026	\$171.49

Skilled Nursing	\$152.63	X 1.0019	X 1.026	\$156.90
Speech-Language Pathology	\$181.34	X 1.0019	X 1.026	\$186.41

The CY 2022 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2020 home health payment update percentage of 2.6 percent minus 2 percentage points and are shown in Table 19.

TABLE 19: CY 2022 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2021 Per-Visit Amount	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update Minus 2 Percentage Points	CY 2022 Per-Visit Amount
Home Health Aide	\$69.11	X 1.0019	X 1.006	\$69.66
Medical Social Services	\$244.64	X 1.0019	X 1.006	\$246.58
Occupational Therapy	\$167.98	X 1.0019	X 1.006	\$169.31
Physical Therapy	\$166.83	X 1.0019	X 1.006	\$168.15
Skilled Nursing	\$152.63	X 1.0019	X 1.006	\$153.84
Speech-Language Pathology	\$181.34	X 1.0019	X 1.006	\$182.77

The following is a summary of the public comments received about the CY 2022 payment update and our response.

Comment: Several commenters stated their support for the CY 2022 home health payment update. However, many stated that with the increasing demand of the home health industry because of the COVID-19 PHE, CMS should consider increasing Medicare payments to ensure that HHAs are able to provide quality care. MedPAC mentioned that though CMS was updating payment rates according to statute, they believe that payments were higher than necessary and should be reduced. Additionally, several commenters recommended that CMS establish a process and methodology to modify HHA payment systems and rates when an extreme and uncontrollable circumstance (for example, PHE) occurs to accurately account for new costs triggered by the emergency, such as personal protective equipment (PPE).

Response: We thank commenters for expressing their concerns. CMS is statutorily required to update the payment rates under the prospective payment system by the home health percentage in accordance with section 1895(b)(3)(B) of the Act. We understand commenters'

request to establish a process to modify payments during an unforeseen circumstance, such as a PHE. However, we do not have the statutory authority to modify the HH PPS methodology, in the event of an extreme and uncontrollable circumstance.

Final Decision: For CY 2022, we are finalizing the national, standardized 30-day payment rates, the per-visit payment rates, and the home health payment update percentage of 2.6 percent for providers submitting quality data and 0.6 percent for those not submitting quality data.

We are reminding stakeholders of the policies finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60544) and the implementation of a new one-time Notice of Admission (NOA) process starting in CY 2022. In that final rule, we finalized the lowering of the up-front payment made in response to Requests for Anticipated Payment (RAPs) to zero percent for all 30-day periods of care beginning on or after January 1, 2021 (84 FR 60544). For CY 2021, all HHAs (both existing and newly-enrolled HHAs) were required to submit a RAP at the beginning of each 30-day period in order to establish the home health period of care in the common working file and also to trigger the consolidated billing edits. With the removal of the upfront RAP payment for CY 2021, we relaxed the required information for submitting the RAP for CY 2021 and also stated that the information required for submitting an NOA for CYs 2022 and subsequent years would mirror that of the RAP in CY 2021. Starting in CY 2022, HHAs will submit a one-time NOA that establishes the home health period of care and covers all contiguous 30-day periods of care until the individual is discharged from Medicare home health services. Also, for the one-time NOA for CYs 2022 and subsequent years, we finalized a payment reduction if the HHA does not submit the NOA within 5 calendar days from the start of care. That is, if an HHA fails to submit a timely NOA for CYs 2022 and subsequent years, the reduction in payment amount would be equal to a 1/30 reduction to the wage and case-mix adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the NOA. In other words, the 1/30 reduction would be to the

30-day period adjusted payment amount, including any outlier payment, that the HHA otherwise would have received absent any reduction. For LUPA 30-day 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 stated 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.

We remind stakeholders that for purposes of determining if an NOA is timely-filed, the NOA must be submitted within 5 calendar days after the start of care for the first 30-day period of care. For example, if the start of care for the first 30-day period is January 1, 2022, the NOA would be considered timely-filed if it is submitted on or before January 6, 2022.

Example:

1/1/2022 = Day 0 (start of the first 30- day period of care)

1/6/2022 = Day 5 (An NOA submitted on or before this date would be considered “timely-filed”.)

1/7/2022 and after = Day 6 and subsequent days (An NOA submitted on and after this date would trigger the penalty.) In the event that the NOA is not timely-filed, the penalty is calculated from the first day of that 30- day period (in the example, the penalty calculation would begin with the start of care date of January 1, 2022, counting as the first day of the penalty) until the date of the submission of the NOA.

Also, in the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized exceptions to the timely filing consequences of the NOA requirements at § 484.205(j)(4). Specifically, we finalized our policy that CMS may waive the consequences of failure to submit a timely-filed NOA if it is determined that a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence. As finalized in the CY 2020 HH PPS final rule with comment period and as set forth in regulation at § 484.205(j)(4), an exceptional circumstance may be due to, 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 be beyond the control of the home health agency.

If an HHA believes that there is a circumstance that may qualify for an exception, the HHA must fully document and furnish any requested documentation to their MAC for a determination of exception.

Though we did not solicit comments on the previously finalized NOA process for CY 2022, we did receive several comments on various components of the finalized policy. However, these comments were out of scope of the proposed rule because we did not propose to make any changes to the finalized policy. For more in-depth information regarding the finalized policies associated with the new one-time NOA process, we refer readers to the CY 2020 HH PPS final rule with comment period (84 FR 60544) as well as the regulations at § 484.205(j).

(4) LUPA Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, 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 with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, 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 final CY 2022 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 would be \$289.50 (1.8451 multiplied by \$156.90), subject to area wage adjustment.

(5) Occupational Therapy LUPA Add-On Factor

In order to implement Division CC, section 115, of CAA 2021, we proposed conforming changes to regulations at § 484.55(a)(2) and (b)(3) that were revised to allow OTs to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but includes either PT or SLP. Because of this change, we proposed to establish a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled occupational therapy visit in LUPA periods that occurs as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. Currently, there is no sufficient data regarding the average excess of minutes for the first visit in LUPA periods when the initial and comprehensive

assessments are conducted by occupational therapists. Therefore, we proposed to utilize the PT LUPA add-on factor of 1.6700 as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts. We believe the similarity in the per-visit payment rates for both PT and OT make the PT LUPA add-on factor the most appropriate proxy. We solicited comments on this proposal.

Comment: Commenters were in support of CMS creating an OT add-on factor for the OT LUPA add-on payments. Additionally, there was support utilizing the PT LUPA add-on factor as a proxy until there is enough CY 2022 data to create an OT add-on factor for the OT LUPA add-on payments.

Response: We thank commenters for their support of the OT add-on factor.

Final Decision: We are finalizing our proposal to use the PT add-on factor as a proxy for the OT add-on factor, until we have sufficient CY 2022 data to create an OT add-on factor

d. Rural Add-On Payments for CY 2022

(1) Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173) required, for home health 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 home health 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 home health 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 home health 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 home health 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 2019 through CY 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 with comment period (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, would increase the CY 2022 30-day base payment rates, described in section III.C.3. of this final rule, by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2019 through CY 2022 rural add-on percentages outlined in law are shown in Table 20.

TABLE 20: HOME HEALTH PPS RURAL ADD-ON PERCENTAGES, CYs 2019-2022

Category	CY 2019	CY 2020	CY 2021	CY 2022
High utilization	1.5%	0.5%	None	None
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	None

Though we did not make any proposals regarding the rural add-on percentages in the CY 2022 HH PPS proposed rule, we did receive some comments as summarized in this section of this final rule.

Comment: While commenters understood the rural add-on payments decrease has been mandated by the BBA of 2018, many expressed continued concern and frustration of the reduction in support for access to rural beneficiaries. Commenters stated that providers in rural areas face higher overhead expenses due to increased travel time between patients as well as demands for extra staff in areas where workforce challenges already exist. A few commenters suggested that CMS should work with Congress to provide immediate relief to rural home health providers that face increased costs responding to patient's during the COVID-19 PHE and to maintain the rural add-on payment at 3 percent in order to protect Medicare beneficiaries' access to home health in rural communities.

Response: We thank commenters for their recommendations. We understand commenter concerns about the phase-out of rural add-on payments and potential effects on rural HHAs. However, because the current rural add-on policy is statutory, we have no regulatory discretion to modify or extend it. CMS will continue to monitor patient access to home health services and the costs associated with providing home health care in rural versus urban areas.

Final Decision: Policies for the provision of rural add-on payments for CY 2019 through CY 2022 were finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56443), in accordance with section 50208 of the BBA of 2018. The data used to categorize each county or equivalent area are 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>. 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.

e. 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 and the previous unit of payment (that is, 60-day episodes), outlier payments were made for 60-day 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 PEP adjustment 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 home health 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, 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 redesignating the existing language as section 1895(b)(5)(A) of the Act and revised 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, 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted 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 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.

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, the per unit rates used to estimate an episode's cost were 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 will continue to monitor the visit length by discipline as more recent data becomes available, and may propose to update the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (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 calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-day periods of care in CY 2020. Given that CY 2020 was the first year of the PDGM and the change to a 30-day unit of payment, we finalized to maintain the same FDL ratio of 0.56 in CY 2021 as we did not have sufficient CY 2020 data at the time of CY 2021 rulemaking to propose a change to the FDL ratio for CY 2021.

(2) Fixed Dollar Loss (FDL) Ratio for CY 2022

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 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 periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must be lower.

The FDL ratio and the loss-sharing ratio are 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. For the proposed rule, with CY 2020 claims data (as of March 30, 2021), we proposed an FDL ratio of 0.41. Using CY 2020 claims data (as of July 12, 2021) showed that for CY 2022 the final FDL ratio would need to be 0.40 to pay up to, but no more than, 2.5 percent of the total payment as outlier payments in CY 2022.

For this final rule, simulating payments using preliminary CY 2020 claims data (as of July 12, 2021) and the CY 2021 HH PPS payment rates (85 FR 70316), we estimate that outlier payments in CY 2021 would comprise 2.1 percent of total payments. Based on simulations using CY 2020 claims data (as of July 12, 2021) and the proposed CY 2022 payment rates presented in Section III.C.2 of this final rule, we estimate that outlier payments would constitute approximately 1.8 percent of total HH PPS payments in CY 2022. Our simulations showed that the FDL ratio would need to be changed from 0.56 to 0.40 to pay up to, but no more than, 2.5 percent of total payments as outlier payments in CY 2022.

Comment: A commenter recommended ending the outlier provision and restore the 5 percent to fund the outlier payments into regular Medicare payments.

Response: The HH PPS allows for outlier payments to be made to providers for episodes that have unusually large amounts of cost because of a patient's home health care needs. Nevertheless, we believe that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. CMS believes the outlier provision is beneficial since it addresses any additional or unpredictable cost that is medically necessary for a patient. In addition, we believe outlier payments are beneficial in helping to mitigate the incentive for HHAs to avoid patients that need higher levels of medical care.

Final Decision: We are finalizing the fixed-dollar loss ratio of 0.40 for CY 2022 so the

estimated total outlier payments are up to, but not more than, 2.5 percent of the payments estimated to be made under the HH PPS.

6. Conforming Regulations Text Changes Regarding Allowed Practitioners

As stated in the May 2020 COVID-19 interim final rule with comment period (85 FR 27550), we amended the regulations at parts 409, 424, and 484 to implement section 3708 of the CARES Act. This included defining a nurse practitioner (NP), a clinical nurse specialist (CNS), and a physician's assistant (PA) (as such qualifications are defined at §§ 410.74 through 410.76) as "allowed practitioners" (85 FR 27572). This means that in addition to a physician, as defined at section 1861(r) of the Act, an allowed practitioner may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. Additionally, we amended the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by a physician or an allowed non-physician practitioner (NPP), as set forth in § 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying allowed practitioner may be different from the physician or allowed practitioner that performed the face-to-face encounter. These regulations text changes are not time limited to the period of the COVID-19 PHE.

When implementing plan of care changes in the CY 2021 HH PPS final rule (85 FR 70298), the term "allowed practitioner" was inadvertently deleted from the regulation text at § 409.43. Therefore, in the CY 2022 HH PPS proposed rule (86 FR 35915), we proposed conforming regulations text changes at § 409.43 to reflect that allowed practitioners, in addition to physicians, may establish and periodically review the plan of care.

Comment: Commenters were supportive of the proposed conforming regulations text changes at § 409.43 and noted that they are appreciative of CMS' attention to updating the regulations to prevent confusion regarding who is authorized to establish and review the home

health plan of care. Additional commenters requested changes to the regulations at 42 CFR 424.22.

Response: We thank commenters for their review of the rule and support of the changes at § 409.43, and note that the suggested changes at 42 CFR 424.22 are out of scope of this final rule and would require a notice of proposed rulemaking.

Final Decision: We are finalizing the conforming regulations at § 409.43, consistent with section 3708 of the CARES Act to allow “allowed practitioners” to establish and periodically review the home health plan of care.

III. Home Health Value-Based Purchasing (HHVBP) Model

A. Expansion of the HHVBP Model Nationwide

1. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the CMS Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing Model (original Model) in nine States on January 1, 2016. The last year of data collection for the original Model ended on December 31, 2020. The original Model design leveraged the successes of and lessons learned from other value-based purchasing programs and demonstrations to shift from volume-based payments to a Model designed to promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original Model were 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 original 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 were required to compete in the original Model. We stated that requiring all Medicare-certified HHAs in the selected States to participate in the Model ensures that there is no selection bias, participants are representative of HHAs nationally, and there would be sufficient participation to generate meaningful results.

The original Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust the Medicare payment amounts under section 1895(b) of the Act based on the competing HHAs' performance on applicable quality measures. Under the original Model, CMS adjusts fee-for-service payments to Medicare-certified HHAs based on each HHA's performance on a set of quality measures in a given performance year measured against a baseline year and relative

to peers in its State. The maximum payment adjustment percentage increased incrementally, upward or downward, over the course of the original 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, which is comprised of performance on: (1) a set of measures already reported via the Outcome and Assessment Information Set (OASIS),⁸ completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and claims-based measures; and (2) three New Measures for which points were achieved for reporting data. Payment adjustments for a given year are based on the TPS calculated for performance 2 years' prior; for example, the CY 2018 payment adjustments were based on CY 2016 performance.

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 original 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.

On January 8, 2021, we announced that the HHVBP Model had been certified for expansion nationwide,⁹ as well as our intent to expand the Model through notice and comment rulemaking beginning no sooner than CY 2022. The original Model has resulted in an average 4.6 percent improvement in home health agencies' quality scores as well as average annual savings of \$141 million to Medicare.¹⁰

As described in this final rule, we proposed to expand the HHVBP Model (expanded

⁸ OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

⁹ <https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf>

¹⁰ <https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt>

Model/Model expansion) to all 50 States, the District of Columbia and the territories starting in CY 2022. We proposed to codify HHVBP Model expansion policies at §§484.340; 484.345; 484.350; 484.355; 484.360; 484.365; 484.370; and 484.375, as discussed in more detail in the sections that follow.

2. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through notice and comment rulemaking, the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) the Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* As observed in the Third Annual Evaluation Report,¹¹ the HHVBP Model resulted in improved quality of care (for example, consistently increasing TPS scores) and a reduction in Medicare expenditures through three performance years of the HHVBP Model (CYs 2016 to 2018). The HHVBP Model's intervention has led to savings without evidence of adverse risks. The evaluation also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) visits, resulting in reductions in inpatient and SNF spending. Based on these findings, the Secretary determined that expansion of the HHVBP Model would reduce spending and improve the quality of care.

- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion

¹¹ The HHVBP Third Annual Evaluation Report is available at <https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt>

of the HHVBP Model would produce Medicare savings if expanded to all States.¹²

- *No Alteration in Coverage or Provision of Benefits:* The HHVBP Model did not make any changes to coverage or provision of benefits for Medicare beneficiaries. Therefore, the Secretary has determined that expansion of the HHVBP Model would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

Consistent with our statutory authority, we stated in the proposed rule that we would continue to test and evaluate the expanded HHVBP Model. In the future, we would assess whether the expanded implementation of HHVBP is continuing to reduce Medicare spending without reducing quality of care or to improve the quality of patient care without increasing spending, and could modify the expanded HHVBP Model as appropriate through rulemaking.

We summarize in this section of this rule comments received regarding the requirements for expansion and our responses.

Comment: Commenters disagreed that CMS has met the statutory requirement that expansion of the HHVBP Model would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries and stated that while incremental improvements in quality performance and cost-savings are encouraging, they questioned whether those numbers are sufficient to justify ending the original model early during a pandemic and expanding it nationwide. Commenters asserted that access under the original Model was negatively impacted and expansion of HHVBP will exponentially worsen access to care.

Response: We disagree that expansion of the HHVBP Model should be suspended or the Model not expanded, or that the Model denies coverage to people who are not expected to improve. As stated previously, the original HHVBP Model did not make any changes to coverage or provision of benefits for Medicare beneficiaries. We further note that evaluation findings to date show that the implementation of the original HHVBP Model did not adversely

¹² The full CMS Actuary Report is available at <https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf>

impact home health utilization or market entries and exits differentially in HHVBP states relative to non-HHVBP states. We refer readers to Section 3, pages 25-36 in the *Evaluation of the Home Health Value-Based Purchasing (HHVBP) Model Third Annual Report*¹³ for our full analysis on beneficiary access to home health care covering the post-implementation period 2016-2018 and to Section 3, pages 25-50 in the *Evaluation of the Home Health Value-Based Purchasing (HHVBP) Model Fourth Annual Report*¹⁴ for an updated analysis covering the post-implementation period 2016-2019. As previously summarized, the CMS Chief Actuary's certification and the Secretary's determination were based on evaluation findings.

3. Overview

We stated in the proposed rule that the proposed HHVBP Model expansion presents an opportunity to improve the quality of care furnished to Medicare beneficiaries nationwide through payment incentives to HHAs. We stated that if finalized, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories would be required to participate in the expanded HHVBP Model beginning January 1, 2022. These HHAs would compete on value based on an array of quality measures related to the care that HHAs furnish.

We stated in the proposed rule that the proposed Model expansion would be tested under section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. The Secretary is not issuing any waivers of the fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act or any other Medicare or Medicaid fraud and abuse laws for this Model expansion at this time. In addition, CMS has determined that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives

¹³ The HHVBP Third Annual Evaluation Report is available at <https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt>.

¹⁴ <https://innovation.cms.gov/data-and-reports/2021/hhvbp-fourthann-rpt>

(42 CFR 1001.952(hh)(9)(ii)) will not be available to protect remuneration exchanged pursuant to any financial arrangements or patient incentives permitted under the Model. Thus, notwithstanding any other provisions of this final rule, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories must comply with all applicable fraud and abuse laws and regulations.

We proposed to use the section 1115A(d)(1) of the Act waiver authority to apply a reduction or increase of up to 5 percent to Medicare payments to Medicare-certified HHAs delivering care to beneficiaries in the 50 States, District of Columbia and the territories, depending on the HHA's performance on specified quality measures relative to its peers. Specifically, the expanded HHVBP Model proposes to utilize the section 1115A(d)(1) of the Act waiver authority to adjust the Medicare payment amounts under section 1895(b) of the Act. We stated in the proposed rule that in accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we would waive section 1895(b)(4) of the Act only to the extent necessary to adjust payment amounts to reflect the value-based payment adjustments under this proposed expanded Model for Medicare-certified HHAs in the 50 States, District of Columbia and the territories. We further stated that we may make changes to the payment adjustment percentage through rulemaking in future years of the expansion, as additional evaluation data from the HHVBP expanded Model become available, and we learn about performance within the Model under the expansion. The evaluation of the expanded Model would use a time series type approach to examine the outcomes of interest (cost or utilization) over time prior to the start of the intervention and follow that outcome after the start of the expansion.

a. Overview of Timing and Scope

As noted, we proposed to begin the expanded HHVBP Model on January 1, 2022. Under this proposal, CY 2022 would be the first performance year and CY 2024 would be the first payment year, with payment adjustments in CY 2024 based on an HHA's performance in CY 2022. Performance year means the calendar year during which data are collected for the purpose

of calculating a competing HHA's performance on applicable quality measures. Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

We proposed that the expanded Model would apply to all Medicare-certified HHAs in the 50 States, District of Columbia and the territories, which means that all Medicare-certified HHAs that provide services in the 50 States, District of Columbia and the territories would be required to compete in the expanded Model. We proposed to codify this requirement at §484.350. We proposed to define a ‘competing HHA’ within the scope of the proposed expanded HHVBP Model as an HHA that has a current Medicare certification and is being paid by CMS for home health care services. We proposed that all HHAs certified for participation in Medicare before January 1, 2021 would have their CY 2022 performance assessed and would be eligible for a CY 2024 payment adjustment. We proposed to base participation in the expanded Model on CMS Certification Numbers (CCNs), meaning that the Total Performance Score as discussed further in section III.A.7.a. of this final rule and payment adjustment would be calculated based on an HHA’s CCN.¹⁵

We summarize in this section of this rule comments received on the proposed timing and scope of the expanded model and our responses.

Comment: The majority of commenters supported a home health value-based purchasing payment model, but were opposed to expansion beginning in CY 2022 as the first performance year. Commenters expressed concern that HHAs continue to contend with challenges of the PHE and that expansion should be postponed until CY 2023 or the calendar year that is 1 year post the public health emergency which they stated would be a more stable time in the trajectory of health care delivery. Commenters expressed that HHAs need more time to prepare, institute operational reforms, and learn about the Model and encouraged CMS to provide technical

¹⁵ HHAs are required to report OASIS data and any other quality measures by its own unique CMS Certification Number (CCN) as defined under title 42, chapter IV, subchapter G, §484.20 Available at URL <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-484?toc=1>.

assistance and training to support HHAs in preparing for the Model. Commenters stated that CMS should allow for more study time/data gathering and extend the original HHVBP Model for another year to collect data that is more reflective of the current state of care before expanding nationwide. A commenter recommended CMS carefully evaluate the impact of the HHVBP Model on hospital-operated HHAs as part of its overall evaluation of the Model before scaling it on a national level and seek broad stakeholder input on the design of the HHVBP expanded model in future rulemaking. Commenters requested that CMS develop a comprehensive plan for implementing the HHVBP model nationwide in CY 2023 after the conclusion of the original model. A commenter recommends that CMS make the first year of expansion voluntary and move to mandatory in CY 2023. We received a few comments that supported a CY 2022 start date for expansion.

Response: We thank the commenters for their support for a value-based purchasing payment model in the home health setting. However, we disagree that additional study time or an extension of the original Model to collect additional data is needed prior to expansion. The original Model was tested for four years, CYs 2016 – 2019. The original Model has met statutory requirements based on the CMS Chief Actuary’s certification and evaluation findings in the Third Annual Evaluation Report covering the implementation period 2016-2018 that showed the Model improved quality of care without increased spending. Updated analysis of the original Model in the Fourth Annual Evaluation Report, covering the implementation period 2016-2019, continues to indicate improved quality of care without increased spending or adverse impacts on home health utilization, or market entries and exits. We note that the Fourth Annual Evaluation Report includes evaluation of the impacts to hospital-operated HHAs, and found that hospital based HHAs (in both HHVBP and non-HHVBP states) do care for higher risk patients. The model payment and the primary evaluation impact estimation use risk adjustment to account for such differences. The evaluation did not specifically analyze the outcomes by free-standing vs hospital-based entities in HHVBP and non-HHVBP states. However, we examined whether there

is a pattern of the Model limiting admissions for more medically complex patients and do not find that to be the case. We continued to observe a pattern of increasing clinical severity over time among all home health patients based on multiple measures of medical complexity or severity, and the trends were generally similar in HHVBP and non-HHVBP states. In addition, the CMS Chief Actuary concluded in its certification that since the selection of the states was random and participation by HHAs in the selected states was mandatory, it is unlikely that these evaluation results were biased.

We understand the PHE, declared in January 2020, has had an impact on HHAs. We also believe that technical assistance and training may help those HHAs not part of the original Model to prepare for successful participation in the expanded HHVBP Model.

After consideration of the comments received, we are therefore finalizing that CY 2022 will be a pre-implementation year, with CY 2023 as the first performance year and CY 2025 as the first payment year, as we discuss further in this section and later in this rule.

Comment: A commenter stated that expansion should be delayed until a payment framework is built to adequately account for the differences in healthcare systems, such as Medicaid safety-net hospitals, that by definition provide a disproportionate share of charity and other forms of uncompensated care to individuals who have a high level of social need, beyond their medical treatment. The commenter also stated that nationwide implementation of the HHVBP model should be delayed until the evaluation of appropriate risk adjustment for types of Social Determinants of Health (SDoH) and payment mechanisms appropriately account for the interaction of biological, behavioral, and social care needs when it comes to providing patient-tailored, comprehensive value-based care.

Response: As shown in Table 21, simulating the expanded HHVBP Model's national volume-based cohorts with CY 2019 data indicates a higher average payment adjustment for HHAs with a high percentage of dually eligible beneficiaries. Consequently, we do not have evidence to suggest that HHAs that care for beneficiaries with more significant social risk factors

would receive decreased FFS payments under the expanded Model. We thank the commenter for their recommendations to evaluate types of Social Determinants of Health (SDoH) to account for the interaction of biological, behavioral, and social care needs when it comes to providing patient-tailored, comprehensive value-based care for potential modifications to risk adjustment and we will take this under consideration. As noted in section III.A.6.e.2 of this final rule, we are working collaboratively with HH QRP to determine how data collected on SDoHs under HH QRP could be part of the HHVBP Model expansion.

Comment: Commenters stated that CMS should include a “shared savings” component to the expanded HHVBP Model to enhance the incentives that led HHAs to achieve significant savings to Medicare.

Response: We appreciate this comment, but it is outside the scope of our proposals on the expansion of the HHVBP Model.

Final Decision: After consideration of comments received, we are finalizing our proposal with modification. We are finalizing a one-year delay in assessing HHA performance and the calculation of a payment adjustment. To allow HHAs time to prepare and learn about the expanded Model, CY 2023 will be the first performance year and CY 2025 will be the first payment year, based on CY 2023 performance. CY 2022 will be a pre-implementation year, as discussed in more detail later in this rule. We will provide learning support about the Model to HHAs during CY 2022. We believe that by delaying payment adjustments by one year and providing HHAs with learning support in the pre-implementation phase, all HHAs will be better prepared to participate in the Model for the CY 2023 performance year. HHAs will incur a 0 percent payment adjustment risk for the CY 2022 pre-implementation year.

We are finalizing as proposed that the expanded Model will apply to all Medicare-certified HHAs in the 50 States, District of Columbia, and the territories, which means that all Medicare-certified HHAs that provide services in the 50 States, District of Columbia, and the territories will be required to compete in the expanded Model. We are also finalizing to codify

this requirement at §484.350. We are finalizing as proposed to define a ‘competing HHA’ within the scope of the expanded HHVBP Model as an HHA that has a current Medicare certification and is being paid by CMS for home health care services. We are finalizing to base participation in the expanded Model on CMS Certification Numbers (CCNs), meaning that the Total Performance Score as discussed further in section III.A.7.a. of this final rule and payment adjustment will be calculated based on an HHA’s CCN. Under our finalized policy to delay application of payment adjustments under the expanded Model, all HHAs certified for participation in Medicare before January 1, 2022, will have their CY 2023 performance assessed and would be eligible for a CY 2025 payment adjustment.

b. Overview of the Payment Adjustment

We proposed that the distribution of payment adjustments would be based on quality performance, as measured by both achievement and improvement, across a proposed set of quality measures constructed to minimize burden as much as possible and improve care. Competing HHAs that demonstrate they can deliver higher quality of care in a given performance year measured against a baseline year relative to peers nationwide (as defined by larger- versus smaller-volume cohorts based upon their unique beneficiary count in the prior calendar year), could have their HH PPS claims final payment amount adjusted higher than the amount that otherwise would be paid. Competing HHAs that do not perform as well as other competing HHAs in the same volume-based cohort might have their HH PPS claims final payment amount reduced and those competing HHAs that perform similarly to others in the same volume-based cohort might have no payment adjustment. This operational concept is similar in practice to what is used in the Hospital Value-Based Purchasing (HVBP) Program (76 FR 26531).

We stated in the proposed rule that we expect that the risk of having payments adjusted in this manner would provide an incentive among all competing HHAs to provide significantly better quality through improved planning, coordination, and management of care. We stated that

under the expanded duration and scope of this Model, we would continue to examine whether the proposed adjustments to the Medicare payment amounts that would otherwise be made to competing HHAs would result in statistically significant improvements in the quality of care being delivered to Medicare beneficiaries, as well as reductions in Medicare spending. The degree of the payment adjustment would be dependent on the level of quality achieved or improved from the baseline year, with the highest upward performance adjustments going to competing HHAs with the highest overall level of performance based on either achievement or improvement in quality. The size of a competing HHA's payment adjustment for each year under the expanded Model would be dependent upon that HHA's performance with respect to the applicable performance year relative to other competing HHAs in the same volume-based cohort and relative to its own performance during the baseline year. These proposals, as well as our finalized policies, are discussed in sections III.A.4, III.A.5, and III.A.7.a of this final rule.

In addition, at §484.345 we proposed to add the following definitions:

- Achievement threshold
- Applicable measure
- Applicable percent
- Baseline year
- Benchmark
- Competing home health agency
- Home health prospective payment system
- Improvement threshold
- Larger-volume cohort
- Linear exchange function
- Nationwide
- Payment adjustment
- Payment year

- Performance year
- Smaller-volume cohort
- Total Performance Score

We note that we are generally finalizing the definitions at §484.345 as proposed, with the addition of the term, *pre-implementation year*, to reflect that under our final policy to delay the application of payment adjustments under the expanded Model, CY 2022 will be a pre-implementation year. We summarize and respond to any comments received on particular proposed definitions in the applicable sections of this rule.

4. Defining Cohorts for Benchmarking and Competition

Under the original HHVBP Model, we grouped HHAs into cohorts by State for setting benchmarks and achievement thresholds and by both State and smaller- versus larger-volume HHAs when determining the cohorts used for competing for payment adjustments, in accordance with §484.330. For the nationwide expansion of the HHVBP Model, we proposed to redefine the cohort structure to account for States, territories, and the District of Columbia with smaller numbers of HHAs, while also allowing for the use of volume-based cohorts in determining benchmarks, achievement thresholds, and payment adjustments.

a. Smaller- and Larger-Volume Cohorts

As discussed further in this section, we believe that separating smaller- and larger-volume HHAs into cohorts under the expanded Model would facilitate like comparisons by allowing for the majority of HHAs to receive benchmarks and compete for payment against other HHAs of similar size and based on the same set of measures. As under the original HHVBP Model, we proposed to align the larger-volume cohort with the group of competing HHAs that administers the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey, in accordance with the HH QRP regulations concerning the HHCAHPS survey in §484.245(b), and we proposed to align the Model's smaller-volume HHA cohort with the group of HHAs that are exempt from submitting the HHCAHPS survey under HH QRP

under §484.245(b)(1)(iii)(A). We clarify in this final rule that, unlike under the HH QRP, and consistent with the original Model, HHAs would not need to submit an exemption request for HHCAHPS in accordance with the regulations at 42 CFR 484.245(b)(1)(iii)(A) for the purposes of qualifying for the smaller-volume HHA cohort. We stated that under the expanded HHVBP Model, we would not alter the HHCAHPS survey current scoring methodology or the participation requirements in any way. Details on HHCAHPS survey scoring methodology are available at: <https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials>.¹⁶

The HH QRP requires, in part, that an HHA submit HHCAHPS survey data to CMS. An HHA that has fewer than 60 unique HHCAHPS survey-eligible patients must annually submit their total HHCAHPS survey patient count to CMS to be exempt from the HHCAHPS survey reporting requirements for a calendar year under the HH QRP. As under the original HHVBP Model, we proposed to align with this HHCAHPS survey reporting requirement by defining the larger-volume cohort as those HHAs that are required to submit an HHCAHPS survey in the performance year. We note that under the original Model, the HHA is not required to secure an exemption in order to qualify for the smaller-volume cohort; rather, CMS assesses whether an HHA qualifies for the smaller-volume cohort based on the volume of unique patients eligible to submit the HHCAHPS survey in a calendar year. As under the original Model, we also proposed to set an HHCAHPS survey measure minimum of at least 40 completed HHCAHPS surveys in the performance year for those HHAs to receive a score on the HHCAHPS survey measure, as reflected in proposed §§484.345 and 484.360. Accordingly, because smaller-volume HHAs are less likely to be assessed on the HHCAHPS survey measure, which would account for 30 percent of the overall performance score in the expanded Model, we stated that we believe that separating smaller- and larger-volume HHAs into distinct cohorts would allow for the majority of HHAs to compete against other HHAs of similar size and based on the same set of measures.

¹⁶ Detailed scoring information is contained in the Protocols and Guidelines manual posted on the HHCAHPS web site and available at <https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials>

b. Cohorts for the Model Expansion

As discussed, we believe that applying separate larger- and smaller-volume cohorts within the expanded HHVBP Model would group HHAs that are of similar size and are more likely to receive scores on the same set of measures for purposes of setting benchmarks and achievement thresholds and determining payment adjustments. However, a valid cohort must have a sufficient number of HHAs to-- (1) create a robust distribution of Total Performance Scores, which allows meaningful and reasonable translation into payment adjustments using the linear exchange function (LEF);¹⁷ and (2) set stable, reliable benchmarks and achievement thresholds that are not heavily skewed by outliers. The LEF is designed so that the majority of the payment adjustment values fall closer to the median and a smaller percentage of HHAs receive adjustments at the higher and lower ends of the distribution. However, when only a small number of HHAs fall within a cohort, one HHA's outlier TPS could skew the payment adjustments and deviate from the intended design of the LEF payment methodology. As a result, a key consideration in defining the cohorts is ensuring sufficient HHA counts within each cohort.

Under the original Model, CMS applied a minimum of eight HHAs for any size cohort, such that a smaller-volume cohort must have a minimum of eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger-volume cohort (81 FR 76742). This policy was based on an analysis of the minimum number of HHAs needed in a smaller-volume cohort in order to insulate that cohort from the effect of outliers. We stated in the proposed rule that expanding the HHVBP Model beyond the nine mid- to large-sized States included in the original Model requires us to re-examine these cohort definitions because, certain territories and the District of Columbia would fall short of the original Model's minimum of 8 HHAs to compose their own cohort even where the volume-based cohorts are combined. This was not an issue in the original Model because the nine

¹⁷ The Linear Exchange Function (LEF) is used to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. For a more detailed description, please see section III.A.8. of this final rule.

selected States are relatively populous as compared to the smaller States, territories, and the District of Columbia that would be included in the expanded Model. Based on CY 2019 Home Health Compare Star Ratings, we evaluated the viability of smaller- and larger-volume cohorts, as defined previously, for each of the 55 States, territories, and the District of Columbia. Based on our analysis, of the 110 potential cohorts based on both State and HHA volume for the expanded HHVBP Model, 46 of the 110 potential cohorts had too few HHAs to reliably meet the original Model minimum of 8 HHAs, after accounting for the risk of attrition from the expanded Model. Under this approach, for 42 of these 46 cohorts, the smaller-volume cohorts would need to be combined with the larger-volume cohorts in their respective States and territories, while 3 territories and the District of Columbia would need to be combined with other States or territories since they do not meet the 8 HHA minimum after consolidating the volume-based cohorts. See Table 21 for the counts of HHAs in each of the potential cohorts, if we were to apply separate State- and volume-based cohorts for each State, territory, and the District of Columbia under the expanded Model.

TABLE 21: HHA COUNTS IN STATE/TERRITORY/DISTRICT OF COLUMBIA- AND VOLUME-BASED COHORTS BASED ON CY 2019 HOME HEALTH CARE COMPARE DATA

State	Large HHAs	Small HHAs	All HHAs	State	Large HHAs	Small HHAs	All HHAs
AK	12	1	13	MT	22	2	24
AL	114	1	115	NC	152	4	156
AR	90	2	92	ND	12	-	12
AZ	106	2	108	NE	40	8	48
CA	993	76	1,069	NH	20	1	21
CO	105	4	109	NJ	42	-	42
CT	74	-	74	NM	58	4	62
DC*	7	-	7	NV	97	8	105
DE	12	-	12	NY	105	-	105
FL	677	54	731	OH	287	10	297
GA	99	-	99	OK	183	10	193
GU*	4	-	4	OR	43	1	44
HI	14	-	14	PA	229	12	241
IA	94	7	101	PR	33	-	33
ID	42	1	43	RI	18	-	18
IL	399	64	463	SC	63	-	63
IN	138	11	149	SD	19	4	23

State	Large HHAs	Small HHAs	All HHAs	State	Large HHAs	Small HHAs	All HHAs
KS	84	5	89	TN	112	1	113
KY	90	-	90	TX	982	97	1,079
LA	167	-	167	UT	68	6	74
MA	127	5	132	VA	187	6	193
MD	49	2	51	VI*	1	-	1
ME	19	1	20	VT	10	-	10
MI	322	54	376	WA	57	-	57
MN	97	9	106	WI	73	-	73
MO	123	9	132	WV	50	1	51
MP*	2	-	2	WY	16	2	18
MS	45	-	45	All	7,084	485	7,569

*These territories and the District of Columbia fall short of the original HHVBP Model's minimum of 8 HHAs to compose their own cohort even where the volume-based cohorts are combined.

As noted, under the original HHVBP Model, a minimum of eight HHAs is required for each size cohort. For the expanded HHVBP Model, we proposed to establish cohorts prospectively and with sufficient HHA counts to prevent the need to combine multiple cohorts retrospectively. We proposed to provide HHAs with their applicable benchmarks and achievement thresholds prior to the start of or during the performance year so that they can be used to set performance targets to guide HHAs' quality improvement projects. To reliably define cohorts prospectively and to avoid regrouping multiple States, territories, or the District of Columbia into a single cohort retrospectively based solely on their lower HHA counts, we estimated that a minimum of 20 HHAs in each cohort would be necessary to ensure that attrition and variation in episode counts do not lead to insufficient HHA counts at the end of the performance year. Based on the data set forth in Table 21, 61 out of the 110 potential cohorts would have fewer than 20 HHAs in a size-based cohort, and 11 out of those potential cohorts would not meet the 20 HHA minimum after combining the size-based cohorts.

To allow for a sufficient number of HHAs in each volume-based cohort, for purposes of setting benchmarks and achievement thresholds and determining payment adjustments, we proposed to use cohorts based on all HHAs nationwide, rather than by State as under the original Model. Referencing the CY 2019 data in Table 21, under this approach, 7,084 HHAs would fall within the larger-volume cohort and 485 HHAs fall within the smaller-volume cohort. These

HHA counts would provide a sufficiently large number of values in each cohort to allow ranking of HHA performance scores and payment adjustment percentages across the range of -5 percent to +5 percent. Further, our analysis found that many of the smaller-volume HHAs would not receive a score on the HHCAHPS survey measures, which were proposed to account for 30 percent of the overall TPS, while most of the larger-volume cohort HHAs would be scored on the full set of applicable measures. Accordingly, and as previously discussed, we stated that we believe the volume-based cohorts would allow for competition among HHAs across similar measures. Using nationwide rather than State/territory-based cohorts in performance comparisons would also be consistent with the Skilled Nursing Facility and Hospital VBP Programs, in addition to the Home Health Compare Star Ratings. Finally, this option would be the least operationally complex to implement.

For the reasons discussed, we stated in the proposed rule that we believe the use of nationwide smaller- and larger-volume-based cohorts would allow for appropriate groupings of HHAs under the expanded Model while also providing sufficient numbers of HHAs in each cohort for purposes of setting stable and reliable benchmarks and achievement thresholds and allowing for a robust distribution of payment adjustments. However, we also considered an alternative approach of using State/territory-based cohorts, without volume-based groupings. Applying the State, territory, and District of Columbia-level cohorts, we found that 11 of the 55 potential cohorts would have fewer than 20 HHAs based on the CY 2019 Home Health Star Ratings data. As noted, we stated that we do not believe this would allow for a sufficient number of HHAs to develop prospective benchmarks and achievement thresholds. While one approach would be to exclude any States, territories, or the District of Columbia from the expanded Model for years in which there are fewer than 20 HHAs in the cohort, we stated that we believe such a policy would be inconsistent with the goal of including all eligible HHAs nationwide in the Model. Another option would be to consolidate those States, territories, and the District of Columbia with less than 20 HHAs in the cohort, and to calculate benchmarks,

achievement thresholds, and payment adjustments based on that consolidated grouping of HHAs. We noted that while slight differences do exist between quality measure scores based on geographic location, we do not believe that codifying these small differences into long-term performance standards is necessary to appropriately determine payment adjustments under the expanded Model.

We proposed to establish nationwide volume-based cohorts for the expanded HHVBP Model, such that HHAs nationwide would compete within either the larger-volume cohort or the smaller-volume cohort. We proposed to codify this policy at §484.370, and to codify the proposed definitions of smaller-volume cohort and larger-volume cohort at §484.345. Under this proposal, HHAs currently participating in the original HHVBP Model would no longer compete within just their State. We also requested comment on the alternative approach of applying State/territory-based cohorts only, without volume-based cohorts.

We sought public comment on these proposals. We summarize in this section of this rule the comments received and provide our responses.

Comment: Most commenters supported the use of State-based rather than national cohorts in order to preserve the geographical differences in quality benchmarks, which they contend result from variation in home health utilization and other differences across regions. They expressed concern that not using State-based cohorts will significantly shift home health payments across State lines, leading to shortages of necessary home health services in certain areas.

Response: We thank commenters for their comments on selection of the appropriate cohorts to compare HHAs. We do not have evidence that suggests that moving to national small- and large-volume cohorts would significantly redistribute resources between states. We refer readers to Table 43 of this final rule for an analysis of expected shifts in FFS expenditures, as represented by the average FFS payment adjustments for small- and large-volume HHAs in each of the States, territories, and the District of Columbia, simulated with the proposed national size-

based cohorts using CY 2019 data and a maximum adjustment of ± 5 percent. We note that when the small- and large-volume HHAs in each of the States, territories, and the District of Columbia are combined, the average payment adjustment for the majority of States, territories, and the District of Columbia is within ± 1 percent, with none exceeding ± 2 percent. Furthermore, as discussed in the proposed rule, using the State-based cohorts could potentially lead to an insufficient count of HHAs in 11 States, territories, and the District of Columbia. It is not apparent that clear similarities exist between those States, territories, or the District of Columbia with less than 20 HHAs in a cohort to support grouping them for competition based solely on their lower HHA counts, nor do we believe excluding these States, territories, or the District of Columbia would be consistent with the goal of including all eligible HHAs nationwide in the expanded Model.

Comment: Several commenters expressed concern that using national rather than State-based cohorts would result in a shifting of resources away from geographic areas with a higher burden of social risk factors and toward areas with less social risk factors.

Response: We thank the commenters for sharing this concern. The commenters' concern appears to assume that quality measure scores and payments would be lower in areas with a higher burden of social risk factors. Table 41 in the proposed rule (86 FR 35996) demonstrates, however, that simulating the proposed national cohorts with CY 2019 data, a high percentage of dually eligible beneficiaries is associated with a higher average payment adjustment under the expanded Model. This association supports that use of national, volume-based cohorts would not disadvantage those HHAs that care for beneficiaries with more significant social risk factors. As noted previously, we also refer readers to Table 43 of this final rule for an analysis of the shifts of expenditures, as represented by the average payment adjustments for small- and large-volume HHAs in each of the States, territories, and the District of Columbia, simulated with the proposed national size-based cohorts using 2019 data and a maximum adjustment of ± 5 percent. When the small- and large-volume HHAs in each of the States, territories, and the District of Columbia are

combined, the average payment adjustment for the majority of States, territories, and the District of Columbia is within ± 1 percent, with none exceeding ± 2 percent. We welcome further feedback or analysis on this issue from the public.

Comment: A commenter, on the other hand, strongly supported using national cohorts, as proposed, stating that Medicare is a national program and beneficiaries should have the same expectations for high-quality care, regardless of which state they live in.

Response: We thank the commenter for this feedback. We agree that since Medicare is a national program, all beneficiaries should have the same expectations for high-quality care. As discussed previously, we believe the use of national cohorts for purposes of the expanded Model would allow for competition among HHAs across similar measures while also providing sufficient numbers of HHAs in each cohort. This is also consistent with value-based purchasing programs and the Home Health Compare star ratings.

Comment: Other commenters requested that HHAs in States that did not compete on quality in the original Model not be compared to the same standard as HHAs in the original nine States, because they have only been subject to publicly reporting of the measures, without payment adjustments, over the past 5 years.

Response: We agree that HHAs in the 9 original Model States may have more knowledge about the expanded Model, given many of these HHAs have participated in the original HHVBP Model since 2016. However, as discussed in section III.A.3.a of this final rule, after consideration of the comments received, we are delaying implementation of payment adjustments for 1 year, with CY 2023 serving as the first performance year and CY 2025 serving as the first payment year, in order to provide all HHAs with additional time to become familiar with and gain experience with the expanded Model. We further note, as stated in section XI.8.F.2 of the proposed rule and this final rule, based on our analysis of the State-level impacts and using CY 2019 data to simulate payment adjustments, we did not see any obvious correlation

of the impacts within States that are currently in the original Model versus those that will be new to the expanded Model of using the national, volume-based cohorts.

Final Decision: After considering the public comments received on the cohorts for model expansion, we are finalizing the use of national, volume-based cohorts in setting payment adjustments under the expanded Model, as proposed, and are also finalizing to codify this policy at §484.370. We are also finalizing the proposed definitions of smaller-volume cohort and larger-volume cohort at §484.345. Consistent with the original HHVBP Model, CMS will assess whether an HHA qualifies for the smaller-volume cohort based on the volume of unique patients eligible to submit the HHCAHPS survey in the prior calendar year.

5. Payment Adjustment Percentage and Performance Assessment and Payment Adjustment Periods

a. Payment Adjustment

Under the original Model, the payment adjustment ranges from a minimum of 3 percent in 2018 to maximum of 8 percent in 2022. For the expanded Model, we proposed that the maximum payment adjustment, upward or downward, would be 5 percent. We stated that we believe that beginning the expansion with a 5 percent maximum payment adjustment would strike a balance between the 3 percent maximum adjustment that applied for CY 2018, the first payment year of the original HHVBP Model, and the 7 percent maximum adjustment currently in place for CY 2021. We proposed that the first payment year of the expanded HHVBP Model would be CY 2024 (January 1, 2024 through December 31, 2024), with payment adjustments based on performance in CY 2022 (January 1, 2022 through December 31, 2022). We stated in the proposed rule that we may consider changes to the proposed 5 percent maximum payment adjustment percentage through rulemaking in future years of the expansion, as additional evaluation data from the original Model and expansion become available. We note that the CMS Actuary certification was based on evaluation of the Model when the maximum payment adjustment was 3 percent. However, in their certification memo, they indicated they believe the

Model would result in savings at higher payment adjustment amounts as well.

We solicited public comment on the proposed payment adjustment percentage. We summarize in this section of this rule the comments received on the proposed payment adjustment percentage and provide our responses.

Comment: Some commenters expressed concern that the proposed 5 percent maximum payment adjustment was too high for the first year of the expanded model. A few commenters suggested a 3 percent maximum payment adjustment to match the first payment adjustment year of the original model, other commenters suggested a 2 percent maximum payment adjustment to match Hospital Value Based Purchasing, and others suggested a 1 percent maximum payment adjustment. A few commenters suggested starting the expanded model at a lower percentage and slowly increasing the maximum payment adjustment over time.

Response: We appreciate commenters sharing their concerns about the potential for a 5 percent payment adjustment. Under the payment adjustment methodology described in III.A.8 of this rule, we anticipate that most HHAs will receive a positive or negative payment adjustment smaller than the proposed 5 percent maximum adjustment. We reviewed the payment distribution under the original HHVBP Model for CY 2019, the second payment adjustment year, when the maximum payment adjustment was 5 percent. During that year, 93.2 percent of the HHAs participating in the original HHVBP Model received a payment adjustment ranging from -3 percent to +3 percent and 98.8 percent of the HHAs received a payment adjustment ranging from -4 percent to +4 percent. Using simulated data with national cohorts, we found 72 percent of HHAs would have received a payment adjustment ranging from -3 percent to +3 percent and 85 percent of HHAs would have received a payment adjustment ranging from -4 percent to +4 percent. In the original HHVBP model, we increased the maximum payment adjustment each year to allow HHAs the opportunity to become familiar with the operation of the model before applying higher percentage payment adjustments in later years, including a maximum payment adjustment of 5 percent for the second payment year. In this final rule, we

are delaying the first payment adjustment year to provide HHAs with learning support in advance of the application of payment adjustments under the expanded Model. As discussed in the proposed rule, we will continue to evaluate the 5 percent payment adjustment and consider any changes for future rule making.

Final Decision: After consideration of the public comments, we are finalizing the payment adjustment as proposed. As discussed previously, we are also finalizing a delay in the start of payment adjustments under the expanded Model, such that CY 2025 would be the first payment year, with payment adjustments based on performance in CY 2023.

b. Baseline Year

(1) General

For the expanded HHVBP Model, due to the potentially de-stabilizing effects of the COVID-19 public health emergency (PHE) on quality measure data in CY 2020, we proposed that the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance year/CY 2024 payment year and subsequent years. The data from this baseline year would provide a basis from which each respective HHA's performance would be measured for purposes of calculating achievement and improvement points under the expanded Model. We stated in the proposed rule that we may propose to update the baseline year for subsequent years of the expanded Model through future rulemaking. We stated that we would also propose the applicable baseline year for any additional quality measures that may be added to the measure set for the expanded HHVBP Model through future rulemaking.

We solicited public comment on the proposed baseline year for the expanded Model. We summarize in this section of this rule the comments received on the proposed baseline year and provide our responses.

Comment: A few commenters supported using CY 2019 as the baseline year. Other commenters cautioned against using 2019 as a baseline year because they asserted it inherently means comparing pre-COVID-19, pre-Patient Driven Grouping Model (PDGM) performance to

performance in a very different environment. A commenter recommended CMS provide clarification on subsequent baseline periods in future years of the Model in a timely fashion so that HHAs have as much advance notice as possible. The commenter also encouraged CMS to eventually automatically advance the baseline period of the model by one year as each performance year is advanced, like other value-based programs.

Response: We proposed using CY 2019 as the baseline year, as opposed to CY 2020, due to the potentially de-stabilizing effects of the PHE on the CY 2020 data and because it was the most recent full year of data available prior to CY 2020 to provide HHAs with achievement thresholds and benchmarks as soon as administratively feasible and prior to the start or soon after the start of the applicable performance year. As noted later in this final rule, the PDGM is a case-mix adjustment model intended to pay for services more accurately and we believe the HHVBP Model can continue unchanged when HHA periods of care are paid according to the case-mix adjustments of the PDGM. We further believe that the payment change should not affect measure scoring between the baseline year and the performance years. However, CMS may consider conducting analyses of the impact of using various baseline periods, and would address any changes to the baseline period in future rulemaking. We appreciate the commenter's suggestion to eventually automatically advance the baseline period by one year as each performance year is advanced in an effort to align with other value-based programs and will take it under consideration.

Final Decision: After consideration of comments received, we are finalizing our proposal to use CY 2019 (January 1, 2019 through December 31, 2019) as the baseline year. As discussed previously, we are also finalizing to delay the first performance and payment year under the expanded Model. Accordingly, the baseline year would be CY 2019 for the CY 2023 performance year/CY 2025 payment year and subsequent years; however, we may conduct analyses of the impact of using various baseline periods and consider any changes for future rulemaking.

(2) New HHAs

As noted previously, we generally proposed that for the expanded Model, the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance year/CY 2024 payment year and subsequent years. For new HHAs, specifically those HHAs that are certified by Medicare on or after January 1, 2019, we proposed that the baseline year under the expanded Model would be the HHA's first full CY of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year would be CY 2021. Furthermore, we proposed that new HHAs would begin competing under the expanded HHVBP Model in the first full calendar year following the full calendar year baseline year. For example, and as previously discussed, we proposed that all HHAs certified for participation in Medicare before January 1, 2021, would have their CY 2022 performance assessed and would be eligible for a CY 2024 payment adjustment. For HHAs certified on January 1, 2020 through December 31, 2020, the baseline year would be CY 2021, the first full CY of services beginning after the date of Medicare certification. For those HHAs certified on January 1, 2019 through December 31, 2019, the baseline year would also be CY 2021, rather than CY 2020 (the first full CY of services beginning after the date of Medicare certification), due to the potentially destabilizing effects of the PHE on quality measure data in CY 2020. For an HHA certified by Medicare on January 1, 2021 through December 31, 2021, for example, the first full calendar year of services that would establish the HHA's baseline year would be CY 2022. The HHA's first performance year would be CY 2023 and the HHA's first payment year, based on CY 2023 performance, would be CY 2025. Table 22 shows the proposed HHA baseline, performance and payment years based on the HHA's Medicare-certification date through December 31, 2021.

TABLE 22: PROPOSED HHA BASELINE, PERFORMANCE AND PAYMENT YEAR BASED ON MEDICARE-CERTIFICATION DATE THROUGH DECEMBER 31, 2021

Medicare-certification Date	Baseline Year	Performance Year	Payment Year
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Prior to January 1, 2019	2019	2022	2024
On January 1, 2019 - December 31, 2019	2021	2022	2024
On January 1, 2020 – December 31, 2020	2021	2022	2024
On January 1, 2021 – December 31, 2021	2022	2023	2025

We also proposed to codify our proposal on new HHAs at §484.350. We solicited public comment on these proposals.

Final Decision: We did not receive any comments on our proposals regarding new HHAs and are finalizing our proposal that for new HHAs, specifically those HHAs that are certified by Medicare on or after January 1, 2019, the baseline year under the expanded Model would be the HHA’s first full CY of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year would be CY 2021. Furthermore, we are finalizing that new HHAs would begin competing under the expanded HHVBP Model in the first full calendar year (beginning with CY 2023) following the full calendar year baseline year. For example, under this final policy, all HHAs certified for participation in Medicare before January 1, 2022, would have their CY 2023 performance assessed and would be eligible for a CY 2025 payment adjustment. For HHAs certified on January 1, 2020 through December 31, 2020, the baseline year would be CY 2021, the first full CY of services beginning after the date of Medicare certification. For those HHAs certified on January 1, 2019 through December 31, 2019, the baseline year would also be CY 2021, rather than CY 2020 (the first full CY of services beginning after the date of Medicare certification), due to the potentially destabilizing effects of the PHE on quality measure data in CY 2020. For an HHA certified by Medicare on January 1, 2021 through December 31, 2021, for example, the first full calendar year of services that would establish the HHA’s baseline year would be CY 2022. The HHA’s first performance year would be CY 2023 and the HHA’s first payment year, based on CY 2023 performance, would be CY 2025. Table 23 shows the finalized HHA baseline, performance and payment years based on the HHA’s Medicare-certification date through December 31, 2021.

**TABLE 23 : FINAL HHA BASELINE, PERFORMANCE AND PAYMENT YEAR
BASED ON MEDICARE-CERTIFICATION DATE
THROUGH DECEMBER 31, 2021**

Medicare-certification Date	Baseline Year	Performance Year	Payment Year
Prior to January 1, 2019	2019	2023	2025
On January 1, 2019 - December 31, 2019	2021	2023	2025
On January 1, 2020 – December 31, 2020	2021	2023	2025
On January 1, 2021 – December 31, 2021	2022	2023	2025

We are also finalizing our proposed codification of this policy at §484.350 with modification to reflect the one-year delay in the first performance year from CY 2022 to CY 2023. Specifically, we are adding “(beginning with CY 2023)” to reflect that for new HHAs certified by Medicare on or after January 1, 2019, the first performance year is the first full calendar year (beginning with CY 2023) following the baseline year.

6. Quality Measures

a. General Considerations Used for the Selection of Quality Measures for the Expanded HHVBP Model

We stated in the proposed rule that we plan to apply, to the extent possible, principles from CMS’ Meaningful Measures Initiative¹⁸ in selecting the applicable measures as defined at §484.345 to be included in the Model expansion. A central driver of the proposed applicable measure set is to have a broad, high impact on care delivery and support priorities to improve health outcomes, quality, safety, efficiency, and experience of care for patients. To frame the selection process, we also considered the domains of the CMS Quality Strategy¹⁹ that maps to the six National Quality Strategy (NQS)²⁰ priority areas: Clinical quality of care; Care coordination; Population/community health; efficiency and cost reduction; safety; and, Patient

¹⁸ <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>

¹⁹ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>

²⁰ For NQF endorsed measures see The NQF Quality Positioning System available at <http://www.qualityforum.org/QPS>. For non-NQF measures using OASIS see links for data tables related to OASIS measures at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits>

and caregiver-centered experience.

We stated that we believe that Medicare-certified HHAs should be evaluated using measures designed to encompass multiple NQS domains, and provide future flexibility to incorporate and study newly developed measures over time. Additionally, so that measures for the expanded HHVBP Model take a more holistic view of the patient beyond a particular disease, functional status, State or care setting, we would prioritize outcome measures that have the potential to follow patients across multiple settings, reflect a multi-faceted approach, and foster the intersection of health care delivery and population health.

The proposed expanded Model measures mostly align with those under the HH QRP. However, we stated in the proposed rule that we intend to consider new measures for inclusion in subsequent years of the expanded HHVBP Model through future rulemaking. We stated that we may consider adding new measures to the expanded HHVBP Model measure set that address gaps within the NQS domains or the home health service line and are good indicators of home health quality of care. When available, NQF endorsed measures would be used. The expanded Model's authority under section 1115A of the Act also affords the opportunity to study other measures, such as, measures developed in other care settings or new to the home health industry, should CMS identify such measures. A key consideration behind this approach is to use measures that are readily available, and, in subsequent Model years, augment the applicable measure set with innovative measures that have the potential to be impactful and fill critical measure gap areas. This approach to quality measure selection aims to balance the burden of collecting data with the inclusion of new and important measures. We stated that we would carefully consider the potential burden on HHAs to report the measure data that is not already collected through existing quality measure data reporting systems and reiterated that we would propose any new measures through future rulemaking.

b. Initial Measure Set for the Expanded Model

We proposed that the initial applicable measure set for the expanded HHVBP Model for

the CY 2022 performance year focus on patient outcome and functional status, utilization, and patient experience. (As discussed in the preceding section, we are finalizing CY 2023 as the first performance year, and CY 2025 as the first payment year, under the expanded Model.) The proposed measures were also used under the original Model (83 FR 56533). However, we noted that no “New Measures” as defined in the original Model (80 FR 68674) were being proposed for data collection under the expanded Model beginning with the CY 2022 performance year given there was sufficient data collected on the “New Measures” under the original Model for analysis of the appropriateness for use in the home health setting. We noted that any future additional measures proposed for the expanded HHVBP Model would not be considered “New Measures” as used in the original Model.

We proposed the measures as detailed in Tables 26 and 27 of the proposed rule (86 FR 35923 through 35926) for inclusion in the expanded Model. The measure set also includes outcome measures, which illustrate the end result of care delivered to HHA patients and address an important quality aim for HHA patients. We stated in the proposed rule that we believe the proposed measure set under the expanded HHVBP Model, where most measures currently align with HH QRP measures, supports enhancing quality because of the value-based incentives provided under the expanded Model. Further, we stated that we believe that the expanded Model measure set, as proposed, includes an array of measures that would capture the care that HHAs furnish and incentivize quality improvement. The measures in the proposed measure set are divided into measure categories based on their data source as indicated in Table 26 of the proposed rule (86 FR 35923 through 35926): claims-based, OASIS-based, and the HHCAHPS survey-based. We note that the HHCAHPS survey-based measure has five individual components. The term “applicable measure” applies to each of the five components for which a competing HHA has submitted a minimum of 40 completed HHCAHPS surveys (This is discussed in more detail in sections III.A.4.a., III.A.7.c., and III.A.7.d. of this final rule). That is, each component counts as one applicable measure towards the five measure minimum that is

required for an HHA to receive a Total Performance Score (TPS) (this is discussed in more detail in section III.A.7.d of this final rule).

(1) Additional Background on the Total Normalized Composite Measures

The proposed measure set includes two composite measures: Total Normalized Composite (TNC) Self-Care and TNC Mobility, which were included in the original HHVBP Model measure set in CY 2019, as finalized in the CY 2019 HH PPS final rule (83 FR 56529 through 56535). The methodology for these measures takes into account patients who may not have goals for improvement.

The proposed TNC Self-Care measure computes the magnitude of change, either positive or negative, based on a normalized amount of possible change on each of six OASIS M items.

These six M items and their short name are as follows:

- Grooming (M1800)
- Upper Body Dressing (M1810)
- Lower Body Dressing (M1820)
- Bathing (M1830)
- Toileting Hygiene (M1845)
- Eating (M1870)

The TNC Mobility measure computes the magnitude of change, either positive or negative, based on the normalized amount of possible change on each of three OASIS M items and their short name are as follows:

- Toilet Transferring (M1840)
- Bed Transferring (M1850)
- Ambulation/Locomotion (M1860)

For each TNC measure, we calculate at the episode level and then aggregate to the home health agency level using a five-step process: Steps 1 to 3 calculate the normalized change values for each applicable OASIS item at the episode level. Steps 4 and 5 aggregate these values to the

agency level. As composite measures, the TNC Self-Care and TNC Mobility measures reflect multiple OASIS items, so there are no numerators or denominators for these two measures. A detailed description of the five steps can be found at:

<https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf>.

We stated in our discussion of the proposed TNC measures in the proposed rule that we expect that HHAs already focus on improvement in such areas not just because such items are included in the OASIS, but because self-care and mobility are areas of great importance to patients and families. In this final rule, we acknowledge that use of the term “improvement” to describe the TNC measures does not take into account the risk adjustment methodology used to calculate these measures or that the structure of the measures also addresses how effectively a HHA can limit any decline of the patient because it implies that the TNC measures would only measure an increase in a patient’s functional status, and we have revised our discussion of these proposed measures in this final rule accordingly. The risk adjustment methodology for these two measures is designed to take into account instances where the goal of home health care is to maintain the patient’s current condition or to prevent or slow further deterioration of the patient’s condition by including risk factors for a wide variety of beneficiary-level characteristics, including age, risk for hospitalization, living arrangements and caregivers available, pain, cognitive function, baseline functional status, and others. For instance, a beneficiary with impaired cognition would not be expected to improve in self-care as much as a beneficiary without cognitive impairment. In effect, the self-care change score would shift up slightly for a beneficiary with impaired cognition relative to a beneficiary without cognitive impairment to account for the difference in expectations. Both TNC measures’ computations can be found at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf> and the technical specifications can be found at: <https://www.hhs.gov/guidance/sites/default/files/hhs->

[guidance-](#)

[documents/hhvpb%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf](#).

As discussed in our response to comments in this section of this rule, the technical specifications for the composite measures have been updated and the updated specifications can be found in the downloads section on the CMS website.²¹ Additional information on the predictive modeling and methodology for the composite measures can be found in the CY 2019 HH PPS final rule (83 FR 56529 through 56535).

We noted in the proposed rule that we had considered the inclusion of stabilization measures which are measures that identify all patients whose function has not declined, including both those who have improved or stayed the same in the original HHVBP Model's measure set and refer readers to the CY 2016 HH PPS final rule (80 FR 68669 through 68670) and the CY 2019 HH PPS final rule (83 FR 56529 through 56535). In the CY 2016 HH PPS final rule, we explained that we considered using some of the stabilization measures for the original Model and found that the average HHA stabilization measure scores ranged from 94 to 96 percent and, with average rates of nearly 100 percent, we do not believe these high measure scores would allow for meaningful comparisons between competing-HHAs on the quality of care delivered. We acknowledge that skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition. However, we stated in the proposed rule that we believe that the two proposed TNC measures represent a new direction in how quality of patient care is measured in home health as patients who receive care from an HHA may have functional limitations and may be at risk for further decline in function because of limited mobility and ambulation.

(2) Additional Background on the Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey Measure

²¹ <https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model>

The Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS) survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The HHCAHPS survey specifically presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1) produce comparable data on the patient’s perspective that allows objective and meaningful comparisons between HHAs on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.²²

We note that the HHCAHPS survey is also part of the HH QRP requirements, which are codified for that program at 42 CFR 484.245(b). As proposed, expanded HHVBP Model participants would not need to submit separate HHCAHPS survey measure data already submitted as a requirement under HH QRP, because the requirements as proposed for the expanded Model are aligned with those currently under HH QRP. For more details about the HHCAHPS Survey, please see <https://homehealthcahps.org/>.

We invited public comment on our proposed measure set. We summarize in this section of this rule the comments and provide our responses.

Comments on the Measure Set Generally

Comment: A commenter encouraged CMS to include more measures in a future nationwide HHVBP, including (but not limited to) measures of outcomes, safety, and caregiver engagement. Another commenter supported the proposed measure set saying the quality measures reflect functional independence and agreed with CMS that using measures that are

²² <https://homehealthcahps.org/General-Information/About-Home-Health-Care-CAHPS-Survey>.

outcome focused and risk adjusted is the most useful to stakeholders to demonstrate value. The commenter stated that process-based measures are of little value and that measures should be a balance of health outcomes, utilization, and patient satisfaction.

Response: We thank the commenters for their recommendations and feedback on the proposed measure set. We agree that outcome, utilization and patient satisfaction measures are good indicators of value-based care and therefore have proposed to include these measure types in the expanded HHVBP Model. We believe the proposed measure set encourages HHAs to provide care that supports patients who wish to remain in their home whether the patient's goal is functional independence, stabilization or to prevent further decline. CMS will continue to monitor measure performance and to seek stakeholder input and may propose measure modification in future rulemaking.

Comment: Commenters supported the removal of the three "New Measures" from the measure set under HHVBP Model expansion.

Response: We thank the commenters for their support.

Comment: Commenters stated that CMS should establish a Technical Expert Panel (TEP) to evaluate the proposed HHVBP measures to ensure that the measures appropriately consider the full scope of the patient population served with the home health benefit, particularly patients not likely to experience condition improvement. Another commenter asserted that there is no evidence that CMS has sought out experts who can determine how to devise meaningful and inclusive measurements, and that there must be measurement experts CMS can engage who can determine how to measure everyone. The commenter further asserted that CMS should have located or developed appropriate quality measurements during the implementation period of the original HHVBP Model or for the Quality Reporting Program.

Response: As described in the CY 2019 final rule (83 FR 56528-56529), CMS received input from a TEP on measure set modifications for the measures under the original Model. As under the original Model, and noted in section III.A.6.5 of this final rule, we plan to continue to

seek input on the measure set, including from stakeholders in relevant fields such as clinicians, statisticians, quality improvement, and methodologists, and to monitor quality measure performance to inform potential measure set changes under the expanded Model. We further note that the majority of the measures in the proposed expanded Model measure set were used since the implementation of the original Model in CY 2016 and that the majority of the measures overlap with the HH QRP, except for the TNC change measures.

Comment: A commenter stated that home health payment reform must be implemented in a way that maintains beneficiary access to care and ensures beneficiaries receive necessary and appropriate care. A commenter stated that excessively stringent model payment design may increase Medicare savings but simultaneously cause HHAs to leave the market, particularly in rural and other underserved areas. The commenter stated that HHAs may also respond to payment pressure by avoiding beneficiaries whose care is perceived as potentially jeopardizing HHAs' performance scores, when those beneficiaries may be the ones having the greatest clinical needs for home health services.

Response: We agree that home health payment reform, specifically for HHVBP, should be implemented so that beneficiaries maintain access to care and receive necessary and appropriate care. We disagree with the comments that the HHVBP model payment design may cause HHAs to leave the market. As previously noted, evaluation findings showed that implementation of the original HHVBP Model did not adversely impact home health utilization, market entry and exit.

Comment: A commenter raised concerns that the measure set should score a small set of outcomes, patient experience, and value (for example, resource use) measures that are not unduly burdensome for providers to report. The commenter suggested that scores could be based on three claims-based measures of quality and resource use: all-condition hospitalizations with the HH stay, successful discharge to the community, and Medicare spending per beneficiary.

Response: The proposed measure set for the expanded HHVBP Model includes measures

that are currently already reported by HHAs and therefore we do not believe these measures would be unduly burdensome for HHAs to report. As discussed in the proposed rule, in evaluating whether to augment the initial measure set, we would consider the potential burden on HHAs to report measure data that is not already collected through existing quality measure data reporting systems. We thank the commenter for their suggestion to score HHAs on three claims-based measures. We note that the HHVBP expanded Model measure set was developed to encourage HHAs to focus on quality, patient-centered care and quality improvement across various focus areas, including those which are not directly measured through claims-based measures, such as patient experience. We further note that we did not propose the claims measures described but we may consider the use of additional claims-based measures in the expanded HHVBP Model for future rulemaking.

Comment: Some commenters stated that quality measures are not always under the control of the HHA. One example they provided is the OASIS quality measure, Self-Management of Oral Medications, where medication management could be done by an assisted living facility rather than the HHA. Commenters requested that CMS take these types of discrepancies into account so that the HHA is not penalized.

Response: We disagree with the commenters that HHAs serving patients in an assisted living facility are at a disadvantage to achieve a higher quality score in this area of measurement. We believe that all HHAs must aim to provide high quality care and therefore assess for and put into place care planning and coordination of services, including the coordination on the management of oral medications, to mitigate poor quality outcomes regardless of care setting.

Comments Regarding Claims-based Measures

Comment: A commenter stated CMS should consider how recent changes to the payment system affect scoring some of the measures. The two claims-based measures, Acute Care Hospitalizations (ACH) and Emergency Department (ED) Use without Hospitalization, are measured during the first 60 days of home health. They encourage CMS to consider how the

changes to the home health payment system from the 60-day unit under the previous case-mix system (in CY 2019) to the 30-day unit under Patient Driven Grouping Model (PDGM) (in CY 2020 and later) could affect HHAs' scores on the ACH and ED use measures between the baseline and performance years.

Response: The PDGM is a case-mix adjustment model intended to pay for services more accurately. We believe the HHVBP Model can continue unchanged when HHA periods of care are paid according to the case-mix adjustments of the PDGM. We may consider conducting analysis of the effects on HHAs' scores for ACH and ED Use measures between the baseline year and a performance year.

Comment: A commenter suggested using functional status as a risk adjuster for the hospitalization measures in the HHVBP model.

Response: Currently, there is no risk adjuster on our proposed claims measures. The proposed initial measure set for the expanded HHVBP Model includes the ACH measure which does not have any functional mobility elements. We thank the commenter for their suggestion and may take into consideration as we move forward in the implementation of the expanded HHVBP Model. We further note that we may make adjustments to the risk adjustment methodology based upon the removal of measures, changes to the assessment instrument, and diagnosis code changes.

Comments Regarding the OASIS-based Measures

Comment: A commenter recommends that CMS replace the OASIS-based Discharge to Community measure in the HHVBP proposed measure set with the new, claims-based Discharged to Community measure used under HH QRP. The commenter stated that maintaining both measures is confusing to HHAs as the measures have similar names but are calculated differently and that the new claims-based measure provides a more accurate score.

Response: We thank the commenter for their recommendation. Additional analysis is needed to evaluate the use of the claims-based Discharge to Community Measure used under the

HH QRP in place of the OASIS-based measure. We will continue to monitor quality measure performance under expansion and will consider any potential measure modifications for future rulemaking.

Comment: A commenter requested more detail on what changed in the updated risk adjustment methodology as it relates to the TNC measures.

Response: We have updated the risk adjustment methodology as it relates to the TNC measures, which is available on the HHVBP Model Expansion webpage.²³ CMS made optional OASIS items (M1030, M1242, M2030, and M2200) collected at the start or resumption of a care that were used in the risk adjustment and the update posted on the HH QRP website.²⁴ Since voluntary items may be missing for some home health quality episodes, these four voluntary items were removed from the risk adjustment model update effective for episodes of care beginning 1/1/2021 and posted on the HH QRP website, as noted above. We note that the updated methodology, posted on the HHVBP Model Expansion webpage noted above, is applicable to episodes of care for the CY 2022 pre-implementation year, however as noted previously in this rule, HHAs will not be assessed on their performance of the TNC measures in CY 2022 that are based on the updated risk adjustment methodology. We note that the next update of the risk adjustment models is planned for the release of OASIS E which would apply to episodes of care beginning 1/1/2023, the first performance year under the expanded HHVBP Model. That is, as CY 2023 is the first performance year under the expanded Model, HHAs would be assessed on their performance on the TNC measures based on the updated risk adjusted methodology for episodes of care that would begin 1/1/2023. We further note that, during that update of the methodology that would be effective with episodes of care beginning 1/1/2023 and

²³ <https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model>.

²⁴ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures> in a file titled Risk Adjustment Technical Specifications.

for which HHA's performance will be assessed, the risk adjustment models will be based on refreshed data and all risk factors will be re-tested for inclusion.

Comment: A commenter strongly supported the use of outcomes measures on functional status, such as the two OASIS composite measures (TNC Change in Mobility and TNC Change in Self-Care), stating that a patient's functional status is inextricably related to their ability to remain in a community setting and avoid unnecessary utilization of health care services. The commenter stated that it appreciates that these measures are broadly risk-adjusted to recognize patients with inherently limited goals for improvement, which can help account for differences in patient type that may affect an HHA's performance on certain measures. The commenter, however, recommended CMS consider whether additional risk adjustment would better account for patient differences, specifically for those with more limited potential for functional improvement.

Response: We thank the commenter for their support of the use of outcome measures on functional status. We appreciate the commenter's suggestion regarding additional risk adjustment to better account for patients with more limited potential for functional improvement and refer readers to our detailed response, discussed later in this section, on the risk adjusted methodology for the TNC measures.

Comment: Commenters expressed concern that the OASIS measures have the potential to reward non-legitimate quality improvement, because HHAs record and report functional assessment data through the OASIS assessment, and this information affects payments for HHAs and the calculation of certain quality metrics. The commenters asserted that providers have an incentive to report the information in ways that raise payments and appear to improve performance, resulting in questionable value for payment, quality measurement, and care planning. A commenter agreed that improving a patient's functional ability is a goal of home health care, but urged CMS not to include these OASIS-based measures of function (for example, TNC Change in Self-Care and TNC Change in Mobility) in the expanded HHVBP

Model until their accuracy is improved.

Response: With regard to concern that the OASIS measures may have the potential to reward non-legitimate quality improvement or that the measures may incentivize providers to report their OASIS assessments in ways that raise payments, we believe that the OASIS-based measures yield reliable information for assessing HHAs' quality performance and capture important information about beneficiaries' function based on reliability testing.²⁵ Most OASIS items achieve moderate to near perfect reliability based on reported Kappa values. With regard to the comment that CMS should not include the TNC measures in HHVBP until their accuracy is improved, we refer readers to our detailed response, that follows this response, on the TNC measures including their methodologies. We believe that our analysis of the TNC measures supports that these measures capture a change in a patient's status for the beneficiary population that may not have goals of improvement. We will continue, as with all measures in the measure set, to evaluate the benefit of the measure as the expanded Model progresses.

Comment: We received many comments about including stabilization/maintenance measures in the expanded Model and the proposed TNC measures. A commenter suggested that there be a modified risk adjustment that accounts for patients in palliative care population (for example, discharge to hospice care). Commenters suggest that a stronger risk adjustment model is needed for HHVBP to recognize that some home health agencies care for a much sicker and more complex population than others so agencies can be compared fairly and to ensure that incentives are aligned to care for patients with complex health and social determinant needs. Alternatively, commenters expressed that CMS could remove all patients with maintenance goals from HHVBP until all measures, incentives, and disincentives equally reflect their needs and qualifications for Medicare coverage as for those beneficiaries who can improve. The commenters suggest that improvement measures coupled with the higher weights assigned to the

²⁵ https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-Field-Test-Summary-Report_02-2018.pdf.

hospitalization and emergency department use claims-based measures may serve to disincentivize home health agencies from accepting into service Medicare beneficiaries that have chronic and/or unstable conditions or that the proposed measure set would negatively impact beneficiary access because HHAs may choose to care for patients who can show improvement in order to maximize their payment adjustment. Commenters stated that expansion should be temporarily halted in order to refine the methodology of how improvement is to be calculated to sufficiently account for patient populations whose appropriate goal may be to slow or temporarily halt functional decline, but who cannot reasonably be expected to make major improvements in activities of daily life (ADL) scores. Some commenters expressed concern that the proposed measures focus largely on improvement and should include stabilization and maintenance measures as well. Commenters asserted that the measure set's improvement standards are relied upon too heavily, which will negatively impact HHAs with chronic care, palliative care, and end of life patient populations, and that CMS's current risk adjuster does not account for these differences sufficiently. A commenter asserted that since the HHVBP Model was first proposed in 2015, quality measures discriminate against Medicare beneficiaries with longer-term, chronic conditions who require skilled care but are not expected to improve – patients covered by the *Jimmo* class action settlement and provided an example of a patient that it asserted would be harmed by expanding HHVBP. The commenter asserted that the proposed TNC Self-Care and TNC Mobility composite measures are not appropriate or adequate for beneficiaries who are not able to improve. The commenter believes that the methodology for the TNC measures does not allow agencies to benefit from providing care to beneficiaries who are not expected to improve, regardless of how high the quality of care.

Response: We believe the goals of home health care are to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute care setting, and/or facilitate transition to end-of-life care, when appropriate. We remind commenters

that the structure of the home health benefit requires a multidisciplinary approach of not only therapy services, but skilled nursing, home health aide, and medical social services. The TNC measures, as previously stated, are not improvement measures but rather, they measure the change in function in either direction, both positive and negative.

The TNC measures, in the proposed measure set, capture any risk-adjusted change (negative and positive). In general, a positive change between Start of Care (SOC) /Resumption of Care (ROC) and End of Care (EOC) assessment increases the measure values more than no change or a negative change. But the risk adjustment methodology for these measures is designed to level the “playing field” based on underlying risk factors. We also have exclusions in place for nonresponsive patients. Relative to the functional improvement measures in the initial HHVBP measure set, the TNC measures reward HHAs that help patients maintain or prevent excessive decline in their functional abilities overall. The TNC measure is a composite of changes, not improvement. We provide an example to help demonstrate how HHAs would not be dis-incentivized to care for beneficiaries who are not expected to improve, demonstrating how the risk-adjustment model recalibrates the scores for HHAs caring for beneficiaries with more complex medical needs relative to HHAs caring for less complex beneficiaries.

Risk Adjustment for Proposed TNC Measures

Risk adjustment is necessary to account for differences in patient case mix among different HHAs that affect performance on outcome measures. That is, age and pre-existing conditions impact how patients perform on outcome measures and risk adjustment accounts for the differing types of patients served by HHAs and enables comparison across HHAs. These same risk adjustment methods are employed in other quality measures, such as the hospital-based mortality measures, to prevent providers from avoiding the sickest patients and preferencing the healthiest.

The general formula for risk adjustment of OASIS outcomes measure is as follows:

$$Outcome_{RA} = (Observed_{HHA} - Predicted_{HHA}) + National$$

Where

Outcome_{RA} is the HHA's risk adjusted outcome measure value,

Observed_{HHA} is the HHA's average observed values for the outcome measure,

Predicted_{HHA} is the HHA's average predicted values for the outcome. Predicted values are obtained from a regression model using a set of risk factors, and

National is the average predicted value across all episodes in the nation.

An HHA's risk adjusted measure value is calculated by averaging the HHA observed measure value across all its patients and subtracting the HHA's average predicted measure value across all its patients. To standardize the result, the national measure value is then added to obtain the risk adjusted outcome measure for the HHA.

The following example demonstrates how the formula, as previously discussed, would work for a hypothetical patient with the following risk factors, as referenced by a commenter:

- Age 56
- Diagnosis of multiple sclerosis
- Use of catheter

Table 24 shows the risk adjustment coefficients on the selected risk factors for OASIS-based measures in the proposed measure set for the HHVBP expansion for this hypothetical beneficiary. The presence of these risk factors is almost always associated with lower predicted measure values for the OASIS-based outcome measures used in the proposed measure set for HHVBP expansion, as evidenced by the negative signs on the coefficients shown in this table.

TABLE 24. RISK ADJUSTMENT COEFFICIENTS FOR SELECT BENEFICIARY RISK FACTORS ACROSS FIVE MEASURES

	TNC MOB	TNC Self	Imprv Dyspnea	Imprv Oral Meds	Disch to Comm
AGE_55_59	-0.0149	-0.0327	-0.0764	-0.0484	-0.1227
URINCONT_CATH	-0.1369	-0.2711	-0.2470	-0.2543	-0.6561
HC DX Nervous	-0.0477	-0.1133	-	-0.1669	0.0880
Sum	-0.1995	-0.4171	-0.3234	-0.4696	-0.6908

Source: Estimated coefficients on risk factors: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvpbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf; <https://www.cms.gov/files/document/risk-adjustment-technicalspecifications508cfinal.pdf>

Negative coefficients lower the predicted value for a beneficiary with these characteristics and positive coefficients increase the predicted value. For each of the measures, summing the coefficients on the three risk factors shows that the presence of all three risk factors contributes negatively to the predicted value for those beneficiaries with the risk factors for all five measures in Table 24. Using the risk adjustment formula as previously discussed, the lower predicted values for these episodes would contribute to boosting the risk adjusted measure value if all other risk adjustment variables are equal across HHAs.

For illustrative purposes, imagine that the national average TNC Mobility score is 0.73 and a particular HHA has an observed score of 0.60. If all the HHA's patients had the three, previously discussed, risk factors (and no others), the HHA's risk adjusted TNC Mobility score would be $0.60 - 0.45^{26} + 0.73 = 0.88$. This score (0.88) is higher than the national score even though the observed value is lower than the national score. Note that this is purely hypothetical – actual episodes for an HHA would trigger multiple different risk factors (there are over a hundred) and the predicted value would be summed over the coefficients for all of these risk factors.

Based on the risk adjustment formula, the lower the average predicted measure value is for an HHA, the higher the HHA's risk adjusted outcome score. That is, patients with multiple risk factors associated with lower measure performance will have a lower predicted value than patients without those risk factors. The lower predicted value will increase the risk-adjusted measure score.

We believe that our analysis of the TNC measures supports that these measures capture a change in a patient's status for the beneficiary population that may not have goals of

²⁶ To calculate the 0.45, we sum the coefficients in the table above with the constant estimated from the updated risk adjustment model (www <https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model>) and apply the logistic formula (see Chapter 6 of <https://www.cms.gov/files/document/hh-qrp-qm-users-manual-v1-addendum.pdf>).

improvement. We will continue, as with all measures in the measure set, to evaluate the benefit of the measures as the Model progresses.

Comment: A commenter suggested that CMS consider including a falls prevention measure as key patient safety data necessary for a comprehensive HHVBP model. The commenter suggested, for example, that NQF 0101/CMIT 1247 Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls could be considered. The commenter stated that a falls prevention measure would help to ensure that HHAs are addressing risks and planning for interventions to minimize patient falls in the home, which can lead to greatly increased cost if a patient requires an emergency room visit, hospitalization, or other care to treat any injuries. Another commenter suggested that because family caregivers often play an important role in caring for the beneficiary, CMS consider adopting a measure for use in both the HHVBP model and HH QRP program that addresses HHAs documenting whether the beneficiary has a family caregiver and provided additional factors for the HHA to collect surrounding a beneficiary's family caregiver.

Response: We thank the commenters for their recommendations and we may consider these measures for inclusion in the expanded Model's measure set in a future year.

Comments Regarding the HHCAHPS Survey Measure

Comment: A commenter was not in favor of the overall quality rating proposed as a HHCAHPS measure as they believe it is not specific or necessarily actionable for improvement opportunities.

Response: We believe that patient experience is an important way to assess quality of care. The HHVBP expanded Model measure set was developed to encompass a home health episode of care from intake through to the patient experience survey encouraging HHAs to focus on quality, patient-centered care and quality improvement across various focus areas, including those which are not directly measured through the claims-based measures, such as patient experience.

Comment: A commenter supported HHCAHPS as part of the expanded Model's measure set. Another commenter stated that since patient experience is a key measure of a provider's quality, the HHVBP Model should continue to score HHCAHPS measures and that the measure set should be revised as other measures become available.

Response: We thank the commenters for their feedback. We agree that the HHCAHPS measure is a key measure of a provider's quality of care provided. We will continue to monitor quality measure performance as we consider any potential measure set changes for future rulemaking.

Final Decision: After consideration of comments received, we are finalizing the measure set as proposed effective with the CY 2022 pre-implementation year and subsequent years. We are also finalizing our proposed regulation text at § 484.355(a)(1) with modification to reflect that an HHA must submit data on the specified measures under the expanded HHVBP model for both the pre-implementation year and each performance year. As discussed in section III.A.3.a of this final rule, we are finalizing CY 2025 as the first payment year, instead of CY 2024. CY 2022 will be a pre-implementation year to allow all HHAs time to prepare and learn about the HHVBP expanded Model for successful implementation. Quality measure data collected during CY 2022 will not be assessed for purposes of a payment adjustment under the expanded HHVBP Model; that is, HHAs will incur zero percent (0%) payment risk based upon CY 2022 performance. CY 2023 will be the first performance year, beginning January 1, 2023; CY 2025 will be the first payment year. Table 25 sets forth the finalized measure set for the expanded HHVBP Model. We note that in Table 26 of the proposed rule, the Measure Steward and Identifier for the Discharged to Community measure was NA and NA, respectively. In Table 25, the finalized measure set for the expanded Model, the Measure Steward and the Identifier is updated to CMS and NQF 3477, respectively.

TABLE 25: FINALIZED MEASURE SET FOR THE EXPANDED HHVBP MODEL

NQS Domains	Measure Full Title/Short Form Name (if applicable)	Measure Type	Measure Steward	Identifier	Data Source	Numerator	Denominator	Link to Measure Specifications/NQF Info
OASIS-based								
Clinical Quality of Care	Improvement in Dyspnea/Dyspnea	Outcome	NA	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
Communication & Care Coordination	Discharged to Community	Outcome	CMS	NQF 3477	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
Patient Safety	Improvement in Management of Oral Medications/Oral Medication	Outcome	CMS	NQF 0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
Patient and Family Engagement	Total Normalized Composite Change in Mobility*/TNC Mobility	Composite Outcome	NA	NA	OASIS (M1840) (M1850) (M1860)	The total normalized change in mobility functioning across three OASIS items (toilet transferring, bed transferring, and ambulation/locomotion)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted - HHA Predicted.	https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf
Patient and Family Engagement	Total Normalized Composite Change in Self-Care**/TNC Self-Care	Composite Outcome	NA	NA	OASIS (M1800) (M1810) (M1820) (M1830) (M1845) (M1870)	The total normalized change in self-care functioning across six OASIS items (grooming, bathing, upper & lower body dressing, toilet hygiene, and eating)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted - HHA Predicted.	https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf

NQS Domains	Measure Full Title/Short Form Name (if applicable)	Measure Type	Measure Steward	Identifier	Data Source	Numerator	Denominator	Link to Measure Specifications/NQF Info
Claims-based								
Efficiency & Cost Reduction	Acute Care Hospitalization During the First 60 Days of Home Health Use/ACH	Outcome	CMS	NQF 0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization During the First 60 Days of Home Health/ED Use	Outcome	CMS	NQF 0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf NQF Measure Information
HHCAHPS Survey-based								
Patient & Caregiver-Centered Experience	Home Health Consumer Assessment Healthcare Providers and Systems (HHCAHPS) Survey	Outcome	CMS	NQF 0517	CAHPS	Survey-based. HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure	Survey-based. HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure	Links provided in Table XX NQF Measure Information

*Because the Total Normalized Composite Change in Mobility measure is a composite measure rather than simply an outcome measure, the terms “Numerator” and “Denominator” do not apply.

**Because the Total Normalized Composite Change in Self-Care measure is a composite measure rather than simply an outcome measure, the terms “Numerator” and “Denominator” do not apply.

Table 26 provides more granular detail on the elements of the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey measure.

TABLE 26: HHCAHPS SURVEY MEASURE COMPONENTS AND COMPONENT QUESTIONS

HHCAHPS Survey-based Component Name/ Short Name and Component Questions*	Type	NQF ID	Data Source	Link to Measure Specs/Response Categories
Care of Patients/Professional Care	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2062
Q9. In the last 2 months of care, how often did home health providers from this agency seem informed and up-to-date about all the care or treatment you got at home?				Never, Sometimes, Usually, Always
Q16. In the last 2 months of care, how often did home health providers from this agency treat you as gently as possible?				Never, Sometimes, Usually, Always
Q19. In the last 2 months of care, how often did home health providers from this agency treat you with courtesy and respect?				Never, Sometimes, Usually, Always
Q24. In the last 2 months of care, did you have any problems with the care you got through this agency?				Yes, No
Communications between Providers and Patients/Communication	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2580

Q2. When you first started getting home health care from this agency, did someone from the agency tell you what care and services you would get?				Yes, No
Q15. In the past 2 months of care, how often did home health providers from this agency keep you informed about when they would arrive at your home?				Never, Sometimes, Usually, Always
Q17. In the past 2 months of care, how often did home health providers from this agency explain things in a way that was easy to understand?				Never, Sometimes, Usually, Always
Q18. In the past 2 months of care, how often did home health providers from this agency listen carefully to you?				Never, Sometimes, Usually, Always
Q22. In the past 2 months of care, when you contacted this agency's office did you get the help or advice you needed?				Yes, No
Q23. When you contacted this agency's office, how long did it take for you to get the help or advice you needed?				Same day; 1 to 5 days; 6 to 14 days; More than 14 days
Specific Care Issues/Team Discussion	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2582
Q3. When you first started getting home health care from this agency, did someone from the agency talk with you about how to set up your home so you can move around safely?				Yes, No
Q4. When you started getting home health care from this agency, did someone from the agency talk with you about all the prescription medicines you are taking?				Yes, No
Q5. When you started getting home health care from this agency, did someone from the agency ask to see all the prescription medicines you were taking?				Yes, No
Q10. In the past 2 months of care, did you and a home health provider from this agency talk about pain?				Yes, No
Q12. In the past 2 months of care, did home health providers from this agency talk with you about the purpose for taking your new or changed prescription medicines?				Yes, No
Q13. In the last 2 months of care, did home health providers from this agency talk with you about when to take these medicines?				Yes, No
Q14. In the last 2 months of care, did home health providers from this agency talk with you about the important side effects of these medicines?				Yes, No
Overall rating of home health care/Overall Rating	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2581
Q20. What number would you use to rate your care from this agency's home health providers?				Use a rating scale (0-10) (0 is worst, 10 is best)
Willingness to recommend the agency/Willing to Recommend	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2583
Q25. Would you recommend this agency to your family or friends if they needed home health care?				Definitely no; Probably no; Probably yes; Definitely yes

*The HHCAPHS survey measure component has five component questions that together are used to represent one NQF-endorsed measure. Detailed scoring information is contained in the Protocols and Guidelines manual posted on the HHCAPHS website and available at <https://homehelathcahps.org/Survey-and-Protocols/Survey-Materials>.

c. Measure Modifications

During the expanded Model, we will monitor the quality measures for lessons learned and address any needed adjustments or modifications to the expanded Model measure set.

(1) Substantive vs. Non-Substantive Changes Policy

Updates to measures may result from various sources including, for example, measure stewards and owners, new clinical guidelines, a public health emergency, CMS-identified, a technical expert panel (TEP), or NQF. We stated in the proposed rule that how we incorporate those updates would depend on whether the changes are substantive or non-substantive.

With respect to what constitutes a substantive versus a non-substantive change, we stated

in the proposed rule that we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We proposed that, in the event that an update to a measure is necessary in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications. Specifically, we would revise the information that is posted on the CMS website so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would provide sufficient lead time for HHAs to implement the changes where changes to the data collection systems would be necessary.

We also proposed to use notice and comment rulemaking to adopt changes to measures that we consider to substantially change the nature of the measure. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting. We stated that we believe that our proposal adequately balances the need to incorporate changes to measures used in the expanded HHVBP Model in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change a measure that it is no longer the same measure originally adopted. We note that CMS adopted a similar policy for the HH QRP in the CY 2015 HH PPS final rule (79 FR 66079 through 66081).

We invited public comment on our proposal. We summarize in this section of this rule the comments received and provide our responses.

Comment: A commenter suggested that ongoing modifications to the HHVBP expanded model (for example, scoring methodology, quality measure inclusion, risk adjustment methodology) are necessary to ensure the expanded model accurately and appropriately reflects the value of services delivered and the beneficiary populations cared for.

Response: CMS will continue to evaluate and monitor the expanded HHVBP Model for potential modifications to ensure the expanded model accurately and appropriately reflects the value of services delivered and the beneficiary populations cared for.

Final Decision: After consideration of comments received, we are finalizing our proposal as proposed.

d. Measure Removals

The measure set used for the expanded Model would be subject to change including the removal of measures during subsequent years. In the proposed rule, for greater transparency, we proposed factors we would consider in proposing to remove a measure as well as a policy for when immediate suspension is necessary.

(1) Removal Factors

We proposed to generally use the following removal factors when considering a quality measure for removal for use in the expanded HHVBP Model:

- Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made (that is, topped out). To determine “topped-out” criteria, we will calculate the top distribution of HHA performance on each measure, and if the 75th and 90th percentiles are statistically indistinguishable, we will consider the measure topped-out.

- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.

- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.
- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

With respect to Factor 8, under our Meaningful Measures Initiative, we are engaging in efforts to ensure that the expanded HHVBP Model measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe that these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the expanded HHVBP Model. We have identified several different types of costs, including, but not limited to the following:

- Provider and clinician information collection burden and burden associated with the submitting/reporting of quality measures to CMS.
- The provider and clinician cost associated with complying with other HH programmatic requirements.
- The provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs.
- The cost to CMS associated with the program oversight of the measure, including measure maintenance and public display.

- The provider and clinician cost associated with compliance with other Federal and State regulations (if applicable).

For example, it may be of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports the expanded HHVBP Model goals (for example, no longer provides incentives for better quality care with greater efficiency). It may also be costly for HHAs to track confidential feedback and publicly reported information on a measure where we use the measure in more than one initiative, model, or program. We may also have to expend resources to maintain the specifications for the measure, including the tools needed to collect, validate, analyze, and publicly report the measure data.

When these costs outweigh the evidence supporting the continued use of a measure in the expanded HHVBP Model, we believe that it may be appropriate to remove the measure from the Model. Although we recognize that the expanded HHVBP Model is to encourage HHAs to improve beneficiary outcomes by incentivizing health care providers, we also recognize that this can have limited utility where, for example, the data is of limited use because it is not meaningful. In these cases, removing the measure from the expanded HHVBP Model may better accommodate the costs of expansion administration and compliance without sacrificing improved health outcomes.

We proposed that we would remove measures based on Factor 8 on a case-by-case basis. For example, we may decide to retain a measure that is burdensome for HHAs to report if we conclude that the benefit to beneficiaries is so high that it justifies the reporting burden. Our goal is to move the expanded HHVBP Model forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We believe that even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant

that removing the measure could result in poor quality. We would apply these factors on a case-by-case basis.

In addition, as noted previously, the authority to expand the HHVBP Model affords the opportunity to study new measures that are not currently collected or submitted to CMS by HHAs. Because of this, there may be other unforeseen reasons that necessitate the removal of a measure that is not currently captured in one of the factors noted previously. In such cases, we would still use notice and comment rulemaking to remove the measure and provide the reasons for doing so.

We solicited public comment on our proposals.

Final Decision: We did not receive any comments on our proposal and are finalizing the measure removal factors as proposed.

(2) Measure Suspension Policy

We stated in the proposed rule that removal of an expanded HHVBP Model measure would take place through notice and comment rulemaking as proposed in the preceding section unless we determine that a measure is causing concern for patient safety or harm. We proposed that in the case of an expanded HHVBP Model measure for which there is a reason to believe that the continued collection raises possible patient safety concerns, we would promptly suspend the measure and immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. We would then propose to remove or modify the measure as appropriate during the next rulemaking cycle.

We solicited public comment on our proposal.

Final Decision: We did not receive any comments on our proposal and are finalizing the measure suspension policy as proposed.

e. Future Topics or Measure Considerations

(1) Consideration to Align or Remove Measures with the HH QRP

In section IV.C. of the proposed rule, CMS proposed to replace the Acute Care

Hospitalization During the First 60 Days of Home Health (ACH) measure and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (ED Use) measure with the Home Health Within Stay Potentially Preventable Hospitalization (PPH) measure beginning with the CY 2023 under the HH QRP. (As discussed in section IV.C of this final rule, CMS is finalizing its proposal to replace the ACH and ED Use measures with the PPH measure for the HH QRP measure set beginning with CY 2023.) We noted in the proposed rule that while both the ACH and ED Use measure were being proposed for removal under the HH QRP, these measures were being proposed for inclusion in the expanded HHVBP Model beginning with the CY 2022 performance year. We solicited public comment on whether we should instead align the expanded HHVBP Model with the proposed changes for HH QRP by proposing to remove the same two measures from the expanded Model in a future year. We noted that any measure removals would be proposed in future notice and comment rulemaking.

We requested public feedback on this future consideration. We summarize in this section of this rule the feedback received and provide our responses.

Comment: Commenters recommended that the HHVBP measure set align to measures of the HH QRP. Another commenter suggested that CMS move to align the included measures with the Star Ratings and other quality reporting activities. Another commenter stated that by bringing consistency to tracked outcomes across the HH QRP, Star Ratings, and HHVBP, CMS will minimize the difficulty of beneficiaries and payers to make comparative assessment of provider quality while also streamlining home health providers' data capture and reporting processes.

Response: We thank the commenters for their suggestions. We note that the proposed measure set for the expanded HHVBP Model generally aligns with the HH QRP. We will take into consideration opportunities for further alignment, including with respect to the claims-based measures. If we consider adding new measures that require data that is not already collected

through existing quality measure data reporting systems, we would propose that in future rulemaking being mindful of provider burden.

Comment: Commenters expressed that they need at least one year to become familiar with the Home Health Within-Stay Potentially Preventable Hospitalization (PPH) measure, and to affect outcomes, if needed, before including it in the HHVBP expanded Model measure set.

Response: We thank the commenters for their feedback and will take into future consideration.

(2) Health Equity Considerations for the Expanded HHVBP Model

In section VIII.B. of the proposed rule, we included a Request for Information on ways to close the health equity gap in post-acute care quality reporting programs, including the HH QRP. In the proposed rule, we referred readers to that section for discussion of our current health equity efforts in quality measurement and reporting and potential modifications we have considered or may consider in the future. However, in recognition of persistent health disparities and the importance of closing the health equity gap, we requested public comment on ways in which we could incorporate health equity goals and principles into the expanded HHVBP Model. Specifically, we sought comment on the challenges unique to value-based purchasing frameworks in terms of promoting health equity, and ways in which we could incorporate health equity goals into the expanded HHVBP Model.

In this section of this rule, we summarize comments received and provide our responses.

Comment: A commenter stated that in an effort to prevent bias in patient selection, it encouraged CMS to consider potential stabilization measures, rather than sole reliance on improvement measures. The commenter stated that this will continue to promote access to care for individuals with chronic illness or limited ability to improve, and is consistent with the renewed focus on health equity. Another commenter generally supported health equity goals and principles incorporated in the expanded HHVBP Model. The commenter recommended CMS collect patient-level demographic information based on segmented demographics (race,

ethnicity, gender, etc.) on existing measures, instead of creating new or more complex measures. The commenter stated that should CMS move forward with adopting new health equity measures, it recommended CMS include these measures in the HH QRP prior to inclusion in the HHVBP Model.

Response: We thank the commenters for their feedback. As discussed in section III.A.6.b of this final rule, we are finalizing the measure set as proposed, which includes improvement, total normalized composite change measures, utilization and patient experience measures. We refer readers to our earlier detailed response in this section of the rule on the TNC change measures, including the measure methodology, and why we believe the measure set would not dis-incentivize HHAs from caring for beneficiaries with chronic illness or limited ability to improve. Health equity including access to care for all beneficiaries is a priority. CMS will continue to monitor beneficiary access under the HHVBP Model expansion.

Comment: A commenter recommended that outcomes measured in the HH QRP and HHVBP Model be stratified by various patient populations to determine how they are affected by Social Determinants of Health (SDOH).

Response: We note that in section VIII.B of this final rule, we are finalizing our proposal to revise compliance dates for HHAs under the HH QRP. This policy includes the submission of certain standardized patient assessment data, some of which address social determinants of health (SDoH). These standardized patient assessment data, in part, support efforts to evaluate health equity in a manner we believe is consistent with the policy set out in Executive Order 13985 of January 20, 2021, entitled “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (86 FR 7009). We are working collaboratively with HH QRP to determine how data collected on SDoHs under HH QRP could be part of the HHVBP Model expansion in the future.

f. Measure Submissions – Form, Manner, and Timing

We proposed at § 484.355 that home health agencies will be evaluated using a set of quality measures, and data submitted under the expanded Model must be submitted in the form and manner, and at a time, specified by CMS. Additional details regarding specific types of measures are discussed later in this section.

As noted in the proposed rule and previously in this final rule, the measures that we proposed and are finalizing for the expanded HHVBP Model measure set would use data currently already reported by HHAs. The measure set includes OASIS²⁷ measures, submitted through the OASIS assessment, which is required to be submitted as part of the Medicare Conditions of Participation (CoPs), the HHCAHPS survey measure, which is required under the HH QRP, and claims-based measures, which are calculated by CMS based on claims data HHAs already submit for purposes of payment. As we stated in the proposed rule, in many cases, measures from the expanded HHVBP Model overlap with those in the HH QRP, and HHAs would only need to submit data once to fulfill requirements of both. However, as described in section III.6.a. of the proposed rule and this final rule, in the future we may propose new measures that may not otherwise already be collected or submitted by HHAs.

We solicited comment on our proposal.

As previously noted, we are finalizing our proposed regulation text at § 484.355 with modification to reflect that an HHA must submit data on the specified measures under the expanded HHVBP model for both the pre-implementation year and each performance year.

(1) Form, Manner, and Timing of OASIS Measure Data

CMS home health regulations, codified at §484.250(a), require HHAs to submit to CMS OASIS data as is necessary for CMS to administer payment rate methodologies. All HHAs must electronically report all Outcome and Assessment Information Set (OASIS)²⁸ data collected in

²⁷ For detailed information on OASIS see the official CMS web resource available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits>

²⁸ For detailed information on OASIS see the official CMS web resource available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits>

accordance with §484.55(b), (c) and (d) in order to meet the Medicare CoPs, and as a condition for payment at §484.205(c). The OASIS assessment contains data items developed to measure patient outcomes and improve home health care. HHAs submit the OASIS assessment in the Internet Quality Improvement Evaluation System (iQIES) (<https://iqies.cms.gov/>). We note that the CoPs require OASIS accuracy and that monitoring and reviewing is done by CMS surveyors (§488.68(c)). It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (SOC) (initial assessment) or Resumption of Care (ROC) OASIS assessment and a Transfer or Discharge OASIS assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs §484.225(i). HHAs do not need to submit OASIS data for patients who are excluded from the OASIS submission requirements Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies final rule (70 FR 76202) where we excluded patients-

- Receiving only non-skilled services;
- For whom neither Medicare nor Medicaid is paying for HH care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement);
- Receiving pre- or post-partum services; or
- Under the age of 18 years.

We proposed that HHAs participating in the expanded HHVBP Model would also be required to submit OASIS data according to the requirements of the CMS home health regulations codified at § 484.250(a) and OASIS data described in §484.55(b), (c) and (d). We stated in the proposed rule that if finalized, this would mean that HHAs would not be required to submit additional data through OASIS specifically for the expanded Model compared to what is already required for COPs, and there would be no additional burden. We note that this proposed

requirement also aligns with requirements under the Home Health QRP (82 FR 4578).

For the expanded Model, we proposed that the underlying source data used to calculate an OASIS quality measure score beginning with the CY 2022 performance year comes from 12 months of OASIS assessment data from the applicable performance period via iQIES. The data extracted from iQIES for all OASIS measures, besides the two TNC measures, are aggregated to the monthly level for each HHA, separated by observed and predicted values used to calculate risk adjusted values. For the two TNC measures, we proposed to use raw OASIS assessments to calculate applicable measure scores consistent with how we developed these measures.

We solicited comment on our proposals. We summarize in this section of this rule comments received and provide our responses.

Comment: Several commenters were interested in knowing, if the HHA discharges the patient to either inpatient hospice care, or home hospice care, will declines in outcomes scored on the Home Health Discharge OASIS be counted against the HHA or would those declines be considered an outlier due to the patient transfer or discharge to a Hospice Provider. Another commenter questioned whether the agency data proposed to be collected from OASIS for completed episodes of care is SOC or ROC to discharge. Commenters expressed concern that if a patient opts for hospice, there is no ability to exclude these patients from the payment calculation at this point.

Response: For some of the HHVBP OASIS measures, such as the TNC measures, OASIS items used in calculating the measure are only collected at discharge²⁹ and therefore episodes that end in transfer are excluded from the measure calculation.³⁰

²⁹ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/draft-OASIS-D-Guidance-Manual-7-2-2018.pdf>.

³⁰ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-QRP-QM-Users-Manual-V10-August-2019.pdf>.

If the home health episode ends with a transfer to an institutional provider (M0100 = 06 or 07) or death (08), then the patient would be excluded from the Dyspnea, Oral Medications, TNC Mobility, and TNC Self-Care measures because the OASIS items that these measures use are not collected at the time of transfer for these patients. Patients who are transferred to an inpatient hospice facility count as a “transfer to an inpatient facility” (07) and are not included in the OASIS-based measures, while patients discharged to in-home hospice count as regular discharges (09) and are included in the OASIS-based measures. The two claims-based measures use the 60 days after the start of home health, and there are no exclusions for patients who go to a hospice. It is correct that an OASIS quality episode of care does go from SOC/ROC to transfer/discharge.

Comment: Commenters discouraged CMS from including future VBP measures that are not collected in the OASIS data set (or through HHCAHPS or claims). Commenters stated that this would help prevent duplicative data collection and reduce administrative burden for agencies and assist HHAs to achieve better outcomes.

Response: We note that we may, through future rulemaking, add new measures to the expanded Model where data is not already collected in order to study them for their appropriateness in the home health setting. As discussed in the proposed rule, if we consider adding new measures that require data that is not already collected through existing quality measure data reporting systems, we would propose that in future rulemaking being mindful of provider burden. We note that the proposed measure set for the expanded Model uses data already collected through OASIS, claims, and HHCAHPS.

Final Decision: After consideration of the comments received, we are finalizing our proposals on the form, manner and timing of OASIS measure data as proposed. We reiterate that CY 2022 quality data will not be used to impact payments to eligible HHAs in CY 2024. CY 2023 will be the first year in which the data collected on the OASIS, claims, and HHCAHPS measures in the expanded HHVBP Model’s set will be assessed to determine payment

adjustments for eligible HHAs in the expanded HHVBP Model in CY 2025, the first payment year under the expanded Model.

(2) Form, Manner, and Timing of HHCAHPS Survey Measure Data

Under the HH QRP, HHAs are required to contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf (42 CFR 484.245(b)(1)(iii)(B)) among other requirements.

For purposes of the expanded HHVBP Model, we proposed similar requirements that align with the HH QRP HHCAHPS survey measure data reporting requirement at §484.245(b)(1)(iii). Specifically, under the expanded Model we proposed that--

- HHAs must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf;
- 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;
- 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;
- No organization, firm, or business that owns, operates, or provides staffing for an 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 are not be approved by CMS as HHCAHPS survey vendors;
- Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors’ company locations; and
- Patient count exemption: HHAs that have fewer than 60 eligible unique HHCAHPS survey patients must annually submit to CMS their total HHCAHPS survey patient count to CMS to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

A CMS contractor provides the agency with the HHCAHPS survey measure score aggregated to the 12-months of data for the applicable performance period.

The list of approved HHCAHPS survey vendors is available at <https://homehealthcahps.org> or contact the HHCAHPS help desk hhcahps@rti.org. Again, we reiterate that these proposed requirements would align with those under the HH QRP and would not add additional burden to HHAs.

We also proposed to codify these proposals at § 484.355(a)(1)(ii).

We requested public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals, including our proposed regulation text at § 484.355(a)(1)(ii), as proposed.

(3) Form, Manner, and Timing of Claims-based Measures

Claims-based measures are derived from claims data submitted to CMS for payment purposes. Claims-based utilization measures provide information related to the use of health care services (for example, hospitals, emergency departments, etc.) resulting from a change in patient health status. We calculate claims-based measures based on claims data submitted to CMS for payment purposes. Therefore, HHAs do not need to submit additional information for purposes of calculating claims-based measures.

We proposed that the underlying source data for claims-based measures is 12 months of claims data during the applicable performance period for purposes of payment under the expanded Model.

We requested comment on our proposal.

Final Decision: We did not receive comments on this proposal and are finalizing our proposal as proposed.

(4) Data Reporting for Monitoring and Evaluation of the Expanded HHVBP Model

Consistent with requirements under the original HHVBP Model at § 484.315(c), we proposed that competing HHAs under the expanded HHVBP Model would be required to collect

and report information to CMS necessary for the purposes of monitoring and evaluating this model as required by statute.³¹ We also proposed to codify this at §484.355(b).

We sought public comment on these proposals.

Comment: A commenter strongly recommended that CMS have a clear, ongoing plan to monitor beneficiary access in place from the inception of the expanded model, including distribution of HHAs in historically underserved areas. The commenter stated that the monitoring plan should be as close to real-time as is operationally feasible and include steps for corrective action for those HHAs found to be avoiding complex patients. The commenter stated that monitoring also should incorporate beneficiary input, such as surveys and focus groups, as well as frequent assessments of the numbers and types of beneficiary complaints and appeals.

Response: We thank the commenter for their recommendations. We will continue to evaluate and monitor the expanded HHVBP Model and will take the commenter's recommendations under consideration.

Final Decision: After consideration of comments received, we are finalizing our proposals as proposed, including our proposed regulation text at § 484.355(b).

(5) Use Authority Under Section 1115A(d)(1) of the Act to Waive Provisions Outlined in 1890A(a)(1) and (3) through (6) of the Act

As discussed in section III.A.11. of the proposed rule and this final rule, we proposed a public reporting framework for the expanded HHVBP Model that would include annual public reporting of quality performance data. This data includes national benchmarks and achievement thresholds, HHA-level performance results for HHAs that qualify for an annual payment adjustment that includes applicable quality measure scores, Total Performance Scores and percentile rankings, improvement thresholds, and payment adjustment percentages. Section 1890A(a)(1) through (6) of the Act set forth requirements regarding the pre-rulemaking process

³¹ See 1115A(b)(4) of the Act (42 U.S.C. 1315a).

for the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act, including quality and efficiency measures used in reporting performance information to the public. We proposed to utilize the Center for Medicare and Medicaid Innovation's waiver authority under section 1115A(d)(1) of the Act to waive the steps outlined in section 1890A(a)(1) and (3) through (6) of the Act that pertain to the pre-rulemaking process for publicly reporting performance information to the extent necessary to test the proposed expanded Model.

Section 1115A(d)(1) of the Act allows the Secretary to waive certain statutory requirements "as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)." Specifically, we proposed to waive section 1890A(a)(1) and (3) through (6) of the Act which pertains to: convening multi-stakeholder groups to provide input to the Secretary on the use of quality and efficiency measures; transmitting the input from the multi-stakeholder groups to the Secretary; consideration of the input by the Secretary from the multi-stakeholder groups; publication in the **Federal Register** of the rationale on the quality and efficiency measures not endorsed for use; and, conduct an impact assessment every three years on the use of such measures.

We note that we did not propose to waive step 2 of the 6 steps in the pre-rulemaking process. Step 2 pertains to the public availability of measures considered for selection. Section 1890A(a)(2) of the Act specifically applies to quality and efficiency measures under Title XVIII, whereas the expanded model would be implemented under section 1115A of the Act, which is in Title XI.

We proposed to waive the steps outlined in sections 1890A(a)(1) and (3) through (6) of the Act to the extent necessary in order to allow maximum flexibility to continue to test the expanded HHVBP Model under authority of section 1115A of the Act. We stated in the proposed rule that the timeline associated with completing the steps described by these provisions would impede our ability to support testing new measures in a timely fashion, as well

as testing new ways to incentivize quality performance in the home health setting and a new way to pay for home health care services. We stated that we plan to continue to seek input from a Technical Expert Panel (TEP) and to monitor quality measure performance to inform potential measure set changes under the expanded Model. We stated that waiving the five steps noted previously for the expanded HHVBP Model would allow for a more flexible timeline with more timely evaluation and monitoring of quality performance and results.

We stated in the proposed rule that flexibility in timing to adjust the quality measure set and/or methodology to respond to unexpected events and trends in home health care, as well as to respond timely to any stakeholder concerns, is critical to the success of the HHVBP Model expansion. The ongoing uncertainty levied by the COVID-19 pandemic, and similar events that may come in the future, requires us to maintain responsiveness to anomalies in the quality measure data. These challenges may require the flexibility to timely implement changes to ensure that measure sets continue to appropriately assess performance in light of external factors. In addition, trends in market consolidation and small business policies in the home health care industry could require certain adjustments to measure methodology, that is, minimum volume requirements, or require adjustment to the applicability of measures. The home health care sector is also becoming a more important source of care for beneficiaries who prefer to age in the community, rather than in an institution. This trend, in addition to the national shift in beneficiary demographics, could require flexibility in the quality measure set. This flexibility would be a key lever to adapt the Model to the unpredictable changes led by beneficiary preference, industry trends, and unforeseen nationwide events that HHAs are particularly sensitive to. We sought comment on our proposal to waive the steps outlined in section 1890A(a)(1) and (3) through (6) of the Act as applicable and to the extent necessary to test the proposed expanded Model.

We summarize in this section of this rule comments received and provide our responses.

Comment: A couple of commenters encouraged CMS to maintain current processes when developing, considering, and implementing new quality measures in any Medicare quality program, particularly for those measures that are not NQF endorsed and suggested CMS consider establishing a streamlined but standardized pathway applicable to the expanded HHVBP model that would allow for stakeholder input without unnecessarily delaying adoption of high-value measures.

Response: We agree that stakeholder input is valuable to future measure set modifications for the HHVBP expanded model. As stated previously, in section III.A.6.5 of this final rule, we plan to continue to seek input on the measure set, including from stakeholders of various fields of expertise and to monitor quality measure performance to inform potential measure set changes under the expanded Model.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal as proposed.

7. Performance Scoring Methodology

a. Considerations for Developing the Total Performance Score Methodology

We considered several factors when we initially developed and subsequently refined the performance scoring methodology over the course of the original Model, and we proposed to apply a similar methodology for the expanded HHVBP Model. We explain later in this section how we proposed to calculate a “performance score” for each applicable measure for each competing HHA, which is defined as the achievement or improvement score (whichever is greater). The “Total Performance Score,” or “TPS,” is the numeric score, ranging from 0 to 100, awarded to each qualifying HHA based on the weighted sum of the performance scores for each applicable quality measure under the HHVBP Model expansion. The following principles guided the original Model’s design, as well as these proposals for the expanded Model.

First, we believe the performance scoring methodology should be straightforward and transparent to HHAs, beneficiaries, and other stakeholders. HHAs should be able to clearly

understand performance scoring methods and performance expectations to optimize quality improvement efforts. The public should also understand performance score methods to utilize publicly-reported information when choosing HHAs.

Second, we believe the performance scoring methodology for the proposed HHVBP Model expansion should be aligned appropriately with the quality measurements adopted for other Medicare value-based purchasing programs, including those introduced in the hospital and skilled nursing home settings. This alignment would facilitate the public's understanding of quality measurement information disseminated in these programs and foster more informed consumer decision-making about their health care choices.

Third, we believe that differences in performance scores must reflect true differences in performance. To make sure that this point is addressed in the performance scoring methodology for the proposed HHVBP Model expansion, we assessed quantitative characteristics of the measures, including the current state of measure development, number of measures, and the number and grouping of measure categories.

Fourth, we believe that both quality achievement and improvement must be measured appropriately in the performance scoring methodology for the expanded HHVBP Model. The proposed methodology specifies that performance scores under the expanded HHVBP Model would be calculated utilizing the higher of achievement or improvement scores for each measure, with achievement out of 10 points and improvement out of 9. We considered the impact of performance scores utilizing achievement and improvement on HHAs' behavior and the resulting payment implications. We stated in the proposed rule that as under the original Model, using the higher of achievement or improvement scores would allow the Model expansion to recognize HHAs that have made improvements, though their measured performance score may still be relatively lower in comparison to other HHAs. We stated that by limiting the improvement score to a scale across 0 to 9, we prioritize achievement relative to improvement.

Fifth, we stated that we intend that the expanded Model would utilize the most currently available data to assess HHA performance, to the extent appropriate and feasible within the current technology landscape. We recognize that not all HHAs have the ability to submit data electronically or digitally and that the proposed quality measure data would not be available instantaneously due to the time required to collect, submit, and process quality measurement information accurately; however, we intend to process data as efficiently as possible.

b. Performance Score Methodology

(1) Overview

We stated in the proposed rule that the goal of the performance scoring methodology would be to produce a TPS for each qualifying HHA based on its raw scores on each applicable quality measure included in the expanded HHVBP Model. We would then use the HHA's TPS to determine the HHA's payment adjustment percentage. At a high level, the following summarizes the proposed steps for determining an HHA's TPS under the expanded Model, which is similar to the approach used under the original Model: (1) each HHA would receive a raw quality measure score for each applicable measure during the performance year; (2) the HHA would receive an "achievement score" for each applicable measure, which is defined as a numeric value between 0 and 10 that quantifies an HHA's performance on a given quality measure compared to other HHAs in the same cohort in the baseline year (calculated using the achievement threshold and benchmark, as defined in section III.A.7.b.2. of this final rule); (3) each HHA would also receive an "improvement score" for each applicable measure, which is defined as a numeric value between 0 and 9, that quantifies an HHA's performance on a given quality measure compared to its own individual performance in the baseline year (the improvement threshold, as defined in section III.A.7.b.2. of this final rule); (4) each HHA would be assigned a "performance score" on each applicable measure that is the higher of the achievement score or the improvement score, as described in section III.A.7.b.2 of this final rule; and (5) each performance score would then be weighted, using each measure's assigned weight,

and summed to generate the HHA's TPS, as described in section III.A.7.e. of this final rule. The result of this process would be a TPS for each competing HHA that can be translated into a payment adjustment percentage using the LEF applicable to each cohort, as described in section III.A.8. of this final rule.

Our proposal for the performance scoring methodology under the expanded HHVBP Model follows closely to that of the original Model. As discussed in more depth in the sections that follow, under the expanded HHVBP Model, we proposed that we would assess each HHA's TPS based upon all applicable quality measures (defined later in this section) in the expanded Model measure set in the applicable performance year. Each competing HHA would receive an interim assessment on a quarterly basis, as described in detail in section III.A.9.a. of this final rule. The performance scoring methodology would be used to determine an annual distribution of value-based payment adjustments among HHAs in a cohort so that HHAs achieving the highest performance scores would receive the largest upward payment adjustment. The proposed methodology includes three primary features, each of which is discussed in more detail in the sections that follow:

- The HHA's TPS would reflect all of the claims- and OASIS-based measures for which the HHA meets the minimum of 20 home health episodes of care per year and all of the individual components that compose an HHCAHPS survey measure for which the HHA meets the minimum of 40 HHCAHPS surveys received in the performance year, defined as "applicable measures".
- An HHA's TPS would be determined by weighting and summing the higher of that HHA's achievement or improvement score for each applicable measure as described in section III.A.7.b. of this final rule.
- The claims-based, OASIS assessment-based, and the HHCAHPS survey-based measure categories would be weighted 35 percent, 35 percent, and 30 percent, respectively, and would account for 100 percent of the TPS. If an HHA is missing a measure category or a

measure within the OASIS-based measure category, the measures would be reweighted, as described further in section III.A.7.e. of this final rule.

As noted, we proposed that many of the key elements from the original Model's performance scoring methodology would also apply for the expanded HHVBP Model, as we discuss in more detail in the sections that follow. We stated in the proposed rule that the primary changes between the original Model and the expanded Model would be that first, because we were not proposing to require submission of the New Measures data, we would not consider New Measures in calculating the TPS under the expanded Model. The New Measures reporting currently accounts for 10 percent of the TPS under the original HHVBP Model. In addition, we proposed small changes to the achievement and improvement score formulas to simplify their calculation and interpretation, without materially changing the output. We also proposed to calculate benchmarks and achievement thresholds based on national volume-based cohorts, as opposed to the State-based cohorts under the original Model, to align with the proposal for volume-based cohorts as described in section III.A.4. of this final rule. Finally, we proposed to change the potential score range for the TNC Mobility and TNC Self-Care measures from 0 to 15 points for achievement and 0 to 13.5 points for improvement as under the original Model, to 0 to 10 points for achievement and 0 to 9 points for improvement in the expanded Model. We stated that this change simplifies and aligns the calculation of the composite measure scores. The proposed weighting in the expanded Model, which follows the original Model, accounts for the intended increase in relative contribution from these composite measures to the TPS.

(2) Calculation of the Benchmark and Achievement Threshold

For scoring HHAs' performance on measures in the claims-based, OASIS-based, and the HHCAHPS survey-based categories, we proposed similar elements of the scoring methodology as set forth in the original Model (as described in §484.320), including allocating points based on achievement or improvement and calculating those points based on benchmarks and thresholds. As finalized in section III.A.5.b.1. of this final rule, with the exception of new HHAs, the

baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2023 performance year/CY 2025 payment year and subsequent years. All benchmarks and achievement thresholds would be set based on HHA performance in the designated baseline year.

We proposed that to determine achievement points for each measure, HHAs would receive points along an achievement range, which is a scale between the achievement threshold and a benchmark. We proposed to define the “achievement threshold” as the median (50th percentile) of all HHAs’ performance scores on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts. We proposed to calculate the benchmark as the mean of the top decile of all HHAs’ performance scores on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts. Unlike the original Model, for the expanded HHVBP Model, we proposed to use a national sample separated into larger-volume and smaller-volume HHA cohorts to calculate both the achievement threshold and the benchmark, rather than calculating individual values for each selected State as in the original Model, as described in section III.A.4.b. of this final rule. We also proposed that to determine improvement points for each measure, HHAs would receive points along an improvement range, which is a scale between an HHA’s performance during the baseline year and the benchmark. The HHA’s baseline year score is termed the “improvement threshold.” The benchmark is the same benchmark used in the achievement calculation. The achievement threshold and benchmarks for each cohort, and the improvement threshold for each HHA, calculated using baseline year performance scores, would be provided to the HHAs as soon as feasible. In addition, benchmarks, achievement thresholds, and improvement thresholds for each measure would be restated on each HHA’s interim performance report (IPR). We also proposed to codify the proposed definitions of achievement threshold, benchmark, and improvement threshold at §484.345. We sought public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing these proposals as proposed, including the proposed definitions of achievement threshold, benchmark, and improvement threshold at §484.345.

(i) Calculation of Achievement Score

In the original Model, we calculated the achievement score by dividing the difference between the HHA's performance score and the achievement threshold by the difference between the benchmark and the achievement threshold, multiplying the quotient by 9, and then taking the product and adding 0.5 (80 FR 68681).

Under the expanded HHVBP Model, we proposed a similar approach, but with minor modifications intended to improve and simplify the calculation and the interpretation of the achievement score. Under the expanded Model, as under the original Model, we proposed that an HHA could earn between 0 to 10 achievement points for each applicable measure based on its performance during the performance year relative to other HHAs in its cohort in the baseline years, quantified by the achievement threshold and the benchmark, as proposed in section III.A.7.b.2. of this final rule. We proposed to calculate the achievement score using the following formula:

$$\text{Achievement Score} = 10 \times \left(\frac{\text{HHA Performance Score} - \text{Achievement Threshold}}{\text{Benchmark} - \text{Achievement Threshold}} \right)$$

Relative to the original Model, this proposed equation is simplified, for ease of calculation and interpretation, by multiplying it by 10, as opposed to 9, and by no longer adding 0.5. The performance rankings would not be materially affected by this change. Should the calculated achievement points exceed 10 in the equation, we proposed that the maximum achievement points would be capped at 10 achievement points. As under the original Model, we proposed to round each measure's achievement points up or down to the third decimal point under the expanded HHVBP Model. For example, an achievement score of 4.5555 would be rounded to 4.556. This ensures precision in scoring and ranking HHAs within each cohort. In determining an achievement score based on the HHA's raw quality measure score, we proposed to apply the

following rules to the achievement score calculation to ensure the achievement score falls within the range of 0 to 10 points to align with the simplified equation:

- An HHA with a raw quality measure score greater than or equal to the benchmark receives the maximum of 10 points for achievement.
- An HHA with a raw quality measure score greater than the achievement threshold (but below the benchmark) receives greater than 0 but less than 10 points for achievement (prior to rounding), by applying the achievement score formula.
- An HHA with a raw quality measure score that is less than or equal to the achievement threshold receives 0 points for achievement.

We proposed to no longer calculate the achievement scoring for the TNC Self-Care and TNC Mobility measures out of 15 possible points, as under the original Model, and to instead simplify and align the calculation with other measures by calculating achievement scoring for the composite measures out of 10 possible points. The proposed weighting, consistent with the original Model, would already assign a larger contribution from these composite measures to the overall OASIS category score, as described in section III.A.7.e.(2).(iii). of this final rule. We also proposed to codify these proposals at §484.360. We sought public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals as proposed, including our proposed regulation text at §484.360.

(ii) Calculation of the Improvement Score

In the original Model, beginning with performance year 4, we calculated improvement scores by dividing the difference between the HHA's performance year score and the HHA's baseline year score by the difference between the benchmark and the HHA's baseline year score, multiplying the quotient by 9, and then taking the product and subtracting 0.5 to calculate the improvement score (83 FR 56543).

Similarly, under the expanded HHVBP Model, we proposed to allocate 0 to 9

improvement points to an HHA for each applicable measure based upon how much an HHA's performance score in the performance year improved relative to its performance score during the baseline year. We stated in the proposed rule that the expanded HHVBP Model aims to ensure that all HHAs provide high quality care and awarding more points for achievement than for improvement supports this goal. This continues to also align with the HVBP Program, where hospitals can earn a maximum of 9 improvement points if their measure score falls between the improvement threshold and the benchmark (76 FR 26515).

We proposed to establish a unique improvement range for each measure and for each HHA that defines the difference between the HHA's baseline year score (referred to as the "improvement threshold") and the benchmark for the applicable measure, calculated for the applicable volume-based HHA cohort, which is the same benchmark used in the achievement scoring calculation. The following proposed improvement score formula quantifies the HHA's performance on each applicable measure in the performance year relative to its own performance in the baseline year by calculating the improvement score:

$$\text{Improvement Score} = 9 \times \left(\frac{\text{HHA Performance Score} - \text{HHA Improvement Threshold}}{\text{Benchmark} - \text{HHA Improvement Threshold}} \right)$$

Relative to the original Model, this proposed equation is simplified, for ease of calculation and interpretation, by no longer subtracting 0.5. Should the calculated points exceed 9, we proposed that the maximum improvement points would be capped at 9 improvement points. Like the achievement points, we proposed to round each measure's improvement points up or down to the third decimal point under the expanded HHVBP Model.

In calculating the improvement score based on the HHA's raw quality measure score, we proposed to apply the following rules to the improvement score calculation to ensure the improvement score falls within the range of 0 to 9 points to align with the simplified equation:

- If the HHA's raw quality measure score is greater than or equal to the benchmark, the HHA would receive an improvement score of 9 points—an HHA with a raw quality measure score greater than or equal to the benchmark could still receive the maximum of 10 points for

achievement.

- If the HHA's raw quality measure score is greater than its improvement threshold but below the benchmark (within the improvement range), the HHA would receive an improvement score that is greater than 0 and less than 9 (before rounding) based on the improvement score formula and as illustrated in the examples in the next section.

- If the HHA's raw quality measure score is less than or equal to or its improvement threshold for the measure, the HHA would receive 0 points for improvement.

We proposed to no longer calculate the improvement scoring for the TNC Self-Care and TNC Mobility measures out of 13.5 possible points, as under the original Model, and to instead simplify and align the calculation with other measures by calculating improvement scoring for the composite measures out of 9 possible points, as previously stated. (We note that the discussion in the proposed rule referred to 10 rather than 9 possible points in error.) The proposed weighting, consistent with the original Model, would already assign a larger contribution from these composite measures to the overall OASIS category, as described in section III.A.7.e.(2).(iii). of this final rule. We also proposed to codify these proposals at §484.360. We sought public comment on these proposals. We summarize in this section of this rule comments received and provide our responses.

Comment: A commenter requested that we no longer score improvement in quality measures relative to the baseline and only use the achievement score for calculating the TPS. The commenter stated that having one continuous performance scale results in every HHA having an incentive to improve, leaving no need for an improvement score, in addition to creating uniform beneficiary expectations.

Response: We thank the commenter for their feedback on the proposed improvement score. While we agree with the commenter that the achievement score maintains the incentive to improve in the long-term, we believe that continuing to include the improvement score methodology is important in the initial years of the expanded model. This will allow HHAs with

lower measure performance historically to be rewarded for improving upon those scores, even if the improvement does not move them into the highest performing tier of HHAs. By setting the highest possible improvement score out of 9 points, compared to the achievement score out of 10 points, we place a stronger emphasis on achievement relative to improvement. Furthermore, we note that this would be consistent with existing value-based purchasing programs.

Comment: Several commenters expressed concern with using the improvement score methodology to assess HHAs on each of the quality measures, asserting that it may lead HHAs to exclude beneficiaries who are unlikely to improve.

Response: We believe that these comments may be in reference to certain quality measures, rather than the improvement score methodology, and refer readers to our earlier responses regarding why we do not believe the measure set would disincentivize HHAs from serving beneficiaries who are less likely to improve. The improvement score methodology assesses improvement of HHAs across each of the applicable measures and does not measure improvement of beneficiaries over time.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals as proposed, including our proposed regulation text at §484.360.

(iii) Examples of Calculating Achievement and Improvement Scores

For illustrative purposes, the following examples demonstrate how the performance scoring methodology would be applied in the context of the measures in the claims-based, OASIS-based, and the HHCAHPS survey-based categories. As previously discussed, we are finalizing CY 2023 as the first performance year and have updated the following examples from the proposed rule to reflect CY 2023 as the performance year. Other than the updating the hypothetical performance year from CY 2022 to CY 2023, all other detail in the following examples from the proposed rule remain the same. These HHA examples are based on illustrative data from CY 2019 (for the baseline year) and hypothetical data for CY 2023 (for the performance year). The benchmark calculated for the Dyspnea measure is 97.676 for HHA A

(calculated as the mean of the top decile of HHA performance from the CY 2019 baseline year for the volume-based cohort). The achievement threshold is 75.358 (calculated as the median or the 50th percentile of HHA performance from the CY 2019 baseline year for the same volume-based cohort).

Figure 4 shows the scoring for HHA ‘A’ as an example. HHA A’s CY 2023 performance year score for the Dyspnea measure was 98.348, exceeding both the CY 2019 achievement threshold and benchmark, which means that HHA A earned the maximum 10 points based on its achievement score. Its improvement score is irrelevant in the calculation because the HHA’s performance score for this measure exceeded the benchmark, and the maximum number of improvement points possible is 9.

Figure 4 also shows the scoring for HHA ‘B.’ HHA B’s performance on the Dyspnea measure was 52.168 for the CY 2019 baseline year (HHA B’s improvement threshold) and increased to 76.765 (which is above the achievement threshold of 75.358) for the CY 2023 performance year. To calculate the achievement score, HHA B would earn 0.630 achievement points, calculated as follows: $10 * (76.765 - 75.358) / (97.676 - 75.358) = 0.630$.³² Calculating HHA B’s improvement score yields the following result: based on HHA B’s period-to-period improvement, from 52.168 in the baseline year to 76.765 in the performance year, HHA B would earn 4.864 improvement points, calculated as follows: $9 * (76.765 - 52.168) / (97.676 - 52.168) = 4.864$.³³ Because the higher of the achievement and improvement scores is used, HHA B would receive 4.864 improvement points for this measure.

In Figure 5, HHA ‘C’ yielded a decline in performance on the TNC Self-Care measure, falling from 70.266 to 58.487. HHA C’s performance during the performance year was lower than the achievement threshold of 75.358 and, as a result, HHA C would receive zero points

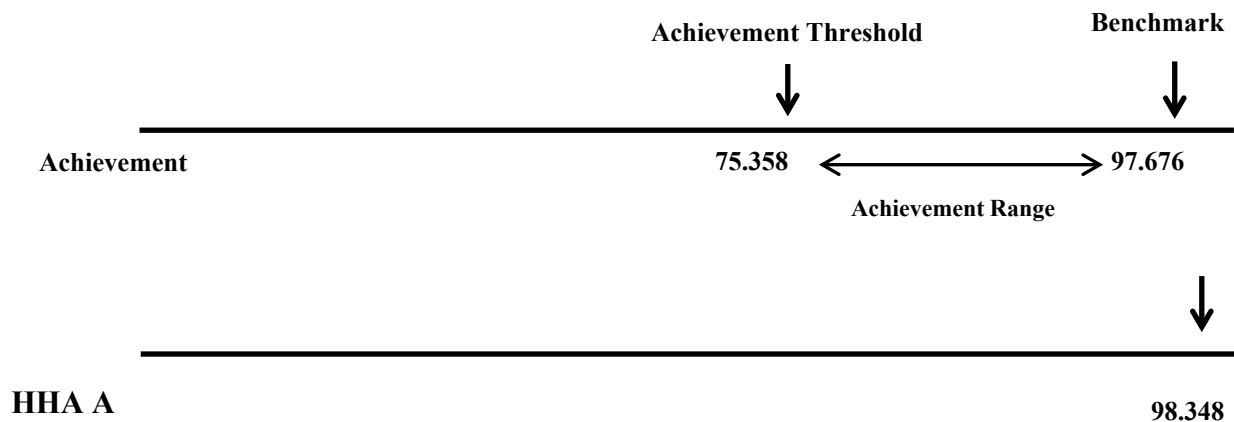
³² The finalized formula for calculating achievement points is $10 * (\text{HHA Performance Year Score} - \text{Achievement Threshold}) / (\text{Benchmark} - \text{Achievement Threshold})$.

³³ The finalized formula for calculating improvement points is $9 * (\text{HHA Performance Year Score} - \text{HHA Improvement Threshold}) / (\text{HHA Benchmark} - \text{HHA Improvement Threshold})$.

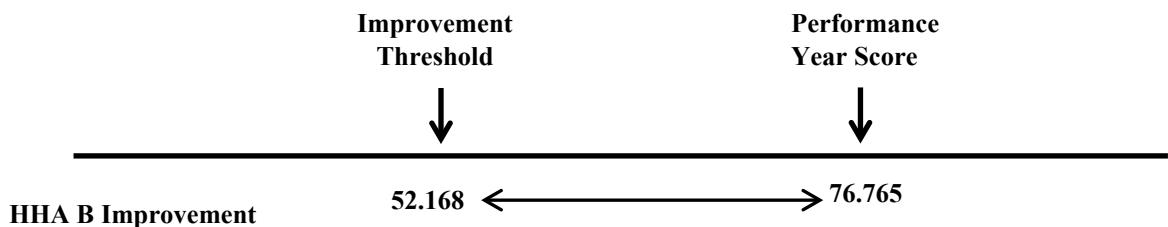
based on achievement. It would also receive zero points for improvement because its performance during the performance year was lower than its improvement threshold.

FIGURE 4: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

Measure: Dyspnea



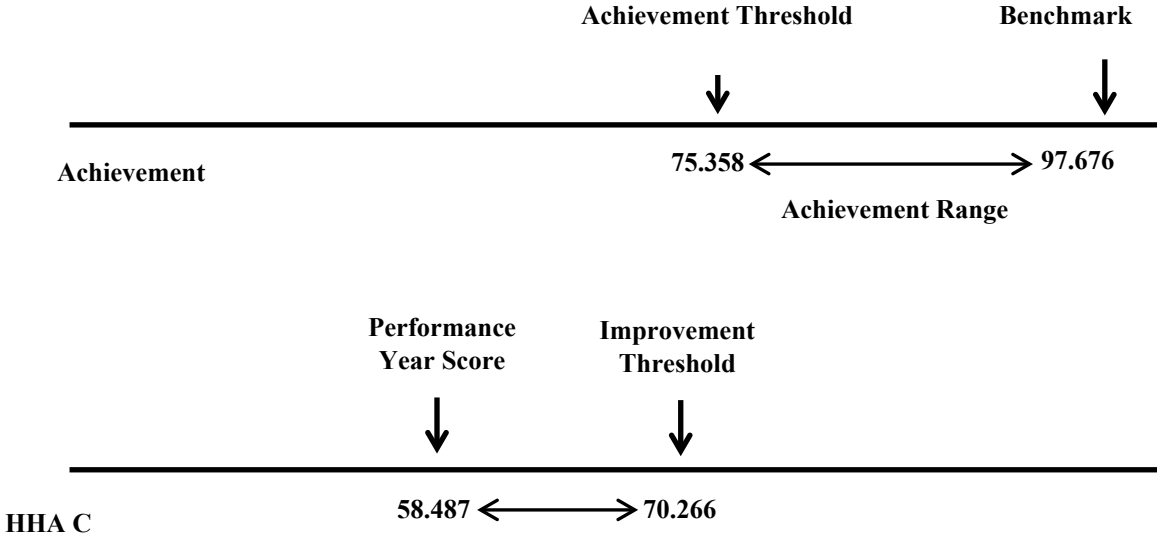
HHA A Score: 10 maximum points for achievement



HHA B Score: The greater of 0.630 points for achievement and 4.864 points for improvement.

FIGURE 5: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

Measure: TNC Self-Care Measure



HHA C Score: 0 points for improvement and 0 points for achievement

c. Minimum Threshold Number of Cases for Claims-based, OASIS-based, and HHCAHPS Survey-based Measures to Receive a Measure Score

For the expanded Model, we proposed to apply the same policies around minimum case counts for each measure as implemented under the original Model, as described in proposed §484.345. We proposed to continue to award an HHA the higher-of achievement or improvement points, as discussed previously, for “applicable measures” only. Under this proposal, for the measures included in the claims-based and OASIS-based measure categories, an “applicable measure” is one for which the HHA has provided a minimum of 20 home health episodes of care per year and, therefore, has at least 20 cases in the denominator. We proposed this minimum to align with the original HHVBP Model and the measure specifications used for the Patient Quality of Care Star Ratings.³⁴ For the individual components that compose the HHCAHPS survey measure, we proposed that an “applicable measure” means a component for which a competing HHA has submitted a minimum of 40 completed HHCAHPS surveys. We stated that a minimum of 40 completed HHCAHPS surveys for each applicable measure for the expanded Model represents a balance between providing meaningful data for payment adjustments and having more HHAs with sufficient numbers of measures with performance scores. Moreover, using a minimum of 40 completed HHCAHPS surveys for each applicable measure would align with the Patient Survey Star Ratings on Home Health Compare.³⁵

We also proposed to codify this proposed definition of an “applicable measure” at §484.345. We solicited public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals as proposed, including the proposed definition of an “applicable measure” at §484.345.

³⁴ Centers for Medicare & Medicaid Services. (2020, April). Quality of Patient Care Star Ratings Methodology. Home Health Quality of Patient Care Star Ratings. <https://www.cms.gov/files/document/quality-patient-care-star-ratings-methodologyapril-2020.pdf>.

³⁵ Centers for Medicare & Medicaid Services. (2016, March). Technical Notes for HHCAHPS Star Ratings. Home Health HHCAHPS Star Ratings. https://homehealthcahps.org/Portals/0/HHCAHPS_Stars_Tech_Notes.pdf.

d. Minimum Number of Applicable Measures for an HHA to Receive a Total Performance Score

For the expanded Model, we proposed to apply the same policies around the minimum number of applicable measures to receive a TPS, as implemented under the original Model. We proposed that, beginning with the CY 2022 performance year, which we are delaying until CY 2023 as the first performance year as described in section III.A.3 of this final rule, and for subsequent years, an HHA that does not meet the minimum threshold of cases or completed HHCAHPS surveys, as applicable, on five or more measures under the expanded Model would not receive a TPS or a payment adjustment based on that performance year. Under the expanded Model, this means 5 of the 12 possible applicable measures in the measure set, which includes two claims-based measures, 5 OASIS-based measures, and the 5 components from the HHCAHPS survey measure. HHAs without five applicable measures for a performance year would be paid for HHA services in an amount equivalent to the amount that would have been paid under section 1895 of the Act. We stated that we believe that a minimum of five applicable measures allows for a robust basis on which to adjust payment while also maximizing the number of HHAs eligible for the payment adjustment.

Although those HHAs that do not meet this minimum would not be subject to payment adjustments under the expanded Model, we proposed that other applicable policies under the expanded HHVBP Model would still apply. We proposed that these HHAs would receive IPRs for any measures that meet the definition of applicable measure, and they would continue to have future opportunities to compete for payment adjustments. Based on the most recent data available at the time of the development of the proposed rule, the vast majority of HHAs are reporting on at least five applicable measures. In 2019, those with less than five applicable measures account for less than 2.4 percent of the claims made (and 2.0 percent of claims payments made) across the 9,526 HHAs delivering care nationwide.

We also proposed to codify this proposal at §484.360(c). We sought public comment on

this proposal.

Final Decision: We did not receive comments on this proposal and are finalizing our proposal as proposed, including our proposed regulation text at §484.360(c). As previously discussed, we are finalizing CY 2023 as the first performance year and CY 2025 as the first payment year under the expanded Model. We reiterate that HHAs will not be assessed on their performance on the quality measures during the CY 2022 pre-implementation year. As noted later in this rule, we will continue to collect and evaluate data under the expanded HHVBP Model during CY 2022 and anticipate providing sample reports to HHAs, where administratively feasible and based on available data, for learning purposes only. The sample report would include the same information as an Interim Performance Report (IPR), and would be based on the same scoring methodologies and other policies as finalized in this rule for a performance year. We also anticipate providing learning support to all HHAs during CY 2022 including, for example, scenario-based performance reports and related learning events on the content of the reports and how they can be used to supplement an HHA's quality improvement efforts.

e. Weights for the Claims-based, OASIS-based, and HHCAHPS Survey Measures

Except for removing the New Measures category, for the expanded HHVBP Model, we generally proposed the same policies regarding the weighting of measures and the redistribution of weights when measures or measure categories are missing as under the original Model (83 FR 56536).

(1) Weighting and Re-distribution of Weights between the Measure Categories

In the proposed rule, we proposed to group the expanded Model proposed measures into measure categories based on their data source as indicated in Table 27: claims-based, OASIS-based, and the HHCAHPS survey-based. We proposed that claims-based, OASIS-based, and the HHCAHPS survey-based categories would be weighted 35 percent, 35 percent, and 30 percent, respectively, when the HHA has applicable measures in all three categories and

otherwise meets the minimum threshold to receive a TPS. Together, all three categories would account for 100 percent of the TPS. The measure weights reflect prioritization of the two claims-based measures because they may have a greater impact on reducing Medicare expenditures. In addition, we also place slightly more weight on the OASIS-based measures since they represent a larger variety of measures covering a range of quality topics as compared to the HHCAHPS survey measure.

We also proposed that where an HHA is missing all measures from a single measure category, the weights for the remaining two measure categories would be redistributed such that the proportional contribution remains consistent with the original weights. For instance, some smaller-volume HHAs may be missing the HHCAHPS survey measure, which would require redistributing weights to the claims-based (otherwise weighted 35 percent) and OASIS-based (otherwise weighted 35 percent) measure categories, such that the claims-based and OASIS-based measure categories would each be weighted at 50 percent of the total TPS. Where an HHA is missing the claims-based category, the OASIS-based (otherwise weighted 35 percent) and the HHCAHPS survey (otherwise weighted 30 percent) measure categories would be reweighted to 53.85 percent for the OASIS-based measures and 46.15 percent for the HHCAHPS survey measure.^{36,37} Finally, we proposed that if two measure categories are missing, the remaining category would be weighted 100 percent. We refer readers to Table 28 for the distribution of measure category weights under various scenarios.

(2) Quality Measure Weights within Measure Categories

Within the measure categories, we proposed to weight certain individual measures differently than other measures in the same category.

³⁶ OASIS-based measures reweighting = $35\% \text{ original OASIS weight} / (35\% \text{ original OASIS weight} + 30\% \text{ original HHCAHPS weight}) = 53.85\% \text{ revised OASIS weight}$

³⁷ HHCAHPS reweighting = $30\% \text{ original HHCAHPS weight} / (35\% \text{ original OASIS weight} + 30\% \text{ original HHCAHPS weight}) = 46.15\% \text{ revised HHCAHPS weight}$

(i) HHCAHPS Survey Measure Category

For the HHCAHPS survey measure category, we proposed that all 5 components are weighted equally to determine the overall HHCAHPS survey measure percentage, which would contribute 30 percent to the overall TPS. This measure category would not require re-distribution of weights for the individual components because HHAs either meet the minimum requirement for number of completed surveys for all HHCAHPS survey measure components or they do not meet the minimum requirements.

(ii) Claims-based Measure Category

For the claims-based measure category, we proposed to weight the ACH measure at 75 percent, and the ED Use measure at 25 percent of the total measure weight for this measure category. We proposed to place a higher weight on the ACH measure because it reflects a more severe health event and because inpatient hospitalizations generally result in more Medicare spending than the average emergency department visit that does not lead to an acute hospital admission. Like the HHCAHPS survey measure components, an HHA would either have sufficient volume for both claims-based measures to be applicable measures or it would have data for neither measure since both measures require the same minimum of 20 episodes per performance year. Consequently, re-distributing weights for either measure within the claims-based measure category should not be necessary.

(iii) OASIS-based Measure Category

For the OASIS-based measure category, we proposed to weight both the TNC Self Care and TNC Mobility measures at 25 percent each; and the Dyspnea, Discharged to Community, and Oral Medications measures at 16.67 percent each of the total measure weight for this measure category. Both the TNC Self-Care and TNC Mobility measures are composed of several measures that are consolidated into two composite measures; because of this, we proposed to weight them slightly more than the other 3 measures, which are not composite measures, as under the original Model. Under this proposal, should any measures in the category be missing,

we proposed to re-distribute weights across the measures such that the original proportions are maintained. For instance, should an HHA be missing both the TNC Self-Care and Dyspnea measures, the remaining measures would be weighted as 42.85 percent for the TNC Mobility measure, 28.57 percent for the Discharged to Community measure, and 28.57 percent for the Oral Medications measure, which reflects the relative ratios of 25 percent to 16.67 percent to 16.67 percent, respectively.^{38,39,40}

See Table 27 for a comprehensive list of the proposed within-category measure weights.

TABLE 27: PROPOSED WITHIN-CATEGORY MEASURE WEIGHTS

Measure Category	Quality Measures	Within-category Weight (percentage)
OASIS	TNC Self-Care	25.00
	TNC Mobility	25.00
	Dyspnea	16.67
	Discharged to Community	16.67
	Oral Medications	16.67
Claims	ACH	75.00
	ED Use	25.00
HHCAHPS Survey	HHCAHPS Professional Care	20.00
	HHCAHPS Communication	20.00
	HHCAHPS Team Discussion	20.00
	HHCAHPS Overall Rating	20.00
	HHCAHPS Willingness to Recommend	20.00

Table 28 presents the proposed weights for the proposed measures and measure categories under various reporting scenarios.

³⁸ TNC Mobility reweighting = 25% original TNC Mobility weight / (25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 42.85% revised TNC Mobility weight.

³⁹ Discharged to Community reweighting = 16.67% original Discharged to Community weight / (25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 28.57% revised Discharged to Community weight.

⁴⁰ Oral Medications reweighting = 16.67% original Oral Medications weight / (25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 28.57% revised Oral Medications weight.

TABLE 28: PROPOSED QUALITY MEASURE WEIGHTING AND RE-WEIGHTING SCHEDULE

Measure	Measure Reporting Scenarios			
	All Measures	No HHC AHPS	No Claims	No Claims or HHC AHPS
OASIS				
TNC Self-Care	8.75%	12.50%	13.46%	25.00%
TNC Mobility	8.75%	12.50%	13.46%	25.00%
Oral Medications	5.83%	8.33%	8.98%	16.67%
Dyspnea	5.83%	8.33%	8.98%	16.67%
Discharged to Community	5.83%	8.33%	8.98%	16.67%
<i>Total for OASIS-based measures</i>	<i>35.00%</i>	<i>50.00%</i>	<i>53.85%</i>	<i>100.00%</i>
Claims				
ACH	26.25%	37.50%	0.00%	0.00%
ED Use	8.75%	12.50%	0.00%	0.00%
<i>Total for claims-based measures</i>	<i>35.00%</i>	<i>50.00%</i>	<i>0.00%</i>	<i>0.00%</i>
HHC AHPS Survey Measure Components				
HHC AHPS Professional Care	6.00%	0.00%	9.23%	0.00%
HHC AHPS Communication	6.00%	0.00%	9.23%	0.00%
HHC AHPS Team Discussion	6.00%	0.00%	9.23%	0.00%
HHC AHPS Overall Rating	6.00%	0.00%	9.23%	0.00%
HHC AHPS Willingness to Recommend	6.00%	0.00%	9.23%	0.00%
<i>Total for the HHC AHPS Survey-based measure</i>	<i>30.00%</i>	<i>0.00%</i>	<i>46.15%</i>	<i>0.00%</i>

We also proposed to codify these proposals at §484.360. We solicited public comment on these proposals.

Final Decision: We did not receive comments on these proposals and are finalizing our proposals as proposed, including our proposed regulation text at §484.360.

f. Examples of the Total Performance Score Calculation

The following are two examples of the finalized performance score calculation, beginning with the assigned achievement vs. improvement points. The following describes the TPS calculations for HHA “D” and HHA “E.”

In this first example, out of a possible 12 applicable measures, which includes two claims-based measures, five OASIS assessment-based measures, and five components that make up the HHC AHPS survey measure, HHA “D” has at least 20 episodes of care and received at least 40 completed HHC AHPS surveys in the 12-month performance year, which means the HHA received scores on all 12 quality measures. Under the finalized scoring methodology outlined previously, for HHA D, the measure category weights would be as follows: 35 percent

for the claims-based measures, 35 percent for the OASIS assessment-based measures, and 30 percent for the HHCAHPS Survey-based measures. See Table 29 for a detailed calculation of the TPS. For each measure in column ①, HHA D receives the highest of its achievement or improvement score, which is listed in column ②. Each applicable measure’s weight is listed in column ③. To determine the weighted points in column ④, multiply the measure score in column ② by the measure’s weight in column ③ and then by 10. The total performance score is the sum of all the weighted points listed in column ④. In the case of HHA D, the TPS is 46.021.

TABLE 29: HHA D TOTAL PERFORMANCE SCORE EXAMPLE

① Quality Measure	② Points for Applicable Measures	③ Weight (percentage)	④ Weighted Points
OASIS			
TNC Self-care	7.661	8.75	6.703
TNC Mobility	5.299	8.75	4.637
Oral Medications	3.302	5.83	1.925
Dyspnea	4.633	5.83	2.701
Discharged to Community	0.618	5.83	0.360
Claims			
ACH	1.180	26.25	3.098
ED Use	0.000	8.75	0.000
HHCAHPS Survey Components			
HHCAHPS Professional Care	10.000	6.00	6.000
HHCAHPS Communication	10.000	6.00	6.000
HHCAHPS Team Discussion	10.000	6.00	6.000
HHCAHPS Overall Rating	5.921	6.00	3.553
HHCAHPS Willingness to Recommend	8.406	6.00	5.044
Total Performance Score		100.00	46.021

In the second example, HHA “E” has only seven applicable measures. Because it did not receive the minimum count of HHCAHPS surveys for all components, HHA E did not receive any scores on the HHCAHPS Survey components. Where an HHA is missing the HHCAHPS Survey components, the HHA’s HHCAHPS Survey measure category is re-weighted at 0 percent and the remaining two measure categories are re-weighted such that their proportional

contribution remains consistent with the original weights and the total of the weights sums to 100 percent. Based on the ratio of the original weights for the claims-based (35 percent) and the OASIS-based (35 percent) measure categories, each category contributes 50 percent to the TPS. See Table 30 for the detailed calculation of the TPS. For each applicable measure in column ①, HHA E received the highest of its achievement or improvement score, which is listed in column ②. Column ② lists N/A for each of the HHCAHPS Survey measure components since this HHA had fewer than 40 HHCAHPS surveys in the performance year. Each applicable measure's weight is listed in column ③. To determine the weighted points in column ④, multiply the measure score in column ② by the applicable measure's weight in column ③ and then by 10. The total performance score is the sum of all the weighted points listed in column ④. In the case of HHA E, the TPS is 27.750.

TABLE 30: HHA E TOTAL PERFORMANCE SCORE EXAMPLE

① Quality Measures	② Points for Applicable Measures	③ Re-Weighting (percentage)	④ Re-Weighted Points
OASIS			
TNC Self-care	7.661	12.5	9.576
TNC Mobility	5.299	12.5	6.624
Oral Medications	3.302	8.33	2.751
Dyspnea	4.633	8.33	3.859
Discharged to Community	0.618	8.33	0.515
Claims			
ACH	1.180	37.50	4.425
ED Use	0.000	12.50	0.000
HHCAHPS Survey Components			
HHCAHPS Professional Care	N/A	0.00	N/A
HHCAHPS Communication	N/A	0.00	N/A
HHCAHPS Team Discussion	N/A	0.00	N/A
HHCAHPS Overall Rating	N/A	0.00	N/A
HHCAHPS Willingness to Recommend	N/A	0.00	N/A
Total Performance Score		100.00	27.750

8. Payment Adjustment Methodology

We finalized the use of the Linear Exchange Function (LEF) for the original Model (80 FR 68686) because it was the simplest and most straightforward option to provide the same

marginal incentives to all HHAs, and we stated in the proposed rule that we believe the same to be true for the HHVBP Model expansion. The LEF is used to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. Performance measurement is based on a linear exchange function which only includes competing-HHAs.

Under the expanded HHVBP Model, we proposed to codify at §484.370 a methodology for applying value-based payment adjustments to home health services. We proposed that payment adjustments would be made to the HH PPS final claim payment amount as calculated in accordance with HH PPS regulations at §484.205 using a LEF, similar to the methodology utilized by the HVBP Program (76 FR 26533). We proposed the function's intercept at zero percent, meaning those HHAs that have a TPS that is average in relationship to other HHAs in their cohort would not receive any payment adjustment. Under this proposal, payment adjustments for each HHA with a score above zero percent would be determined by the slope of the LEF. We proposed to set the slope of the LEF for the given performance year so that the estimated aggregate value-based payment adjustments for that performance year are equal to 5 percent (the proposed maximum payment adjustment for CY 2024; as previously discussed, we are finalizing CY 2025 as the first payment year of the expanded Model) of the estimated aggregate base operating payment amount for the corresponding payment year, calculated separately for the larger and smaller volume cohorts nationwide. The estimated aggregate base operating payment amount is the total amount of payments made to all the HHAs by Medicare nationwide in each of the larger- and smaller-volume cohorts.

We proposed that the LEF would be calculated using the following steps, after calculating and ranking the Total Performance Score (TPS) (the range of the TPS is 0-100) for each HHA in the cohort:

- Step 1, Determine the 'Prior Year Aggregate HHA Payment Amount' that each HHA was paid in the prior year.
- Step 2, Determine the 'X-percent (the applicable payment year payment adjustment

percent) Payment Reduction Amount' by multiplying the Prior Year Aggregate HHA Payment Amount per HHA by the 'X-percent Reduction Rate'; the sum of these amounts is the numerator of the LEF.

- Step 3, Determine the 'TPS Adjusted Reduction Amount' by multiplying the 'X-percent Payment Reduction Amount' by the TPS/100 . The sum of these amounts is the denominator of the LEF.

- Step 4, Calculate the LEF by dividing the sum of all HHAs' 'X-percent Payment Reduction Amount' by the sum of the 'TPS Adjusted Reduction Amount'.

- Step 5, Determine the 'Final TPS Adjusted Payment Amount' by multiplying the LEF by the 'TPS Adjusted Reduction Amount' for each HHA.

- Step 6, Determine the 'Quality Adjusted Payment Rate' by dividing the 'Final TPS Adjusted Payment Amount' by the 'Prior Year Aggregate HHA Payment Amount'.

- Step 7, Determine the 'Final Percent Payment Adjustment' that will be applied to the HHA payments by subtracting the 'X-percent Reduction Rate' from the 'Quality Adjusted Payment Rate'.

Table 31 provides an example of how the LEF would be calculated and how it would be applied to calculate the percentage payment adjustment to an HHA's TPS. For this example, we applied the maximum 5-percent payment adjustment proposed for the expanded HHVBP Model for the proposed CY 2024 payment year.

Step #1 involves the calculation of the 'Prior Year Aggregate HHA Payment Amount' (C2 in Table 31) that each HHA was paid from claims data under the HH PPS in the year prior to the performance year. For the proposed CY 2024 payment year, from claims data, all payments are summed together for each HHA for CY 2021, the year prior to the proposed performance year.

Step #2 involves the calculation of the '5-percent Payment Reduction Amount' (C3 of Table 31 for each HHA, which is calculated by multiplying the 'Prior Year Aggregate HHA

Payment Amount', from Step #1 by the '5-percent Payment Reduction Rate'. The aggregate of the '5-percent Payment Reduction Amount' is the numerator of the LEF.

Step #3 involves the calculation of the 'TPS Adjusted Reduction Amount' (C4 of Table 31) by multiplying the '5-percent Payment Reduction Amount' from Step #2 by the TPS (C1) divided by 100. The aggregate of the 'TPS Adjusted Reduction Amount' is the denominator of the LEF.

Step #4 involves calculating the LEF (C5 of Table 31) by dividing the sum of '5- percent Payment Reduction Amount' calculated in Step #2 by the sum of 'TPS Adjusted Reduction Amount' calculated in Step #3.

Step #5 involves the calculation of the 'Final TPS Adjusted Payment Amount' (C6 of Table 31) by multiplying the 'TPS Adjusted Reduction Amount' from Step #3 (C4) by the LEF from Step #4 (C5). The 'Final TPS Adjusted Payment Amount' is an intermediary value used to calculate 'Quality Adjusted Payment Rate'.

Step #6 involves the calculation of the 'Quality Adjusted Payment Rate' (C7 of Table 31) by dividing the 'Final TPS Adjusted Payment Amount' from Step #5 by the 'Prior Year Aggregate HHA Payment Amount' from Step #1. This is an intermediary step to determining the payment adjustment rate.

Step #7 involves the calculation of the 'Final Percent Payment Adjustment' (C8 of Table 31) by subtracting 5 percent from 'Quality Adjusted Payment Rate'. The 'Final Percent Payment Adjustment' would be applied to the HHA payments for the payment adjustment year. We proposed that the payment adjustment percentage would be capped at no more than plus or minus 5 percent for the applicable performance year and the payment adjustment would occur on the final claim payment amount for the applicable payment year.

We also proposed to codify this payment methodology policy at §484.370. We invited comments on this proposal. We summarize in this section of this rule comments received and provide our responses.

TABLE 31: 5-PERCENT REDUCTION SAMPLE

		Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
HHA	TPS	Prior Year Aggregate HHA Payment Amount*	5-Percent Payment Reduction Amount (C2*5 percent)	TPS Adjusted Reduction Amount (C1/100)*C3	Linear Exchange Function (LEF) (Sum of C3/ Sum of C4)	Final TPS Adjusted Payment Amount (C4*C5)	Quality Adjusted Payment Rate (C6/C2)	Final Percent Payment Adjustment +/- (C7-5%)
	(C1)	(C2)	(C3)	(C4)	(C5)	(C6)	(C7)	(C8)
HHA1	38	\$100,000	\$5,000	\$1,900	1.931	\$3,669	3.669%	-1.331%
HHA2	55	\$145,000	\$7,250	\$3,988	1.931	\$7,701	5.311%	0.311%
HHA3	22	\$800,000	\$40,000	\$8,800	1.931	\$16,995	2.124%	-2.876%
HHA4	85	\$653,222	\$32,661	\$27,762	1.931	\$53,614	8.208%	3.208%
HHA5	50	\$190,000	\$9,500	\$4,750	1.931	\$9,173	4.828%	-0.172%
HHA6	63	\$340,000	\$17,000	\$10,710	1.931	\$20,683	6.083%	1.083%
HHA7	74	\$660,000	\$33,000	\$24,420	1.931	\$47,160	7.146%	2.146%
HHA8	25	\$564,000	\$28,200	\$7,050	1.931	\$13,615	2.414%	-2.586%
Sum			\$172,611	\$89,379		\$172,611		

*Example cases.

Comment: A commenter asked about the "X-percent Adjustment Percentage" and how would an HHA know this value.

Response: We believe the commenter is inquiring about the "X-percent Payment Reduction Amount." The "X-percent Payment Reduction Amount" is the maximum payment adjustment possible for an HHA under the HHVBP expanded model for the payment year. As discussed in section III.A.5.a of this final rule, we are finalizing that the maximum payment adjustment under the expanded Model would be 5 percent for CY 2025, the first payment year under the expanded Model, and subsequent years.

Comment: A few commenters stated that there is likely no significant difference between an HHA in 45th percentile and 55th percentile, but the HHA in the 45th percentile will receive a payment reduction and the HHA in the 55th percentile will receive a payment increase. A commenter asked CMS to make it more realistic to achieve the maximum bonus or penalty. Another commenter asked CMS to re-evaluate the current payment adjustment structure because it is difficult to score within the top or bottom decile. The commenter stated that most HHAs fall

in the middle of the curve and relatively neutral payment impact does not incentivize them to make significant changes. Conversely, a commenter recommended that we reward positive performance and not apply a negative adjustment to low performing HHAs.

Response: Under the original HHVBP Model, we used the LEF to translate an HHA's TPS into a percentage of the value -based payment adjustment earned by each HHA. The LEF is similar to the methodology utilized by the HVBP program. The LEF was identified by the HVBP Program as the simplest and most straightforward option to provide the same marginal incentives to all hospitals, and we found the same to be true for HHAs under the original HHVBP Model. It is true that an HHA in the 45th percentile and an HHA in the 55th percentile could have a similar TPS and one could have a small positive payment adjustment and one could have a small negative payment adjustment. The possibility of either a negative or a positive payment adjustment incentivizes HHAs to improve quality. While we agree that a majority of the HHAs fall into the middle of the pack and most do not receive the maximum positive or negative payment adjustment, we disagree that HHAs are not incentivized to make significant changes unless it is easier to receive the maximum positive or negative payment adjustment. During the original HHVBP Model, we noted improvements in quality, as noted by a decrease in unplanned hospitalizations, emergency department visits leading to inpatient admission and skilled nursing facility use, and a \$604.8 million (1.3 percent) reduction of Medicare spending as noted in the HHVBP Fourth Annual Evaluation Report.⁴¹

Comment: A commenter expressed concern about an endless loop of rewarding the top half of HHAs and penalizing the lower half of HHAs.

Response: We appreciate the concern of the commenter, but based on our examination of the data from the original HHVBP Model, we found that many HHAs moved between negative and positive payment adjustments. Of the HHAs that received a payment adjustment under the original Model in both CY 2019 and CY 2020, 15.4 percent moved from a negative adjustment

⁴¹ <https://innovation.cms.gov/data-and-reports/2021/hhvbp-fourthann-rpt>.

to a positive adjustment, 15.5 percent moved from a positive adjustment to a negative adjustment, 33.6 percent had a negative adjustment in both years, and 35.5 percent had a positive adjustment in both years. Accordingly, because many HHAs moved from negative adjustments to positive adjustments and vice versa under the original Model, we disagree that there would be an endless loop of rewarding the top half and penalizing the lower half of HHAs.

Final Decision: After consideration of the public comments we received, we are finalizing the payment adjustment methodology as proposed, including our proposed regulation text at §484.370.

9. Performance Feedback Reports

We proposed to use two types of reports that would provide information on performance and payment adjustments under the expanded HHVBP Model. These reports would mirror those we have distributed to HHAs under the original Model.

a. Interim Performance Report

The first report is the Interim Performance Report (IPR) that would be distributed to HHAs quarterly. The IPR would contain information on the interim quality measure performance based on the 12 most recent months of data available. The IPR would provide feedback to HHAs regarding performance relative to quality measure achievement thresholds and benchmarks and would provide competing HHAs the opportunity to assess and track their performance relative to their peers and their own past performance. HHAs would receive both a preliminary and final version of the IPR each quarter. We proposed that the Final IPR would become available, as soon as administratively feasible, after the preliminary IPR is distributed and after recalculation requests are processed, in accordance with the process discussed in section III.A.10. of this final rule (Appeal Processes).

In the proposed rule, beginning with the data collected during the first quarter of CY 2022 (that is, data for the period January 1, 2022 to March 31, 2022), and for every quarter of the expanded HHVBP Model thereafter, we proposed to provide each HHA with an IPR that

contains information on its performance during the 12 most recent months of data available. We proposed to provide the 12 most recent months of data because the OASIS and claims data are available with different lag times and measures are reported in 12-month intervals on Care Compare. By using 12 months of data, we are able to remove seasonality issues and help to ensure a sufficient number of cases to provide meaningful information to HHAs. By providing HHAs with the most recent 12 months of data, the IPRs provide as close to real-time performance information as possible. We stated in the proposed rule that we expect to make the first IPR available in July 2022 and make IPRs for subsequent quarters available in October, January, and April. We stated that the July 2022 IPR would be the first IPR issued that includes CY 2022 performance year data for the first quarter quality measure performance scores on the proposed OASIS-based measures and baseline data for the HHCAHPS survey and claims-based measures. We proposed that the IPRs would include a competing HHA's expanded HHVBP Model-specific performance results with a comparison to other competing HHAs within its applicable nationwide cohort (larger- or smaller-volume). We proposed that the IPRs would be made available to each HHA through a CMS data platform, such as the Internet Quality Improvement and Evaluation System (iQIES), and would include each HHA's relative estimated ranking amongst its cohort along with measurement points and total performance score based on the 12 most recent months of data available. We noted that the IPRs would likely differ from the final data used to assess performance during a given performance year because the time periods used to develop the IPR data (the 12 most recent months) would differ from the actual performance years under the expanded Model (for example, as proposed, CY 2022 data used to determine CY 2024 payment adjustments).

These performance results would complement quality data sources provided through the iQIES and other quality tracking systems possibly being employed by HHAs to help drive quality improvement. The iQIES –generated reports would provide quality data earlier than the expanded HHVBP Model-specific performance reports (that is, IPR or Annual) because

iQIES-generated reports are not limited by a quarterly run-out of data and a calculation of competing peer-rankings. The primary difference between iQIES-generated reports and expanded HHVBP Model-specific performance reports is that the Model-specific performance report we proposed would consolidate the applicable performance measures used in the expanded HHVBP Model, provide a peer-ranking to other competing HHAs within the same volume-based cohort, and provide the TPS based on the interim data. In addition, Model-specific performance reports would provide the competing HHAs with a Scorecard and TNC Change Reference. The TNC Change Reference data would help HHAs gauge their performance on the individual OASIS items included in the two composite measures. It would also tell HHAs the percentage of episodes in which there was no change, positive change, or negative change for each OASIS item. The Scorecard would help HHAs better understand how each individual measure contributes to the TPS. For more information on the accessibility and functionality of the iQIES, please reference the iQIES manuals.⁴² We noted that all quality measures, except for the TNC Mobility and TNC Self-Care measures and the HHCAHPS survey measure, in the proposed measure set for the proposed CY 2022 performance year of the expanded HHVBP Model are already made available in the iQIES. For the HHCAHPS survey measure, HHAs can access their Data Submission Reports on <https://homehealthcahps.org> under the “For HHAs” tab. We also suggest HHAs contact their survey vendor regarding data on the HHCAHPS survey measure.

We invited public comment on our proposals. We summarize and respond to comments on both the proposed IPRs and the proposed Annual Reports and present our final policies in the next section.

b. Annual TPS and Payment Adjustment Report

We proposed that the second report, the Annual TPS and Payment Adjustment Report (Annual Report), would be made available to each of the competing HHAs in approximately

⁴² iQIES manuals are available at <https://qtso.cms.gov/software/iqies/reference-manuals>.

August of each year preceding the proposed payment adjustment year, expected beginning in August 2023. We proposed to make the report available via a CMS data platform, such as the iQIES. The Annual Report would focus primarily on the HHA's payment adjustment percentage for the upcoming CY and include an explanation of when the adjustment would be applied and how this adjustment was determined relative to the HHA's performance scores. Each competing HHA would receive its own confidential Annual Report viewable only to that HHA. We proposed that the Annual Report would have three versions: a Preview Annual Report, a Preliminary Annual Report (if applicable), and a Final Annual Report. We would make available to each competing HHA the Preview Annual Report in approximately August of each year preceding the calendar year for which the payment adjustment would be applied. We proposed that HHAs would have 15 days to review and request recalculations in accordance with the proposed process discussed in section III.A.10. of this final rule (Appeal Processes). For HHAs that request a recalculation, we would make available a Preliminary Annual Report as soon as administratively feasible after the recalculation request is processed. If we do not receive a recalculation request as a result of the Preview Annual Report, a Preliminary Annual Report would not be issued. We proposed that HHAs that receive a Preliminary Annual Report would have 15 days to review and submit a reconsideration request in accordance with the proposed process discussed in section III.A.10. of this final rule (Appeal Processes). As under the original Model, we proposed to make available the Final Annual Report after all reconsideration requests are processed and no later than 30 calendar days before the payment adjustment takes effect annually, both for those HHAs that requested a reconsideration and all other competing HHAs.

We stated that under this proposed approach, HHAs would be notified in advance of the first annual total performance score and payment adjustment being finalized for CY 2024. We proposed that the total performance score and payment adjustment would be based on the CY 2022 performance year (January 1, 2022 to December 31, 2022), with the first payment adjustment to be applied to each HH PPS final claim payment amount as calculated in

accordance with HH PPS policies as codified at §484.205 for HHA services furnished January 1, 2024 through December 31, 2024.

Subsequent payment adjustments would be calculated based on the applicable full calendar year of performance data from the final IPRs, with competing HHAs notified and payments adjusted, respectively, every year thereafter. We stated that as a sequential example, the second payment adjustment would apply for services furnished January 1, 2025 through December 31, 2025, based on a full 12 months of the CY 2023 performance year. We stated that notification of the second pending payment adjustment would occur in approximately August 2024 when the Preview Annual Report is issued, followed by the Preliminary (if applicable) and Final Annual Reports, as described previously.

We stated that data related to performance on quality measures would continue to be provided for the baseline year and all performance years of the expanded Model via a CMS data platform, such as the iQIES (this platform would present and might archive the previously described IPR and Annual Reports). We presented a sample timeline in Table 33 of the proposed rule showing the availability of each expanded HHVBP Model-specific performance report and the data included for the proposed CY 2022 performance year and CY 2024 payment year.

We sought public comment on our proposals related to the Interim Performance and Annual Reports. We summarize in this section of this rule comments received and provide our responses.

Comment: A commenter requested that CMS continue to provide quarterly reports to HHAs.

Response: We are committed to providing the quarterly IPRs to HHAs in the expanded HHVBP Model, just as we did in the original HHVBP Model.

Comment: A few commenters requested that performance feedback reports be completed in a timely manner. Another commenter requested that performance feedback reports be

provided earlier so HHAs have the opportunity to adjust operations as early as possible. Another commenter requested that performance feedback reports be provided no later than January 2022.

Response: We are committed to providing performance feedback reports, both the quarterly IPRs and Annual Reports, as soon as administratively feasible. We understand that both the IPRs and Annual reports are important tools that HHAs use to help adjust operations to improve quality. Due to the lag time between data submission and data processing of claims, HHCAHPS, and OASIS data, CMS is unable to provide the first IPR that includes CY 2023 performance year data for the first quarter quality measure performance scores any earlier than July 2023, as detailed in Table 32. As described in section III.A.3 of this rule, We have finalized the payment adjustments for the expanded HHVBP model to start in CY 2025 instead of CY 2024. We will provide sample reports as soon as administratively feasible and learning support during CY 2022 on the content of the IPRs and Annual Reports to allow HHAs to learn how the HHVBP quarterly reports can support their quality improvement efforts and potentially make adjustments to their operations as they see fit.

Comment: A commenter requested that CMS provide the baseline report as soon as possible, another commenter suggested CMS provide the baseline report before the performance year starts and another commenter suggested publishing the baseline report with this final rule.

Response: We understand that HHAs want to have time to examine their baseline data as soon as possible and anticipate making available baseline reports using the CY 2019 baseline year data in advance of the first performance year under the expanded Model (CY 2023). As noted, we will also make available during the CY 2022 pre-implementation year sample reports to individual HHAs via iQIES as soon as administratively feasible. The sample reports will provide, based on the data available, achievement threshold, benchmark, improvement threshold, and quality performance data.

Comment: A commenter requested that CMS thoroughly test the iQIES system to ensure that it is capable and prepared to provide the IPRs and Annual Reports to HHAs.

Response: We note that the iQIES already provides similar functionality in providing reports to HHAs for other purposes, and we have tested iQIES for acceptance of the file format to be used for the HHVBP model-reports and the test was successful.

Final Decision: After consideration of the public comments we received, we are finalizing our proposals for the proposed IPRs and Annual TPS and Payment Adjustment Reports, with modification, to reflect that CY 2023 will be the first performance year and CY 2025 the first payment year under the expanded Model, with CY 2022 as a pre-implementation year. We will continue to collect and evaluate data under the expanded HHVBP Model during CY 2022 and anticipate providing sample reports to HHAs, where administratively feasible and based on available data, for learning purposes only. The sample report would include the same information as an IPR, and would be based on the same scoring methodologies and other policies as finalized in this rule for a performance year. We also anticipate providing learning support to all HHAs during CY 2022 including, for example, scenario-based performance reports and related learning events on the content of the reports and how they can be used to supplement an HHA's quality improvement efforts.

As noted, CY 2023 will be the first performance year and CY 2025 will be the first payment year under the expanded Model. We expect to make the first IPR available in July 2023 and make IPRs for subsequent quarters available in October, January, and April. The July 2023 IPR would be the first IPR issued that includes CY 2023 performance year data for the first quarter quality measure performance scores on the OASIS-based measures and baseline data for the HHCAHPS survey and claims-based measures. HHAs will be notified in advance of the first annual total performance score and payment adjustment being finalized for CY 2025. The total performance score and payment adjustment will be based on the CY 2023 performance year (January 1, 2023 to December 31, 2023), with the first payment adjustment to be applied to each HH PPS final claim payment amount as calculated in accordance with HH PPS policies as codified at §484.205 for HHA services furnished January 1, 2025 through December 31, 2025.

Subsequent payment adjustments will be calculated based on the applicable full calendar year of performance data from the final IPRs, with competing HHAs notified and payments adjusted, respectively, every year thereafter. As a sequential example, the second payment adjustment would apply for services furnished January 1, 2026 through December 31, 2026, based on a full 12 months of the CY 2024 performance year. Notification of the second pending payment adjustment would occur in approximately August 2025 when the Preview Annual Report is issued, followed by the Preliminary (if applicable) and Final Annual Reports, as described previously.

We present in Table 32 a sample timeline showing the availability of each expanded HHVBP Model-specific performance report and the data included for the CY 2023 performance year and CY 2025 payment year.

TABLE 32: TIMELINE FOR CY 2023 PERFORMANCE YEAR AND CY 2025 PAYMENT YEAR BY REPORT TYPE AND DATA TYPE

Report Type (Approximate Date Issued)	OASIS-Based Measures	Claims-Based and HHC AHPS-Based Measures
July 2023 IPR (July 2023)	12 months ending 3/31/2023	Baseline data only
October 2023 IPR (Oct 2023)	12 months ending 6/30/2023	12 months ending 3/31/2023
January 2024 IPR (Jan 2024)	12 months ending 9/30/2023	12 months ending 6/30/2023
April 2024 IPR (April 2024)	12 months ending 12/31/2023	12 months ending 9/30/2023
July 2024 IPR (July 2024)	12 months ending 3/31/2024	12 months ending 12/31/2023
Annual TPS and Payment Adjustment Report (Aug 2024)*	12 months ending 12/31/2023	12 months ending 12/31/2023

*The Annual Report made available to HHAs in approximately August 2024 is the Preview Annual Report. The Final Annual Report is issued after the recalculation and reconsideration request periods and no later than 30 days prior to the calendar year which the payment adjustment will take effect.

10. Appeals Processes

As codified at §484.335, the appeals process under the original HHVBP Model allows HHAs to submit recalculation requests for the IPRs and Annual TPS and Payment Adjustment Report. Under this process, an HHA may also make a reconsideration request if it disagrees with the results of a recalculation request for the Annual TPS and Payment Adjustment Report. We

refer the reader to the CY 2017 HH PPS final rule for further discussion of the appeals process under the original HHVBP Model (81 FR 76747 through 76750).

Under the expanded Model, we proposed to use the same appeals process as the original Model. We proposed that competing HHAs be provided the opportunity to appeal certain information provided in the IPRs and the Annual Report, as discussed in more detail in the following sections.

a. Recalculation Request Process

Under the expanded HHVBP Model, we proposed that HHAs be provided two separate opportunities to review scoring information and request recalculations.

HHAs would have the opportunity to request a recalculation if a discrepancy is identified due to a CMS error in calculations after review of their: (1) Preliminary IPRs following each quarterly posting; or (2) Preview Annual Report. Specifically, we proposed that an HHA would have 15 calendar days from the date either the Preliminary IPR or the Preview Annual Report is provided to request a recalculation of measure scores if it believes there is evidence of a discrepancy in the calculation of the measure. We proposed that we would adjust the score if it is determined that the discrepancy in the calculated measure scores was the result of our failure to follow measurement calculation protocols. An HHA would also have the opportunity to request recalculation if it wishes to dispute the application of the formula to calculate the payment adjustment percentage.

Under this proposal, for both the Preliminary IPRs and the Preview Annual Report, competing HHAs would only be permitted to request scoring recalculations or, for the Preview Annual Report, to dispute the application of the formula used to calculate the payment adjustment percentage, and must include a specific basis for the requested recalculation. Any changes to underlying measure data cannot be made. We would not provide HHAs with the underlying source data utilized to generate performance measure scores.

We proposed that HHAs that choose to request a recalculation would submit

recalculation requests for both quarterly Preliminary IPRs and for the Preview Annual Reports via instructions provided on a CMS webpage. We proposed that the request form would be entered by the primary point of contact, a person who has authority to sign on behalf of the HHA.

We proposed that recalculation requests (quarterly Preliminary IPR or Preview Annual Report recalculations) must contain all of the following information:

- The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).
- The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.
- Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, e-mail address, telephone number, and mailing address (must include physical address, not just a post office box).
- A copy of any supporting documentation the HHA wishes to submit in electronic form via the Model-specific webpage.

Following receipt of a recalculation request, we proposed that CMS or its agent would--

- Provide an e-mail acknowledgement, using the contact information provided in the recalculation request, to the HHA contact notifying the HHA that the request has been received;
- Review the request to determine validity, and determine whether the requested recalculation results in a score change altering performance measure scores or the HHA's TPS;
- If the recalculation request results in a performance measure score change, conduct a review of data and if an error is found, recalculate the TPS using the corrected performance data; and
- Provide a formal response to the HHA contact, using the contact information provided in the recalculation request, notifying the HHA of the outcome of the review and recalculation process. The Final IPR and Preliminary Annual Report would reflect any changes noted from

recalculation process. As under the original Model, we stated that we anticipate providing this response as soon as administratively feasible following the submission of the request.

We also proposed to codify the recalculation process at §484.375(a). We invited comment on our proposals.

Comment: A commenter requested that CMS consider 30 calendar days for HHAs to review and request recalculations.

Response: While we appreciate that HHAs may want additional time to review the IPRs and Annual Reports, we believe that this proposed timeframe for submission of reconsideration requests is needed to allow for two levels of appeal prior to the payment adjustments being applied. The original HHVBP model used the same appeal process, including the 15 calendar day period for HHAs to submit recalculation requests, to allow for recalculations of the IPRs to be completed prior to the posting of the Annual Report in August and to allow both levels of appeals to be completed prior to the generation and submission of the final data files in advance of the applicable payment year. We proposed this same timeframe for submission of recalculation requests under the expanded Model in order to complete the entire appeals process for all HHAs timely, both the recalculations and reconsideration requests, and allow the Medicare Administrative Contractors (MACs) time to update each HHA's payment adjustment before the payment adjustment year. As discussed in the proposed rule, the recalculation process allows HHAs to request scoring recalculations or address discrepancies in the payment adjustment calculation, but changes cannot be made to the underlying data. We therefore believe that 15 calendar days is a sufficient amount of time to determine whether a recalculation is needed, collect supporting data, and submit a recalculation request following the posting of the Preliminary IPRs and Preview Annual Reports.

Final Decision: After consideration of the public comments we received, we are finalizing the proposed reconsideration process. We are also finalizing our proposed regulation text at §484.375(a).

b. Reconsideration Process

Under the expanded Model, we proposed that if we determine that the original calculation was correct and deny the recalculation request for the scores presented in the Preview Annual Report, or if the HHA otherwise disagrees with the results of a CMS recalculation as reflected in the Preliminary Annual Report, the HHA may submit a reconsideration request for the Preliminary Annual Report. We proposed that an HHA may request reconsideration of the outcome of a recalculation request for its Preliminary Annual Report only. We stated that we believe that the ability to review the IPRs and submit recalculation requests on a quarterly basis provides competing HHAs with a mechanism to address potential errors in advance of receiving their Preview Annual Report. Therefore, we stated that we expect that in many cases, the reconsideration request process proposed would result in a mechanical review of the application of the formulas for the TPS and the LEF, which could result in the determination that a formula was not accurately applied.

Under this proposal, the reconsideration request and supporting documentation would be required to be submitted via instructions provided on the CMS webpage within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation request for the Preview Annual Report. This proposed timeframe would allow a decision on the reconsideration to be made prior to the generation of the final data files containing the payment adjustment percentage for each HHA and the submission of those data files to the Medicare Administrative Contractors (MACs) to update their provider files with the payment adjustment percentage. We stated that we believe that this would allow for finalization of the annual performance scores, TPS, and annual payment adjustment percentages in advance of the application of the payment adjustments for the applicable performance year. Reconsiderations would be conducted by a CMS designated official who was not involved with the original recalculation request.

We proposed that the final TPS and payment adjustment percentage be provided to competing HHAs in a Final Annual Report no later than 30 calendar days in advance of the

payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual Reports are posted and the appeals process is completed.

We proposed to codify the reconsideration process at § 484.375(b).

We solicited comments on these proposals. We did not receive any comments on the proposed reconsideration process.

Final Decision: We are finalizing the reconsideration process as proposed. We are also finalizing our proposed regulation text at § 484.375(b).

11. Public Reporting Under the Expanded HHVBP Model

a. Background

Consistent with our discussions on public reporting under the original Model in prior rulemaking, in the CY 2020 HH PPS final rule (84 FR 60552), we finalized a policy to publicly report on the CMS Website the following two points of data from the final CY 2020 Annual Report for each participating HHA in the original Model that qualified for a payment adjustment for CY 2020: (1) the HHA's TPS from performance year 5; and (2) the HHA's corresponding performance year 5 TPS Percentile Ranking. We stated that these data would be reported for each such competing HHA by agency name, city, State, and by the agency's CCN (84 FR 60552 through 60553). We refer readers to section III.B.3. of this final rule, where we discuss our proposal to modify our public reporting policy for the original Model, given our proposal as discussed in section III.B.2. of this final rule to not use CY 2020 data to make payment adjustments for CY 2022.

Publicly reporting performance data under the expanded Model would enhance the current home health public reporting processes, as it would better inform beneficiaries when choosing an HHA, while also incentivizing HHAs to improve performance. It would also be consistent with our practice of publicly reporting performance data under other value-based initiatives such as the SNF VBP and HVBP Programs (42 CFR 413.338) (42 CFR 412.163). CMS publicly reports both facility-specific SNF VBP Program performance information (such as

achievement scores, improvement scores, rankings, and incentive payment multipliers), as well as aggregate-level program performance information on the CMS website (42 CFR 413.338). Similarly, for the HVBP Program, CMS publicly reports quality measures, baseline and performance years used, domain scores, total performance scores, and aggregate payment adjustment amounts on the CMS website (42 CFR 412.163).

Publicly reporting performance data for the expanded HHVBP Model would also be consistent with other agency efforts to ensure transparency and publicly report performance data. For example, the HH QRP requires HHAs to submit data in accordance with 42 CFR 484.245(b)(1). Furthermore, section 1895(b)(3)(B)(v)(III) of the Act requires, in part, that the Secretary establish procedures for making certain HH QRP data available to the public. HHAs have been required to collect OASIS data since 1999 and to report HHCAHPS data since 2012 (64 FR 3764 and 76 FR 68577). These data are available to providers, consumers, beneficiaries, and other stakeholders on the *Care Compare* website.

b. Public Reporting for the Expanded Model

We stated in the proposed rule that we believe that publicly reporting performance data under the expanded HHVBP Model would be an important way of incentivizing HHAs to improve quality performance under the Model. Therefore, we proposed to publicly report performance data for the expanded HHVBP Model beginning with the proposed CY 2022 performance year/CY 2024 payment adjustment and for subsequent years. For all years of the expanded HHVBP Model, we proposed to publicly report the following information:

- Applicable measure benchmarks and achievement thresholds for each small- and large-volume cohort.
- For each HHA that qualified for a payment adjustment based on the data for the applicable performance year--
- Applicable measure results and improvement thresholds;
- The HHA's Total Performance Score (TPS);

- The HHA's TPS Percentile Ranking; and
- The HHA's payment adjustment for a given year.

We proposed to report these data by State, CCN, and agency name through a CMS website. We noted that quality measure results for many of the measures proposed to be included in the expanded HHVBP Model are already currently reported on *Care Compare*; however, we proposed to also separately publicly report applicable measure results for such measures in the expanded HHVBP Model, because the public reporting periods for the Model would differ from those used for the HH QRP public reporting on *Care Compare*. We stated that we believe this would be clear and transparent for the public. In addition, to the extent that any new measures or measures that are otherwise not included in the HH QRP and are thus not already reported on *Care Compare* are included in the expanded HHVBP Model in the future, we proposed to publicly report those measure results as well.

We stated that we would also provide definitions for the TPS and the TPS Percentile Ranking methodology, as well as descriptions of the scoring and payment adjustment methodology, on the CMS website to ensure the public understands the relevance of these data points and how they were calculated. We note that this information would include a broader range of data elements than we previously finalized to publicly report for the original HHVBP Model. We proposed a broader range of data elements for the expanded HHVBP Model for several reasons. First, this publicly reported information would align more closely with the SNF VBP and HVBP Programs, both of which publicly report a broad range of information, including measure results and payment adjustment percentages. Second, we note that measure results for those quality measures included in the HH QRP are already publicly reported on the *Care Compare* website. We stated that we believe that publicly reporting the corresponding benchmarks for all expanded Model measures (including those aligned with the HH QRP as well as measures that may not be aligned), by cohort, and other quality performance information for the expanded HHVBP Model would further promote transparency and incentivize quality

improvements under the expanded Model.

We stated in the proposed rule that we anticipate this information would be made available to the public on a CMS website on or after December 1, 2023, the date by which we stated we would intend to complete the proposed CY 2022 Annual Report appeals process and issuance of the Final Annual Report to each competing HHA. For each year thereafter, we stated that we anticipate following the same approximate timeline for publicly reporting the payment adjustment for the upcoming calendar year, as well as the related performance data as previously described.

As the expanded Model's performance data would be supplemental to the Home Health Quality of Patient Care and Patient Survey Star Ratings, and does not form a part of these or other star ratings, we intend to also include a reference to the Home Health Star Ratings available on the CMS website.

We also proposed to codify these proposals at §484.355(c).

We sought public comment on these proposals.

Comment: A commenter expressed concern that publicly reported measure scores may be misinterpreted since non-identical results could be generated between the HHVBP and HH QRP measure sets on Care Compare due to different baseline periods and scoring methodologies. Another commenter had a similar concern related to inconsistencies between the TPS and the star rating system. Both commenters recommended CMS take extra effort in the presentation of the results in order to assist beneficiaries in understanding why the results may not be identical.

Response: As noted in the proposed rule, we will provide definitions for the TPS and the TPS Percentile Ranking methodology on the CMS website to assist in interpretation of these results. As the commenter notes, the TPS and the star rating system may have non-identical results; however, we believe this increases the information available to the beneficiary and their family, and allows for greater transparency. In consideration of the public comments we

received, we are considering additional methods to clarify this publicly reported data to assist in accurate public interpretation and understanding of the data results.

Final Decision: After consideration of comments received, we are finalizing our proposal with modification. As previously described in this final rule, payment adjustments under the expanded HHVBP model will start in calendar year 2025 instead of calendar year 2024. As such, public reporting of performance data for the expanded HHVBP Model will begin with the CY 2023 performance year/CY 2025 payment adjustment and for subsequent years. We anticipate this information would be made available to the public on a CMS website on or after December 1, 2024, the date by which we would intend to complete the CY 2023 Annual Report appeals process and issuance of the Final Annual Report to each competing HHA. For each year thereafter, we anticipate following the same approximate timeline for publicly reporting the payment adjustment for the upcoming calendar year, as well as the related performance data as previously described.

We are finalizing codification of this proposal at §484.355(c).

12. Extraordinary Circumstances Exception Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances outside of their control that impact their ability to operate in the ordinary course of business for short-term, or sometimes even extended periods. The United States is currently responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as COVID-19, which creates serious public health threats that have greatly impacted the U.S. health care system, presenting significant challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events may also occur in the future that have a disruptive impact. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other extreme and uncontrollable circumstances. Such events may strain health care resources, and CMS understands that HHAs may have limited

capacity to continue normal operations and fulfill expanded HHVBP Model participation requirements. In situations such as these, we believe CMS should make adjustments to the requirements of the expanded HHVBP Model to ensure the delivery of safe and efficient health care.

Therefore, generally, we proposed to adopt an extraordinary circumstances exception (ECE) policy for the expanded HHVBP Model that aligns, to the extent possible, with the existing HH QRP exceptions and extension requirements at 42 CFR 484.245(c). Section 484.245(c) permits HHAs to request and CMS to grant an exception or extension from the reporting requirements in the event of extraordinary circumstances beyond HHAs' control.

Specifically, we proposed that for the expanded HHVBP Model, CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. We proposed that CMS may grant an exception as follows:

- An HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception would be available on the CMS website ([cms.gov](https://www.cms.gov)).
- CMS may grant an exception to one or more HHAs that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.

We stated that we would strive to provide our formal response notifying the HHA of our decision within 90 days of receipt of the HHA's ECE request, however, the number of requests we receive and the complexity of the information provided would impact the actual timeframe to make ECE determinations. When an ECE for HHAs in the nation, region or locale is granted, CMS would communicate the decision through routine channels to HHAs and vendors,

including, but not limited to, the PAC QRP listserv, Open Door Forum MLN Connects, and notices on the CMS Home Health Quality Reporting Spotlight webpage. Specific instructions for requesting exceptions or extensions would be provided on the CMS website.

We also proposed to codify our ECE policy at § 484.355(d).

We solicited public comment on our proposals.

Final Decision: We did not receive comments on this proposal and are finalizing our proposals as proposed, including our proposed regulation text at § 484.355(d).

B. Provisions under the Home Health Value-Based Purchasing (HHVBP) Original Model

1. Background

We stated in the proposed rule that the last year of data collection for the original Model ended on December 31, 2020 and the last payment adjustment year of the original Model would end on December 31, 2022. Payment adjustments are based on each HHA's TPS in a given performance year, which is comprised of performance on: (1) a set of measures already reported via the Outcome and Assessment Information Set (OASIS),⁴³ completed Home Health Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys, and select claims data elements; and (2) three New Measures for which points are achieved for reporting data. Payment adjustments for a given year are based on the TPS calculated for performance two years' prior. We stated that under current policy for the original Model, the CY 2022 payment adjustments would be based on CY 2020 (performance year 5) performance. The maximum payment adjustment for CY 2022 is upward or downward 8 percent.

In the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** (May 2020 COVID-19 IFC) (85 FR 27553 through 27554; 85 FR 70328 through 70330), in response to the COVID-19 PHE to assist HHAs while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff, we adopted a policy to align the original Model data submission requirements with any exceptions or extensions granted for purposes

⁴³ OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

of HH QRP during the COVID-19 PHE. We also established a policy for granting exceptions to the New Measures data reporting during the COVID-19 PHE, including the codification of these changes at § 484.315(b).

The original Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including HHCAHPS survey data. The other measures used in the original Model are calculated using OASIS data; claims-based data; and New Measure data. In response to the COVID-19 PHE, on March 27, 2020, CMS issued public guidance (<https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>) excepting HHAs from the requirement to report HH QRP data for Q4 2019 and Q1 – Q2 2020. Under our policy to align the original Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID-19 PHE, HHAs in the nine original Model States were not required to separately report measure data for these quarters for purposes of the original Model. Specific to the original Model, we granted an exception for reporting New Measures data for the April 2020 (data collection period October 1, 2019 – March 31, 2020) and July 2020 (data collection period April 1, 2020 – June 30, 2020) New Measure submission periods. We further noted that HHAs may optionally submit part or all of these data by the applicable submission deadlines.

We acknowledged that the exceptions to the HH QRP reporting requirements, as well as the modified submission deadlines for OASIS data and our exceptions for the New Measures reporting requirements, may impact the calculation of performance under the original Model for performance year 5 (CY 2020). We also noted that while we are able to extract the claims-based data from submitted Medicare FFS claims, we may need to assess the appropriateness of using the claims data submitted for the period of the COVID-19 PHE for purposes of performance calculations under the original Model. We further explained that we are evaluating possible changes to our payment methodologies for CY 2022 in light of this more limited data, such as

whether we would be able to calculate payment adjustments for participating HHAs for CY 2022, including those that continue to report data during CY 2020, if the overall data is not sufficient, as well as whether we may consider a different weighting methodology given that we may have sufficient data for some measures and not others. We stated that further, we are also evaluating possible changes to our public reporting of CY 2020 performance year data. We stated that we intend to address any such changes to our payment methodologies for CY 2022 or public reporting of data in future rulemaking.

2. CY 2022 Payment Adjustments

For the reasons discussed in this section, we proposed not to use the CY 2020 (performance year 5) data for purposes of payment adjustments under the HHVBP Model and to instead end the original Model early, with the CY 2021 payment year. Specifically, we proposed that we would not use the annual TPS calculated using the performance year 5 data to apply payment adjustments for CY 2022 and to instead end the original Model early, such that HHAs in the nine original Model States would not have their HH PPS claims payments adjusted by the current maximum payment adjustment factor of upward or downward 8 percent in CY 2022.

In light of the data reporting exceptions under the HHVBP Model for Q1 and Q2 2020 in response to the COVID-19 PHE, as discussed previously, we reviewed available quality data from Q1 and Q2 2020 as compared to Q1 and Q2 2019 for the nine original Model States to determine whether it may be appropriate to use data from the time period during which data reporting exceptions were in place (Q1 and Q2 2020). The comparison showed a decrease of 8.9 percent in OASIS assessments. We could not directly compare HHCAHPS results from Q1 and Q2 because our data are calculated on a 12-month rolling basis. However, we also examined claims data during this same time period to determine whether volume and utilization patterns changed and observed a 20.2 percent decrease in claims-based home health stays in Q1 and Q2 2020 as compared to Q1 and Q2 2019. The change in volume and utilization was observed across time (that is, the change was not limited to a certain point of time during the Q1 and Q2

2020 time period) and within and across States. We stated in the proposed rule that we believe these changes could be the result of the impacts of the COVID-19 PHE, including patients avoiding care or dying, reduced discharges to the home, and increased use of telehealth in lieu of in-person home health care. We also observed a 10.5 percent decrease in New Measures data submissions for Q1 and Q2 2020 as compared to Q1 and Q2 2019, consistent with what we would expect given the New Measures reporting exceptions we issued for this time period.

Based on the patterns we observed for the first two quarters of CY 2020, we stated in the proposed rule that we do not believe it would be appropriate to utilize data from that time period to calculate a TPS for CY 2020 that would be used to make payment adjustments in CY 2022. The changes in volume and utilization could skew performance assessments on quality measures for HHAs, such that the calculated TPS may not accurately reflect the quality of care provided by the HHAs. Additionally, we stated that we are concerned that because the COVID-19 PHE has not impacted all HHAs equally, implementing payment adjustments based on the impacted data for the period of the COVID-19 PHE could unfairly penalize certain HHAs.

We also considered whether to use only Q3 and Q4 CY 2020 quality measure data to calculate CY 2020 annual total performance scores for CY 2022 payment adjustments. However, we stated that we believe that using only two quarters of data may not be sufficiently representative of the care provided by the HHA during a given calendar year for purposes of calculating quality measure scores and determining payment adjustments under the Model, and could potentially disadvantage those HHAs in an area of a State more heavily affected by the pandemic in Q3 and Q4 of CY 2020. In addition, as HHAs in different States continued to be impacted by the COVID-19 PHE during the second half of CY 2020, we stated that we believe patterns of home health care may also have continued to be impacted during that timeframe, similar to the changes we observed for the Q1 and Q2 2020 time period. We stated that as more data become available from the latter half of CY 2020, we will continue to examine home health care patterns in the nine original Model States in order to determine whether the same patterns

we observed in the Q1 and Q2 2020 data persisted into the latter half of the year, and to assess whether it would be appropriate to utilize such data for CY 2022 payment adjustments.

Finally, we noted that several commenters on the exceptions policies that we adopted in the May 2020 COVID-19 IFC requested that we not use any performance data from CY 2020 and terminate or suspend the original Model early (85 FR 70328 through 70330).

Based on data available for this final rule, we note that, as found in Q1 and Q2 2020, OASIS assessments and claims-based home health stays decreased in Q3 and Q4 2020 as compared to Q3 and Q4 2019. We observed a 1.3 percent decrease in OASIS assessments and a 10.2 percent decrease in claims-based home health stays when comparing Q3 and Q4 2020 to Q3 and Q4 2019.

As stated in the proposed rule, after consideration of these issues, we proposed to not apply any payment adjustments for CY 2022 of the original HHVBP Model based on data reported in CY 2020 and to instead end the original Model early, with the CY 2021 payment adjustment year. We stated that we will continue to examine data for CY 2020 as it becomes available in order to determine whether it would be appropriate to utilize such data for CY 2022 payment adjustments, in accordance with current Model policies. Based on data available for this final rule, we observed that using two quarters of 2020 data (Q3 and Q4 2020) as compared to using four quarters of 2020 data (Q1 through Q4 2020), would result in two-thirds of episodes of care being eliminated. As previously noted, data submissions in Q3 and Q4 2020 also remained lower than Q3 and Q4 2019 submissions. We stated in the proposed rule that we will also continue to provide HHAs with the Interim Performance Reports with CY 2020 performance data and the Annual Report with the calculated TPS and payment adjustment amount based on the CY 2020 performance data, consistent with our current policies. We stated that if we finalize our proposal, as previously discussed, we would not use the TPS calculated using the performance year 5 data to apply payment adjustments for CY 2022.

We noted that if we finalize this proposal to end the original Model early, the evaluation

would include the period through CY 2019 (performance year 4) and CY 2021 (payment year 4). We stated that as we proposed to not use CY 2020 (performance year 5) data to calculate CY 2022 (payment year 5) payment adjustments, these years would not be evaluated. As we clarify in response to comments in this section, CMS does intend to include CY 2020 in its evaluation, during which the 6 percent payment adjustment is applied.

We stated that we believe that our proposed policy to not use CY 2020 performance year data to determine payment adjustments under the HHVBP Model would be consistent with how other quality reporting and VBP programs proposed to utilize data that has been significantly affected by circumstances caused by the COVID-19 PHE. In the FY 2022 Hospice proposed rule (86 FR 19755), we proposed to modify the HH QRP public display policy to display fewer quarters of data than what was previously finalized for certain HH QRP measures for the January 2022 through July 2024 refreshes (86 FR 19755 through 19764). For the January 2022 refresh, data for OASIS-based and certain claims-based measures would include Q3 2020 through Q1 2021 data. For HHCAHPS, data would cover the four quarters Q3 2020 through Q2 2021. We noted that Q1 2020 and Q2 2020 data would not be included in the proposed Care Compare refresh schedule for any measures. The SNF VBP program proposed in the FY 2022 SNF PPS proposed rule (86 FR 19954) to suppress the use of the SNF readmission measure (SNFRM) for scoring and payment adjustment purposes for the FY 2022 program year. The HVBP program proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25469 through 25496) to suppress the use of a number of measures for the FY 2022 or FY 2023 program years for purposes of scoring and payment adjustments, along with proposals to revise the baseline periods for certain measures due to the extraordinary circumstances exception we granted in response to the COVID-19 PHE.

We proposed to amend at §484.305 the definition of “applicable percent” by removing paragraph (5) of the definition ((5) For CY 2022, 8 percent) to reflect our proposal not to apply any payment adjustments for FY 2022 and to end the original Model early.

We invited public comment on our proposal. We summarize in this section of this rule comments received and provide our responses.

Comment: Several commenters opposed ending the model early and stated CMS should provide the 2022 incentive payments that would otherwise be made to HHAs in the nine states. Commenters opposed ending the model early stating that the final year should be evaluated. A commenter did not support ending the original model early, stating that if there is concern with impacts to the data due to the PHE, CMS should apply a risk adjuster to account for it.

Response: As previously described, based on our analyses of the CY 2020 data for this final rule, the volume and utilization patterns we observed in the Q1 and Q2 2020 data were also observed in the data for Q3 and Q4 2020, when compared to the same time period in CY 2019. Because the COVID-19 PHE did not impact all HHAs equally, we continue to believe that implementing payment adjustments based on the impacted data could unfairly penalize certain HHAs. While we also considered using only Q3 and Q4 CY 2020 quality measure data to calculate CY 2020 annual total performance scores for CY 2022 payment adjustments, we found that, when compared to using four quarters of CY 2020 data, 13 percent of HHAs would no longer have enough data at all to receive a TPS; only one state would have enough HHAs for a small cohort (compared to four states with full year data); 15 percent of HHAs would no longer have enough claims data to contribute to their TPS; and, 22 percent of HHAs would no longer have enough HHCAHPS data to contribute to their TPS. Based on our analyses, we continue to believe that using only two quarters of data is not sufficient representation of the care provided by the HHA in CY 2020 for purposes of calculating quality measure scores and determining payment adjustments under the Model, and would disadvantage HHAs in an area of a State more heavily affected by the pandemic in Q3 and Q4 of 2020. We also continue to believe that the changes in volume and utilization for CY 2020, which, as noted, were also observed in the Q3 and Q4 2020 data, could skew performance assessments on quality measures for HHAs such that the calculated TPSs may not accurately reflect the quality of care provided by HHAs.

In addition, not using the CY 2020 performance year data to determine payment adjustments under the HHVBP Model would be part of a larger set of policies we have adopted to deal with quality data we believe have been significantly affected by circumstances caused by the COVID-19 PHE. For example, in the FY 2022 Hospice final rule (86 FR 42590-42598), we addressed how HH QRP data affected by the PHE would be publicly displayed. We finalized a policy that will use three quarters rather than four quarters of data for the January 2022 refresh affecting OASIS-based measures. For certain claims-based measures, we will use three quarters rather than four quarters of data for refreshes between January 2022 and July 2024. Public reporting with refreshed data will begin in January 2022. For HHCAHPS, we finalized that data would cover the four quarters Q3 2020 through Q2 2021. We note that Q1 2020 and Q2 2020 data would not be included in the proposed Care Compare refresh schedule for any measures.

CMS finalized in the FY 2022 SNF PPS final rule (86 FR 19954) to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2022 SNF VBP Program Year because circumstances caused by the PHE for COVID-19 have significantly affected the measure and the ability to make fair, national comparisons of SNFs' performance scores. Under the special scoring policy CMS finalized for FY 2022, CMS will assign a performance score of zero to all participating SNFs, to mitigate the effect that PHE-impacted measure results would otherwise have on SNF performance scores and incentive payment multipliers. CMS also finalized that it would assign an identical incentive payment multiplier, resulting in no payment adjustments for SNFs in FY 2022. We would then apply the Low-Volume Adjustment policy as previously finalized in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we would assign that SNF a performance score resulting in a net neutral payment incentive multiplier. SNFs will not be ranked for the FY 2022 SNF VBP Program.

CMS finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45266 through 45277) that for FY 2022, it would suppress the use of measure data for a number of measures because circumstances caused by the COVID-19 PHE have affected those measures and the resulting quality scores significantly. Because calculating Total Performance Scores (TPSs) for hospitals based on the remaining measures would not result in a fair national comparison, CMS also finalized that it would not calculate a TPS for any hospital and would instead award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (2 percent).

With regard to the comment that CMS should apply a risk adjustor to account for the PHE, we note that we did not propose to modify the risk adjustment methodology for the quality measures in the original Model's measure set. Regarding the comment that the final year of the Model should be evaluated, we clarify that the Model will be evaluated through the full period of performance. CY 2020 will be evaluated as this year reflects the 6 percent payment adjustment applied, based on CY 2018 performance.

Final Decision: After consideration of public comments, we are finalizing our proposal not to apply any payment adjustments for CY 2022 and to end the original Model early as proposed. We are also finalizing to amend at §484.305 the definition of "applicable percent" by removing paragraph (5) of the definition ((5) For CY 2022, 8 percent) to reflect this final policy.

3. Public Reporting Under the Original Model

In the CY 2020 HHS PPS final rule (84 FR 60551 through 60553), we finalized a policy to publicly report on the CMS website the following two points of data from the final CY 2020 performance year 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 performance year 5; and (2) the HHA's corresponding performance year 5 TPS Percentile Ranking. We stated that 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 expected that these data would be made public

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

For the reasons discussed in section III.B.2. of this final rule, we proposed to not use CY 2020 data for CY 2022 payment adjustments under the HHVBP Model. Consistent with this proposal, we also proposed to modify our existing policy and not publicly report performance data for the HHAs included in the original Model. We stated that we do not believe that it would be appropriate to publicly report performance data for a time period for which HHAs would not be held financially accountable for quality, nor do we believe that reporting data for this time period would assist beneficiaries and other public stakeholders in making informed choices about HHA selection, as the patterns of care during CY 2020 may not be representative of performance under the original Model as a whole due to the COVID-19 PHE. However, as discussed in section III.A.11. of this final rule, we proposed to begin public reporting for the expanded HHVBP Model with the proposed CY 2022 performance year data, continuing for all performance years thereafter, and are finalizing to publicly report performance data under the expanded Model beginning with the CY 2023 performance year data, continuing for all performance years thereafter.

We proposed to amend §484.315 to reflect our proposal not to publicly report performance data from the CY 2020 performance year by removing paragraph (d). We solicited comments on this proposal.

Final Decision: We received no comments on this proposal and are finalizing as proposed, including our proposed amendment to §484.315.

IV. Home Health Quality Reporting Program (HH QRP) and Other Home Health Related Provisions

A. Vaccinations for Home Health Agency Health Care Personnel

Health Care Personnel (HCP) are at risk of carrying COVID-19 infection to patients, experiencing illness or death as a result of COVID-19 themselves, and transmitting it to their families, friends, and the general public. We believe home health agencies should educate and promote vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID-19. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care. Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel (<https://www.cdc.gov/flu/toolkit/long-term-care/why.htm>). Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients, Measure Application Committee Coordinating Committee Meeting Presentation (http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx). We believe HCP COVID-19 vaccination among Home Health staff could similarly increase uptake among that patient population.

B. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patients' access to their health information. To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) (<https://pacioproject.org/>) to facilitate collaboration with industry stakeholders to develop Fast Healthcare Interoperability Resources (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the minimum data set (MDS), inpatient rehabilitation facility

patient assessment instrument (IRF-PAI), long-term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources, including the Hospice Outcome and Patient Evaluation Assessment (HOPE) if implemented in the Hospice Quality Reporting Program through future rulemaking. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage PAC provider and health IT vendor participation as these efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes and Systematized Nomenclature of Medicine. The DEL furthers CMS' goal of data standardization and interoperability. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision-making. Standards in the Data Element Library (<https://del.cms.gov/DELWeb/pubHome>) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at <https://www.healthit.gov/isa>.

The 21st Century Cures Act (Cures Act) (Pub. L. 114-255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision⁴⁴ that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For

⁴⁴ ONC, *Draft 2 Trusted Exchange Framework and Common Agreement*, <https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf>.

more information on current developments related to TEFCA, we refer readers to <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement> and <https://rce.sequoiaproject.org/>.

The ONC final rule entitled “21st Century Cures Act: Interoperability, Information Blocking and the ONC Health IT Certification Program” (85 FR 25642) published May 1, 2020, (hereinafter “ONC Cures Act Final Rule”) implemented policies related to information blocking required under Section 4004 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the Secretary of HHS as a reasonable and necessary activity that does not constitute information blocking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.⁴⁵ For a healthcare provider (as defined in 45 CFR 171.102), the law specifies that the provider knows that the practice is unreasonable as well as likely to interfere with, prevent, or materially discourage access (see 45 CFR 171.103), exchange, or use of electronic health information. To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to \$1 million per violation. Appropriate disincentives for health care providers need to be established by the Secretary through rulemaking. Stakeholders can learn more about information blocking at <https://www.healthit.gov/curesrule/final-rule-policy/information-blocking>. ONC has posted information resources including fact sheets (<https://www.healthit.gov/curesrule/resources/fact-sheets>), frequently asked questions (<https://www.healthit.gov/curesrule/resources/information->

⁴⁵ For other types of actors (health IT developers of certified health IT and health information network or health information exchange, as defined in 45 CFR 171.102), the definition of “information blocking” (see 45 CFR 171.103) specifies that the actor “knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.”

[blocking-faqs](#)), and recorded webinars (<https://www.healthit.gov/curesrule/resources/webinars>).

We invite providers to learn more about these important developments and how they could affect HHAs.

C. Home Health Quality Reporting Program (HH QRP)

1. 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 following rules:

- CY 2007 HH PPS final rule (71 FR 65888 through 65891).
- CY 2008 HH PPS final rule (72 FR 49861 through 49864).
- CY 2009 HH PPS update notice (73 FR 65356).
- CY 2010 HH PPS final rule (74 FR 58096 through 58098).
- CY 2011 HH PPS final rule (75 FR 70400 through 70407).
- CY 2012 HH PPS final rule (76 FR 68574).

- CY 2013 HH PPS final rule (77 FR 67092).
- CY 2014 HH PPS final rule (78 FR 72297).
- CY 2015 HH PPS final rule (79 FR 66073 through 66074).
- CY 2016 HH PPS final rule (80 FR 68690 through 68695).
- CY 2017 HH PPS final rule (81 FR 76752).
- CY 2018 HH PPS final rule (82 FR 51711 through 51712).
- CY 2019 HH PPS final rule with comment period (83 FR 56547).
- CY 2020 HH PPS final rule with comment period (84 FR 60554).
- CY 2021 HH PPS final rule (85 FR 70326 through 70328).

2. 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 with comment period (83 FR 56548 through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

3. Quality Measures Currently Adopted for the CY 2022 HH QRP

The HH QRP currently includes 20 measures for the CY 2022 program year, as outlined in Table 28 of the CY 2020 HH PPS final rule (84 FR 60555).^{46, 47}

TABLE 33: MEASURES CURRENTLY ADOPTED FOR THE CY 2022 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).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (NQF #0526).

⁴⁶ The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

⁴⁷ Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider.

Short Name	Measure Name & Data Source
TOH - Provider	Transfer of Health Information to Provider-Post-Acute Care ⁴⁸
TOH - Patient	Transfer of Health Information to Patient-Post-Acute Care ⁴⁹
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) (NQF #3477)
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) ⁵⁰ <ul style="list-style-type: none"> - 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.

4. Changes for the HH QRP

- a. Removal of the Drug Education on all Medications Provided to Patient/Caregiver Measure Beginning with the CY 2023 HH QRP

The CMS Meaningful Measures framework seeks to identify the highest priorities for quality measurement and improvement and reduce where possible the burden on providers and clinicians.⁵¹ In line with our meaningful measures initiative, we proposed to remove the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure from the HH QRP under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096), we adopted the Drug Education on all Medications Provided to Patient/Caregiver measure, an OASIS-based measure, beginning with the CY 2010 HH QRP. This process measure reports the percentage of home health quality episodes during which the patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems (at the time of or at any time since the most recent SOC/ROC assessment). This

⁴⁸ Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider.

⁴⁹ *Ibid.*

⁵⁰ The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

⁵¹ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>.

measure is calculated using data collected on OASIS Item M2016.⁵²

The Drug Education on all Medications Provided to Patient/Caregiver measure has very high measure performance such that it meets our Meaningful Measure Removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. The mean and median agency performance scores for this measure, from January 1, 2019 to December 31, 2019, were 97.1 percent and 99.2 percent, respectively. The mean and median agency performance score for this measure in 2010 were 85.4 percent and 97.0 percent respectively. This indicates that an overwhelming majority of patients (or their caregivers) in an HHA received drug education on all medications and demonstrated improvement over time. In addition, during the same timeframe, the 75th percentile measure score (99.9 percent) and the 90th percentile measure score (100 percent) were statistically indistinguishable from each other, meaning that measure scores do not meaningfully distinguish between HHAs.⁵³ Further, the truncated coefficient of variation for this measure was 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.⁵⁴

We note that the HH QRP also has another measure that we believe better addresses the Meaningful Measure area of medication management. The Improvement in Management of Oral Medications (# 0176) measure is an NQF-endorsed outcome measure that assesses the percentage of home health quality episodes during which the patient improved in the ability to take their oral medications correctly. The OASIS item used for this measure (M2020) is currently collected at Start of Care, Resumption of Care, and Discharge. The M2020 Management of Oral Medications assessment item asks about the patient's current ability to

⁵² Home Health Quality Reporting Program Measure Calculations and Reporting User's Manual <https://www.cms.gov/files/document/hh-qrp-qm-users-manual-v1-addendum.pdf>.

⁵³ Analysis of Home Health OASIS episodes from 2010 to 2019.

⁵⁴ The truncated coefficient of variation (TCV) is the ratio of the standard deviation to the mean of the distribution of all scores, excluding the 5 percent most extreme scores. A small TCV (≤ 0.1) indicates that the distribution of individual scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual performance scores.

prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. This measure focuses on improving medication management through medication education provided to the patient. The measure performance statistics demonstrate good variation among providers and room for improvement: from January 1, 2019 to December 31, 2019, the mean and median agency performance scores for this measure was 69.4 percent and 71.9 percent, respectively; the 75th percentile measure score (79.7 percent); the 90th percentile measure score (87 percent); and the truncated coefficient of variation for this measure was 0.17. Thus, we believe this outcome measure The Improvement in Management of Oral Medications (NQF #0176) both better addresses quality issues of medication education and has better performance measure properties than the Drug Education on all Medications Provided to Patient/Caregiver process measure. Additionally, the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care measure was removed from the HH Quality of Patient Care Star Ratings in April 2019 (now Care Compare) and replaced by the Improvement in Management of Oral Medications measure (NQF #0176). The removal of Drug Education on All Medications Provided to Patient/Caregiver process measure from the HH Quality of Patient Care Star Ratings in April 2019 and replacement with the Improvement in Management of Oral Medications ensured that there was not a gap in this important topic area.

We proposed to remove the Drug Education on all Medications Provided to Patient/Caregiver measure under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made, beginning with the CY 2023 HH QRP.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M2016, Patient/Caregiver Drug Education Intervention for the purposes of this measure

beginning January 1, 2023.⁵⁵ If finalized as proposed, data for this measure would be publicly reported on Care Compare through October 1, 2023, after which it would be removed from the site.

We invited public comments on these proposals.

Comment: Most commenters supported the removal of the Drug Education on all Medications Provided to Patient/Caregiver measure. They supported the rationale supporting our proposal that showed the measure was less useful to the broader public as a measure with limited variation in scores across providers.

Response: We thank commenters for their support of the proposal to remove the Drug Education on all Medications Provided to Patient/Caregiver measure from the HH QRP. We will continue assess the value of each measure in the HH QRP to ensure it provides value to patients, providers and other stakeholders.

Comment: Some commenters supported the measure removal yet expressed concerns that removal of this measure would result in a significant impact on the drug education that HHAs have provided and requested that CMS continue to monitor drug education. A few commenters did not support the removal of the drug education measure out of concern that its removal as one of the patient safety measures would adversely affect patients.

Response: We appreciate commenters raising the issue of patient safety. We continue to prioritize patient safety regarding patient medications. We believe other measures in the HH QRP, specifically the Improvement in Management of Oral Medications measure, adequately addresses this domain of patient safety with respect to medications along with other measures such as the Drug Regimen Review measure.

Final Decision: After careful consideration of the public comments we received, we are finalizing our proposal to remove of the Drug Education on All Medications Provided to

⁵⁵ The removal or addition of an item from the OASIS instrument is subject to public comment and approval from OMB. We cannot cease reporting of this measure any earlier given the need to extend OASIS-D and submit another PRA package in January 2022 for OMB approval for OASIS-E beginning January 1, 2023.

Patient/Caregiver During All Episodes of Care measure from the HH QRP under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made beginning January 1, 2023. HHAs will no longer be required to submit OASIS Item M2016, Patient/Caregiver Drug Education Intervention beginning January 1, 2023.⁵⁶ We are finalizing that data for this measure will be publicly reported on Care Compare through October 1, 2023, after which it would be removed from the site.

b. Replacement of the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) Measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) Measure with the Home Health Within Stay Potentially Preventable Hospitalization Measure Beginning with the CY 2023 HH QRP

In the CY 2017 HH PPS final rule, we finalized a policy for replacing quality measures in the HH QRP. Specifically, we defined “replace” to mean adopting a different quality measure in place of a quality measure currently in the HH QRP based on one or more of the HH QRP’s measure removal factors (81 FR 76754 through 76754). We proposed to replace the Acute Care Hospital During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure under measure removal factor 6: a measure that is more strongly associated with desired patient outcomes for the particular topic is available, with the Home Health Within Stay Potentially Preventable Hospitalization Measure beginning with the CY 2023 HH QRP.

The proposed Home Health Within Stay Potentially Preventable Hospitalization (which we will refer to as the “PPH” measure) measure assesses the agency-level risk-adjusted rate of potentially preventable inpatient hospitalization or observation stays for Medicare fee-for-service (FFS) beneficiaries that occur within a home health (HH) stay for all eligible stays for an agency.

⁵⁶ The removal or addition of an item from the OASIS instrument is subject to public comment and approval from OMB. We cannot cease reporting of this measure any earlier given the need to extend OASIS-D and submit another PRA package in January 2022 for OMB approval for OASIS-E beginning January 1, 2023.

This proposed measure is claims-based, requiring no additional data collection or submission burden for HHAs. Our approach for defining potentially preventable hospital admissions is described in more detail in this section of this rule in the Measure Calculations section.

A HH stay is defined as a sequence of HH payment episodes that are within 2 days or fewer from an adjacent payment episode. Payment episodes separated from other HH payment episodes by greater than 2 days are considered separate stays. Full details of the PPH specifications may be found at “Proposed PPH Measure Specifications for the CY 2022 HH QRP NPRM” at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures>.

(1) Background

Hospitalizations among the Medicare population are common, costly, and often preventable.^{57, 58, 59} The Medicare Payment Advisory Commission (MedPAC) and a study by Jencks et al. estimated that 17-20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. Among these hospital readmissions, MedPAC has estimated that 76 percent were considered potentially avoidable and associated with \$12 billion in Medicare expenditures.^{60,61} An analysis of data from a nationally representative sample of Medicare FFS beneficiaries receiving HH services in 2004 show that HH patients receive significant amounts of acute and post-acute services after discharge from HH care.⁶² Focusing on readmissions, Madigan and colleagues studied data on 74,580 Medicare HH patients and found that the 30-day rehospitalization rate was 26 percent, with the largest proportion related to a

⁵⁷ Friedman, B. and J. Basu, The rate and cost of hospital readmissions for preventable conditions. *Med Care Res Rev*, 2004. 61(2): p. 225-40.

⁵⁸ Moy, E., Chang, E., and Barret, M. Potentially Preventable Hospitalizations — United States, 2001–2009. *MMWR*, 2013, 62(03);139-143.

⁵⁹ Jencks, S.F., M.V. Williams, and E.A. Coleman, Rehospitalizations among Patients in the Medicare Fee-for-Service Program. *New England Journal of Medicine*, 2009. 360(14): p. 1418-1428.

⁶⁰ *Ibid.*

⁶¹ MedPAC, Payment policy for inpatient readmissions, in Report to the Congress: Promoting Greater Efficiency in Medicare. 2007: Washington D.C. p. 103-120.

⁶² Wolff, J. L., Meadow, A., Weiss, C.O., Boyd, C.M., Leff, B. Medicare Home Health Patients' Transitions Through Acute And Post-Acute Care Settings." *Medicare Care* 11(46) 2008; 1188-1193.

cardiac-related diagnosis (42 percent).⁶³ A study of data on dually eligible Medicare and Medicaid beneficiaries hospitalizations from nursing home and home and community based services waiver programs found that 39 percent of admissions were potentially avoidable.⁶⁴

Analysis of the home health patient population has revealed some key factors associated with hospitalizations from HH including functional disability, primary diagnoses of heart disease, and primary diagnosis of skin wounds.⁶⁵ An additional beneficiary characteristic that is associated with a potential for hospitalization is the time since a beneficiary's most recent hospitalization⁶⁶ and chronic conditions such as chronic obstructive pulmonary disease and congestive heart failure.⁶⁷ How HHAs address these factors, including how HHAs address chronic conditions present before the HH stay, can determine whether beneficiaries can successfully avoid hospitalizations.⁶⁸ Understanding these factors can help HHAs design strategies to address avoidable hospitalizations.

Observation stays are also increasing nationally and can have costly financial impacts, especially for patients.^{69,70} Patients admitted for an observation stay can often be treated in the same medical units and have similar medical needs as a patient admitted for inpatient care, but the service is billed as outpatient services and does not count as a referent patient stay in the

⁶³ Madigan, E. A., N. H. Gordon, et al. Rehospitalization in a national population of home health care patients with heart failure." *Health Serv Res* 47(6): 2013; 2316-2338.

⁶⁴ Walsh, E. G., J. M. Wiener, et al. (2012). "Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and Home- and Community-Based Services waiver programs." *J Am Geriatric Soc* 60(5): 821-829.

⁶⁵ Lohman MC, Cotton, BP, Zagaria, AB, Bao, Y, Greenberg, RL, Fortuna, KL, Bruce, ML Hospitalization Risk and Potentially Inappropriate Medications among Medicare Home Health Nursing Patients,(2017) *J Gen Intern Med.* 32(12):1301-1308.

⁶⁶ Hua M, Gong, MN, Brady J, Wunsch, H, Early and late unplanned rehospitalizations for survivors of critical illness(2015) *Critical Care Medicine*;43(2):430-438.

⁶⁷ Dye C, Willoughby D, Aybar-Damali B, Grady C, Oran R, Knudson A, Improving Chronic Disease Self-Management by Older Home Health Patients through Community Health Coaching (2018). *Int J Environ Res Public Health.* 15(4): 660.

⁶⁸ Lohman MC, Cotton, BP, Zagaria, AB, Bao, Y, Greenberg, RL, Fortuna, KL, Bruce, ML Hospitalization Risk and Potentially Inappropriate Medications among Medicare Home Health Nursing Patients, (2017) *J Gen Intern Med.* 32(12):1301-1308.

⁶⁹ Lind KD, Noel-Miller CM, Sangaralingham LR, Shah ND, Hess EP, Morin P, Fernanda Bellolio M. Increasing Trends in the Use of Hospital Observation Services for Older Medicare Advantage and Privately Insured Patients. *Med Care Res Rev.* 2019. Apr;76(2):229-239.

⁷⁰ Feng Z, Wright B, Mor V. Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. *Health Aff (Millwood).* 2012. Jun;31(6):1251-9.

calculations of readmissions.⁷¹ Limitation of observation stays should be a goal of HHAs along with efforts to limit inpatient hospitalizations.

We have addressed emergency department use, hospitalizations, and readmissions with a number of home health measures. Measures including the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171); Emergency Department Use without Hospitalization During the First 60 days of Home Health (NQF #0173); and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for the HH QRP. The HH QRP has long sought to address hospitalization and emergency department use by home health patients since decreasing hospitalizations and use of the emergency department are important areas of quality to promote patient health outcomes and reduce unnecessary healthcare costs. Before the adoption of the Acute Care Hospitalization during the First 60 Days of Home Health (NQF # 0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measures, the HH QRP utilized OASIS-based iterations of these measures. In the CY 2012 HH PPS final rule (76 FR 68526), we adopted the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health claims-based measure to replace the OASIS-based Emergency Department Use Without Hospitalization measure since the claims data offered a more robust source of data for the measure. The M2300 item used to calculate OASIS-based ED Use QM was deemed to be insufficiently reliable in capturing emergency department visits. In the CY 2013 HH PPS final rule (77 FR 67902), we adopted the Acute Care Hospitalization During the First 60 Days of Home Health claims-based measure to replace the OASIS-based Acute Care Hospitalization measure since it made the determination that claims data provided a more robust data source for accurately measuring acute care hospitalizations.

The Acute Care Hospitalization During the First 60 Days of Home Health measure (NQF

⁷¹ Sabbatini AK, Wright B. Excluding Observation Stays from Readmission Rates - What Quality Measures Are Missing, *New England Journal of Medicine*, 31;378(22):2062-2065.

0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure are claims-based and were an improvement on addressing issues related to emergency department use and acute hospitalization but they also had limitations related to issues of attribution. In prior feedback from an NQF technical review panel on the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #1073), concerns were raised regarding the HHAs' ability to prevent an emergency department visit, especially for visits that do not result in a hospitalization. While some evidence suggests that care coordination and HHA engagement can impact emergency department use by patients, experts raised concerns that there were several drivers of emergency department use outside the control of an HHA that could result in an emergency department visit.⁷²

Concerns related to attribution were also raised by reviewers of the Acute Care Hospitalization during the First 60 Days of Home Health when the measure was reviewed for NQF endorsement by the Steering Committee at the National Voluntary Consensus Standards for Care Coordination 2012 meetings. Reviewers acknowledged the difficulty in determining appropriate attribution for hospitalization between different providers and settings, especially when evaluating all cause hospitalization that does not require the reason for hospitalization to be related to the reason for home health care.⁷³

The proposed PPH measure addresses the limitations of the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) and Acute Care Hospitalization During the First 60 Days of Home Health measures (NQF #0171). First, the PPH proposed measure assesses potentially preventable observation stays instead of just emergency department use. As noted previously, observation stays are costly clinical events that require a patient to be monitored by a medical team. Limiting the occurrence of avoidable observation stays would improve patient outcomes and reduce costs. The PPH measure is focused on the

⁷² National Voluntary Consensus Standards for Care Coordination 2012 Draft Technical Report. Available from <https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70600>.

⁷³ Ibid.

subset of observation stays that technical experts determined could be addressed by HHA intervention. Similarly, the PPH proposed measure focuses on the subset of inpatient hospitalizations that could be avoided by HHA intervention. We believe the proposed PPH measure will better provide an assessment on HH quality by focusing on observation stays and acute hospitalizations that could be prevented by HHA intervention.

Several general methods have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators,⁷⁴ approaches developed by MedPAC, and proprietary approaches, such as the 3MTM algorithm for potentially preventable hospitalizations.^{75,76,77} The existing literature addresses both hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care and highlights issues relevant to the development of potentially preventable hospitalization measures for a post-acute care setting such as home health.^{78,79}

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

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital admission and observation stays for HH. TEP meetings were held in April, June, and December 2018. The TEP supported the definition of potentially preventable developed by the measure development team for both inpatient admissions and observation stays. The TEP further provided extensive guidance in refining the list of primary

⁷⁴ Prevention Quality Indicators Overview. Available at:

https://www.qualityindicators.ahrq.gov/modules/pqi_resources.aspx.

⁷⁵ Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al. Identifying potentially preventable readmissions. *Health Care Finan. Rev.* 30(1):75-91, 2008. Available from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/>.

⁷⁶ National Quality Forum: Prevention Quality Indicators Overview. 2008.

⁷⁷ MedPAC: Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly. pp. 1-12, prepared for Chapter 4, 2011. Available from

http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0.

⁷⁸ Gao, J., Moran, E., Li, Y.-F., et al. Predicting potentially avoidable hospitalizations. *Med. Care* 52(2):164-171, 2014. doi:10.1097/MLR.000000000000041.

⁷⁹ Walsh, E.G., Wiener, J.M., Haber, S., et al. Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. *J. Am. Geriatr. Soc.* 60(5):821-829, 2012. doi:10.1111/j.1532-5415.2012.03920.

conditions that lead to the inpatient admission or observation stay that could be reasonably deemed preventable by HHA intervention. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/PPH-TEP-Summary-Report-Final-101019.pdf>.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 18 through December 16, 2019. The major comment received focused on considering the implication of implementation of the Patient-Driven Groupings Model (PDGM) on the specifications of this measure. CMS has undertaken a review of the implications on the new payment model on this and other claims-based QMs in the HH QRP and determined that the claims-based measures are not adversely affected by the new model.

(3) Measure Application Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures under Consideration (MUC) List that the Secretary is considering adopting through the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The PPH quality measure was published in the 2019 MUC list for the HH QRP.⁸⁰

The PPH quality measure was presented to the 2019 NQF-convened Measure Application Process (MAP) Post-Acute Care/Long-Term Care (PAC-LTC) workgroup and the MAP recommended conditional support for rulemaking for a single measure under consideration for the HH QRP, MUC2019-34 PPH. The MAP conditionally supported MUC2019-34 PPH, pending NQF review and endorsement. CMS clarified that it intends to eventually replace

⁸⁰ <https://www.cms.gov/files/document/2019muc-listclearancert.pdf>.

related measures, NQF 0171 Acute Care Hospitalization during the First 60 Days of Home Health and NQF 0173 Emergency Department Use (ED Use) Without Hospitalization During the First 60 days of Home Health with the PPH measure under consideration.

The MAP agreed that the PPH measure adds value to the HH QRP's measure set by adding measurement of potentially preventable hospitalizations and observation stays that may occur at any point in the home health stay. No measure in the program currently provides this information.

The MAP encouraged the consideration of including Medicare Advantage patients in future iterations of the measure. CMS is supportive of this suggestion when reliable Medicare Advantage data is available nationally. The MAP also encouraged the NQF All-Cause Admissions and Readmissions Standing Committee to consider the definition for preventable hospitalization to ensure HHAs can take adequate steps to improve these outcomes. The issue of what could be determined to be potentially preventable by HHAs was discussed extensively at multiple TEP meetings. The TEP adopted a listing of conditions that could be prevented by standard care HHAs are required to provide. The MAP encouraged CMS to provide detailed performance feedback to providers to help providers differentiate the causes of hospitalizations for quality improvement purposes. More information about the MAP's recommendations for this measure is available at

https://www.qualityforum.org/Publications/2020/02/MAP_2020_Considerations_for_Implementing_Measures_Final_Report_-_PAC_LTC.aspx.

At the time of the MAP, the initial risk-adjustment model tested measure validity and reliability as identified in the measure specifications document, as previously provided. Testing results were very strong and showed more robust results than outcome measures previously finalized through rulemaking including the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure.

(4) Quality Measure Calculation

We reviewed established scientific research, analyzed home health claims data, and obtained input from a technical expert panel (TEP) to develop a definition and list of conditions for which types of hospital admissions are potentially preventable. The defining of potentially preventable hospitalization relies on the previously developed conceptual framework that certain diagnoses, proper management, and care of the condition by the home health agency, combined with appropriate, clearly explained, and implemented discharge instructions and referrals, can potentially prevent a patient's admission to the hospital. On the basis of this framework, the team followed the working conceptual definition for potentially preventable hospitalizations for home health created during the development of the HH QRP measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program. Although not specific to PAC or hospitalizations, the team used AHRQ Prevention Quality Indicators (PQIs) and Ambulatory Care Sensitive Conditions (ACSCs) as a starting point for this work. The list of ACSCs consists of conditions for which hospitalization can potentially be prevented, given good outpatient care and early intervention.⁸¹

We also performed analyses on Medicare claims data to identify the most frequent diagnoses associated with admissions among home health beneficiaries, and then applied the conceptual potentially preventable hospitalization definition to evaluate whether these common conditions for a hospitalization may be considered potentially preventable. This list of conditions identified from literature and claims analysis formed the preliminary potentially preventable hospitalization definition. We grouped these conditions based on clinical rationale, and the major groups are: (1) Inadequate management of chronic conditions; (2) Inadequate management of infections; (3) Inadequate management of other unplanned events; and (4) Inadequate injury prevention.

⁸¹ Agency for Healthcare Research and Quality: AHRQ Quality Indicators—Guide to Prevention Quality Indicators: Hospital Admission for Ambulatory Care Sensitive Conditions. AHRQ Pub. No. 02-R0203. Rockville, MD. Agency for Healthcare Research and Quality, 2001.

Additional details regarding the definition for potentially preventable hospitalizations are available in the document titled “Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM” available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures>.

This proposed PPH measure is focused on inpatient admissions or observation stays that are potentially preventable (PP) and unplanned. Thus, planned admissions are not counted in the numerator. Planned inpatient admissions and observation stays are defined largely by the definition used for the Hospital Wide Readmission⁸² and Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities⁸³ measures.

The process for classifying a planned inpatient admission or observation stay is determined based on the following parameters. If an inpatient or outpatient claim contains a code for a procedure that is frequently a planned procedure, then that inpatient admission or observation stay is designated a planned inpatient admission or observation stay and is not included in the numerator. Similarly, if an inpatient or outpatient claim contains a code for a diagnosis that is frequently associated with a planned admission, then that inpatient admission or observation stay is designated to be a planned inpatient admission or observation stay and also not included in the numerator. However, the planned inpatient admission or observation stay is reclassified as unplanned if the claim also contains a code indicating one or more acute diagnoses from a specified list that is included in the criteria material described in the next sentence. Full details on the planned admissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled “Proposed PPH Measure Specification for the CY 2022 HH QRP

⁸² <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html>.

⁸³ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html>.

NPRM” at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures>.

The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of potentially preventable inpatient hospital admission or observation stay. More specifically, the risk-adjustment model for HHAs entails the following:

- Demographic characteristics (age, sex, original reason for Medicare entitlement).
- Care received during prior proximal hospitalization⁸⁴ (if applicable) (including the length of the hospitalization and principal diagnoses during the prior proximal hospitalization).
- Other care received within a year of stay (including number of prior acute discharges, number of outpatient emergency department visits, number of skilled nursing visits, number of inpatient rehabilitation facility visits, number of long term care hospital visits, and comorbidities from a prior proximal hospitalization [if applicable] or other visits in the last year).

The proposed measure is calculated using a calendar year of Medicare FFS data. In addition, we proposed a minimum of 20 eligible HH stays as defined in the introduction to this proposal for public reporting of the proposed measure. All HH stays during the year time window, except those that meet the exclusion criteria, would be included in the measure. The PPH observation window begins from the start of HH stay and spans to 1 day after discharge. Data from all HH stays beginning from 1/1/2016 - 12/31/2016, was used for the PPH measure development. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, we refer readers to our Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures>.

⁸⁴ Prior proximal hospitalizations for this measure are defined as inpatient stays within 30 days prior to home health admission.

To meet the requirements of the CMS Meaningful Measures framework which seeks to identify the highest priorities for quality measurement and improvement and to reduce where possible the burden on providers and clinicians,⁸⁵ we proposed to remove the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure and replace them with the PPH measure. We proposed to remove these two measures from the HH QRP beginning with the CY 2023 HH QRP under our measure removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

The Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measures are both claims-based and have some notable limitations related to appropriate attribution of the acute hospitalization or emergency department visit to an HHA. These measures focus on hospitalization regardless of whether a HHA could provide care that could prevent the visit whereas the proposed PPH measure addresses the limitations of these measures by focusing on inpatient admissions and observation stays that research establishes could be prevented by HHA care provided to patients they serve.

We proposed to remove the Acute Care Hospitalization during the First 60 Days of Home Health (NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure and replace them with the Home Health Within- Stay Potentially Preventable Hospitalization claims-based measures beginning with the CY 2023 HH QRP.

We invited public comments on this proposal.

⁸⁵ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy>.

Comment: Most commenters supported our proposal to Replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #1071) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization measure beginning with the CY 2023 HH QRP.

Response: We thank commenters for their support of the proposal to replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #1071) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization measure. We regularly strive to improve domains of quality and this policy seeks to improve how hospitalizations are addressed in home health.

Comment: Some commenters supported the PPH measure replacement with a condition that providers be given some time to adjust before it is added to either the HH QRP or HHVBP program.

Response: We disagree with the commenters recommendation to be given additional time to adjust under the HH QRP. We interpret the comment to convey that finalization of this policy in the CY 2022 rule, confidential feedback to providers in October 2022, and reporting commencing no sooner than October 1, 2023, is too soon. We contend that HHAs would have more than a year after finalization of this policy to review their PPH measure scores and implement quality improvement measures if needed.

At the present time, we only proposed the PPH measure under the HH QRP. We will note that where possible, CMS does seek alignment across our post-acute care quality programs.

Comment: A few commenters supported the PPH replacement of the ACH and ED Use measures but had suggested modification to the PPH measure specification, including the removal of the observation stays from the numerator, addition of ED use to the numerator, and a strengthening of the risk adjustment model for the measure. Commenters were concerned with

the launch of OASIS E and use of items associated with the HH Patient-Driven Groupings Model (PDGM) implemented January 2020 and concurrent with the development of the PPH measure.

Response: With respect to modifications of the PPH measure, we continually seek improvement to the specifications of measures and anticipates a robust risk adjustment approach consistent with other claims-based outcome measures currently under the HH QRP. As is our practice, we will assess the appropriateness of inclusion of any new assessment items available for use to improve risk adjustment as those items are available. We have also assessed the importance of the inclusion of observation stays in the PPH measure and do believe that addressing preventable observation stays as well as inpatient stays are important aspects of quality improvement based on clinical research showing the trends of observation stays in inpatient settings and an improvement on addressing only ED use in the numerator. Observation stays are an important form of hospitalization and in the process of assessing for observation stays, ED use is also captured. As with other claims-based measures in the HH QRP, CMS will assess the impact of PDGM implementation on measure specification and update measure details as necessary.

Comment: Some commenters suggested that it is important for the PPH measure to obtain NQF endorsement if the measure is to be added to the HH QRP.

Response: We intend to submit the PPH measure for NQF endorsement.

Final Decision: After careful consideration of the public comments we received, we are finalizing the replacement of the Acute Care Hospital During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measures under measure removal factor 6: a measure that is more strongly associated with desired patient outcomes for the particular topic is available, with the Home Health Within Stay Potentially Preventable Hospitalization Measure beginning with the CY 2023 HH QRP.

c. Schedule for Publicly Reporting Quality Measures Beginning with the CY 2022 HH QRP

Section 1899B(g)(1) of the Act requires, in part, that the Secretary provide for public reporting of PAC provider performance, including HHAs, on quality measures under section 1899B(c)(1) of the Act, including by establishing procedures for making available to the public information regarding the performance of individual PAC providers with respect to such measures. Section 1899B(g)(2) of the Act requires, in part, that CMS give HHAs opportunity to review and submit corrections to the data and information to be made public under section 1899B(g)(1) of the Act prior to such data being made public. Section 1899B(g)(3) of the Act requires that such procedures provide that the data and information with respect to a measure and PAC provider is made publicly available beginning not later than 2 years after the applicable specified application date applicable to such measure and provider.

In the CY 2018 HH PPS final rule, we adopted the Percent of Residents Experiencing One or More Falls with Major Injury measure beginning with the CY 2020 HH QRP under section 1899B(c)(1)(D) of the Act (82 FR 51727 through 51730). Under section 1899B(a)(2)(E)(i)(IV)(bb) of the Act, the specified application date for HH QRP measures adopted under section 1899B(c)(1)(D) of the Act is January 1, 2019; two years after this date is January 1, 2021.

We also adopted in the CY 2018 HH PPS final rule the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment measure beginning with the CY 2020 HH QRP (82 FR 51722 through 51727) under section 1899B(c)(1)(A) of the Act. Under section 1899B(a)(2)(E)(i)(I)(cc) of the Act, the specified application date for HH QRP measures adopted under section 1899B(c)(1)(A) of the Act is January 1, 2019; 2 years after this date is January 1, 2021.

We proposed to publicly report the Percent of Residents Experiencing One or More Major Falls with Injury measure and 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) measure beginning in April 2022.

As required by section 1899B(g)(2) of the Act, to date CMS has made these two measures available for review by HHAs the HH confidential feedback reports. The Percent of Residents Experiencing One or More Major Falls with Injury measure was added to the HHA Review and Correct Report effective 04/01/2019, and the HHA Outcome Measures Report effective 01/01/2020. 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) was added to the HHA Review and Correct Report effective 04/01/2019, and the HHA Process Measures Report effective 01/01/2020. HHAs' HH QRP measure scores for these two measures would additionally be made available for review on the HH Provider Preview Report, which would be issued in January 2022, 3 months in advance of the inaugural display of these measures on Care Compare.

We invited public comments on our proposed schedule to publicly display these measures.

Comment: A few commenters requested clarification regarding what could be considered a major injury resulting from a fall for the Percent of Residents Experiencing One or More Major Falls with Injury measure.

Response: We refer readers to the measure details outlined in the CY 2018 HH PPS final rule (82 FR 51727 through 51730) for the Percent of Residents Experiencing One or More Major Falls with Injury measure.

Final Decision: We are finalizing our proposal to publicly report the Percent of Residents Experiencing One or More Major Falls with Injury measure and 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) measure beginning in April 2022.

d. Revised Compliance Date for Certain HH QRP Reporting Requirements

(1) Background

In the May 8, 2020 **Federal Register** (85 FR 27550), we published an interim final rule with comment period titled “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (which we will refer to as “IFC-2”). In IFC-2, we delayed the compliance date for certain reporting requirements under the HH QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for HHAs to begin reporting the Transfer of Health (TOH) Information to PAC and the TOH Information to Patient-PAC measures and the requirement for HHAs to begin reporting certain Standardized Patient Assessment Data Elements to January 1st of the year that is at least one full calendar year after the end of the COVID–19 Public Health Emergency (PHE). CMS also delayed the adoption of the updated version of the Outcome and Assessment Information Set (OASIS) assessment instrument (OASIS-E) for which HHAs would report the Transfer of Health (TOH) measures and certain Standardized Patient Assessment Data Elements.

Under IFC-2, HHAs must use OASIS–E to begin collecting data on the two TOH Information measures beginning with discharges and transfers on January 1st of the year that is at least one full calendar year after the end of the COVID–19 PHE. HHAs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the OASIS-E, beginning with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) on January 1st of the year that is at least 1 full calendar year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was to provide relief to HHAs from the added burden of implementing an updated instrument during the COVID-19 PHE. We wanted to provide maximum flexibilities for HHAs to respond to the

public health threats posed by the COVID-19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC-2, we believed that the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements would not have a significant impact on the HH QRP. However, the COVID-19 PHE showed the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the HH QRP. The PHE's disproportionate impact on minority populations demonstrates the importance of analyzing this impact and the needs for these populations to improve quality of care within HHAs, especially during a public health emergency.

(2) Current Assessment of HHAs

To accommodate the COVID-19 PHE, CMS has provided additional guidance and as a result HHAs have adopted new processes as well as modified existing processes. For example, HHAs currently have the option to complete what was required to be a face-to-face encounter to qualify for home health via telehealth and the completion of aspects of required comprehensive assessments via telehealth.⁸⁶ CMS also supported PAC providers, including HHAs, by providing requested flexibilities in the delivery of care in response to the PHE. In addition, we assisted providers by conducting sessions for HHAs to share best practices that agencies have identified to address many of the challenges posed by the PHE.

Based upon other flexibilities such as the examples provided and the adoption of best practices, and since finalizing IFC-2, HHAs are in a better position to accommodate reporting of the TOH measures and certain Standardized Patient Assessment Data Elements. Also, recent reports (not available at the time CMS IFC-2 was finalized) suggest that HHAs have the capacity to begin reporting the TOH measures and certain Social Determinant of Health (SDOH)

⁸⁶ <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>

Standardized Patient Assessment Data Elements.⁸⁷ Since IFC-2 was finalized, the industry has identified a growing demand for home health services and has noted their ability to meet this demand.^{88, 89, 90, 91}

In addition, after evaluating the impact of the compliance date under IFC-2, feasibility around data collection by HHAs, and the support needs of providers during the COVID-19 PHE, we have determined that HHAs now have the administrative capacity to attend trainings, train their staff, and work with their vendors to incorporate the updated assessment instrument, the OASIS-E into their operations.

We now believe that based upon the processes adopted by HHAs, as previously described, the flexibilities afforded to HHAs since the beginning of the COVID-19 PHE, and the importance of the data to the HH QRP, it would be appropriate to modify the compliance date finalized in IFC-2. This may support future activities under Executive Order 13985, entitled “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” issued January 20, 2021

(<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>).

3. Collection of the Transfer of Health Information to Provider-PAC measure, the Transfer of Health Information to Patient-PAC measure, and Certain Standardized Patient Assessment Data Elements Beginning January 1, 2023

We proposed to revise the compliance date from IFC-2 to January 1, 2023. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized

⁸⁷ <https://www.healthaffairs.org/doi/10.1377/hblog20201214.543463/full/>

⁸⁸ <https://www.hartfordbusiness.com/article/demand-for-home-health-care-surges-amid-covid-19-shifting-industry-landscape>

⁸⁹ <https://www.forbes.com/sites/sethjoseph/2020/08/05/home-health-care-is-a-bright-light-during-covid-19-with-an-even-brighter-future/?sh=2bfa2c513891>

⁹⁰ <https://www.wsj.com/articles/demand-for-in-home-care-rises-during-coronavirus-11588003076>

⁹¹ https://www.csbj.com/premier/businessnews/healthcare/covid-19-boosts-demand-for-home-health-care/article_c65d2b4e-3b17-11eb-a46e-97a2079b065f.html

Patient Assessment Data Elements on the updated version of the OASIS assessment instrument referred to as OASIS-E. This revised date of January 1, 2023, which is a 2-year delay from this original compliance date finalized in the CY 2020 HH PPS final rule (84 FR 60557 through 60610), balances the support that HHAs needed during much of the COVID-19 PHE as CMS provided flexibilities to support HHAs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and Transfer of Health data have shown to be even more pressing with issues of inequities that the COVID-19 PHE laid bare. This data that includes addressing SDOH provides information that is expected to improve quality of care for all. Consequently, we proposed to revise the compliance date to reflect this balance and assure that this data collection begins on January 1, 2023.

As stated in the CY 2020 HH PPS final rule, CMS will provide the training and education for HHAs to be prepared for this implementation (84 FR 60554). In addition, if CMS adopts a January 1, 2023 compliance date, CMS would release a draft of the updated version of the OASIS instrument, OASIS-E, in early 2022.

Based upon our evaluation, we proposed that HHAs would collect the Transfer of Health Information to Provider Post-Acute Care measure, the Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning January 1, 2023. We proposed that, accordingly, HHAs would begin collecting data on the two TOH measures beginning with discharges and transfers on January 1, 2023 on the OASIS-E. We also proposed that HHAs would begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the OASIS-E, with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) beginning on January 1, 2023.

We invited public comment on these proposals.

Comment: Most commenters supported our plan to establishing the OASIS-E effective January 1, 2023 for the corresponding collection of transfer and standardized patient data elements on the assessment tool.

Response: We thank commenters for their support.

Comment: Many commenters who were supportive of this proposal requested that CMS consider the overall burden associated with OASIS-E and to consider ways to mitigate the burden of reporting additional OASIS-E items.

Response: We appreciate the importance of avoiding unnecessary burden on HHAs and will continue to evaluate and consider any burden associated with changes to the OASIS. We have taken into consideration any new burden that our proposals might place on HHAs outlined in the CY 2020 HH PPS final rule (84 FR 60566 through 60608).

Comment: Some commenters did not support the launch of OASIS-E in January 1, 2023, citing the ongoing PHE and the additional burdens an assessment tool launch would incur.

Response: We considered the ongoing impact of the PHE, provisions implemented to support HHAs, in managing the PHE impacts, and management of care provision since the start of the PHE (86 FR 35955 through 35955). Based on a review of the current impacts of the PHE on HHAs nationally, we believe HHAs are well-positioned to successfully implement OASIS-E beginning January 1, 2023.

Comment: Most commenters supported the collection of the Transfer of Health Information to Provider Post-Acute Care and Transfer of Health Information to Patient Post-Acute Care measures and certain standardized patient assessment data elements beginning in January 1, 2023, highlighting the importance of these measures and items in support of CMS quality efforts.

Response: We thank the commenters for their support of this proposal and outcome of these data collection efforts to further build on our ability to assess quality in HHAs.

Comment: Some commenters did not support our proposal to revise the compliance date for the Standardized Patient Assessment Data Elements while the PHE continued, and suggested that CMS defer collection until after the conclusion of the PHE.

Response: We considered the ongoing impact of the PHE, provisions implemented to support providers, including HHAs, in managing the PHE impacts and HHA management of care provision since the start of the PHE. Based on a review of the current impacts of the PHE on HHAs nationally, we believe HHAs are well-positioned to successfully collect these Standardized Patient Assessment Data Elements.

Final Decision: After consideration of the public comments, we are finalizing our proposal that HHAs will collect the Transfer of Health Information to Provider Post-Acute Care measure, the Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning January 1, 2023. We are finalizing that HHAs will begin collecting data on the two TOH measures beginning with discharges and transfers on January 1, 2023 on the OASIS-E. We are also finalizing that HHAs will collect data on the six categories of Standardized Patient Assessment Data Elements on the OASIS-E, with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) beginning on January 1, 2023.

D. Changes to the Home Health Conditions of Participation

1. Background and Statutory Authority

Since March 2020, CMS has issued a number of regulatory waivers in response to the COVID-19 PHE under the statutory authority granted the Secretary by section 1135 of the Act. That statute permits the Secretary to waive certain statutes and regulations during a public health emergency declared by the President, in order to expand healthcare system capacity while continuing to maintain public and patient safety, and to hold harmless providers and suppliers who may be unable to comply with existing regulations after a good faith effort. Specifically, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements (and associated provisions in Title XI) to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid and CHIP in the emergency area during the emergency period. In such circumstances, providers can be reimbursed and exempted from sanctions under these programs (absent any determination of fraud or abuse).

We have issued HHAs a variety of regulatory waivers. Sections 1861(o) and 1891 of the Act authorize the Secretary to establish the requirements that an HHA must meet to participate in the Medicare Program, and these conditions of participation (CoPs) are set forth in regulations at 42 CFR part 484. We waived selected requirements for HHAs within part 484 for the duration of the PHE. While some of these waivers simply delay certain administrative deadlines, others directly impact the provision of patient care. We have identified waivers related to the requirements for the supervision of home health aides at § 484.80(h)(1) and (2) that we believe will be appropriate as permanent policy. These proposed changes and their respective background information are discussed in detail below.

In addition, in order to implement section 115 of Division CC of the CAA 2021, we proposed to modify the requirements for the home health initial assessment visit and comprehensive assessment. This statutorily-required modification allows an occupational

therapist to complete the initial and comprehensive assessments for Medicare patients when occupational therapy is ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility. This would only be permitted if skilled nursing services have not been ordered.

2. Regulatory Provisions

We proposed the following revisions to the HHA CoPs.

a. Home Health Aide Supervision

Home health aides deliver a significant portion of direct home health care. Ensuring that aide services are meeting the patient's needs is a critical part in maintaining safe, quality care. At § 484.80(h)(1) and (2), we differentiate aide supervision requirements based on the level of care required by the patient. Aides caring for a patient receiving skilled care from nurses or therapists must currently have an on-site supervisory visit every 14 days, while aides caring for a patient who is not receiving skilled care must have an on-site supervisory visit every 60 days.

We believe the current 14-day on-site supervisory visit requirement when a patient is receiving skilled services is an important component to assessing the quality of care and services provided by the HHA aide, and to ensure that aide services are meeting the patient's needs. Currently, the regulations require that the 14-day supervisory assessment be conducted by the registered nurse (RN) or other appropriate skilled professional who is familiar with the patient, the patient's plan of care and the written care instructions as described in § 484.80(g). However, we believe it is important to permit HHAs to complete this assessment virtually, in the rare circumstance that an onsite visit cannot be coordinated within the 14-day time period.

We proposed that HHAs be permitted to use interactive telecommunications systems for purposes of aide supervision, on occasion, not to exceed 2 virtual supervisory assessments per HHA in a 60-day period. We proposed to revise the language at § 484.80(h)(1)(i) to require that if a patient is receiving skilled care (that is, skilled nursing, physical or occupational therapy, or speech language pathology services), the home health aide supervisor (RN or other appropriate

skilled professional) must complete a supervisory assessment of the aide services being provided, either onsite (that is, an in person visit) or by using interactive telecommunications systems to ensure aides are furnishing care in a safe and effective manner, no less frequently than every 14 days. The home health aide does not need to be present during this supervisory assessment. As outlined in regulation at § 484.80(h)(4), the home health aide supervisory assessment is required to ensure that the aide is furnishing care in a safe and effective manner, such as: following the patient's plan of care for completion of tasks assigned to the home health aide; maintaining an open communication process with the patient, representatives, caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring the patient's rights. We proposed to define interactive telecommunications systems as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. The use of interactive telecommunications systems for the aide supervisory assessment could not exceed 2 virtual supervisory assessments per HHA in a 60-day period, regardless of the number of aides or patients associated with a given HHA. If the supervising individual noted an area of concern during the 14-day supervisory assessment, the supervising individual would have to make an on-site in-person visit to the location where the patient was receiving care while the aide performed care, in order to observe and assess the aide, as required at § 484.80(h)(1)(ii) and (iii).

While we proposed to allow this flexibility, we expect that in most instances, the HHAs would plan to conduct the 14-day supervisory assessment during an on-site, in person visit, and that the HHA would use interactive telecommunications systems option only for unplanned occurrences that would otherwise interrupt scheduled in-person visits. Examples of circumstances in which a scheduled on-site in-person visit might not be able to be rescheduled timely within the 14-day window could include a severe weather occurrence, a patient requests

to change the date of the scheduled visit, or unexpected staff illness or absence on the planned day for the visit.

We did not propose changes to the requirements for annual aide assessments at § 484.80(h)(1)(iii). In addition to the regularly-scheduled 14-day supervisory assessment and as-needed observation visits for aides providing care to patients receiving skilled services, HHAs are required to make an annual on-site, in person, visit to a patient's home to directly observe and assess each home health aide while he or she is performing patient care activities. The HHA is required to observe each home health aide annually with at least one patient.

We also proposed revisions to the supervisory assessment requirements for aides providing care to patients who are not receiving skilled care services. At § 484.80(h)(2), we currently require that if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care from such aide. Such visits must occur at least once every 60 days in order to observe and assess each home health aide while he or she is providing care. This supervisory visit must be performed by a RN because these patients are not otherwise receiving HHA services from other professionals, such as therapists. We continue to receive feedback that this requirement is overly burdensome for the patient and the HHA if multiple home health aides provide care to the same patient. For instance, if a patient has three different home health aides providing care, the nurse is currently required to observe and assess each of the three home health aides while the aide is giving care to the patient. This circumstance would entail three separate nursing supervision visits on the same patient every 60 days. While we believe that the HHA's observation of an aide providing direct care to the patient is important to ensure quality, requiring a patient to receive three separate supervision visits every 60 days may be onerous on the patient and the HHA.

We proposed to maintain the first part of this requirement, that the registered nurse must make a visit in person every 60 days, but would remove the requirement that the RN must directly observe the aide in person during those visits. We would accomplish this by removing

the language from 42 CFR 484.80(h)(2) that states, “in order to observe and assess each home health aide while he or she is performing care,” and replacing it with “to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient’s needs”. In addition, we proposed to further revise the requirement to state that the home health aide would not need to be present during this visit. We believe that these proposed revisions from an on-site (direct) observation of each aide while performing care, to an indirect supervision visit to assess the adequacy of the aide care plan, the patient’s perception of services provided, and hear any concerns from the patient, may better support the patients’ needs by allowing for open communication between the nurse and patient. If the assessment found deficiencies in the aide’s performance, the agency would have to conduct (and the home health aide would have to complete) retraining and a competency evaluation for the deficient and all related skills.

In order to ensure appropriate RN supervision of HHA aides caring for patients who are not receiving skilled services, we proposed to add a new requirement to 42 CFR 484.80(h)(2) that would require the RN to make a semi-annual on-site visit to the location where a patient is receiving care in order to directly observe and assess each home health aide while he or she is performing care. This semi-annual in-person assessment would occur twice yearly for each aide, regardless of the number of patients cared for by that aide.

Supervisory visits allow professionals to evaluate whether aides are providing appropriate care as ordered by the patient’s plan of care. When RNs or qualified professionals identify a deficiency in aide services, § 484.80(h)(3) requires that the agency conduct, and the home health aide complete, retraining and a competency evaluation related to the deficient skill(s).

We proposed to maintain this requirement at § 484.80(h)(3), but to modify it by adding “and all related skills.” We believe that when a deficient area(s) in the aide’s care are assessed and verified by the RN, additional related competencies may reflect deficient practice areas that should be addressed. For example, if the patient informs the nurse that they almost fell when the

aide was transferring them from bed to a chair, the nurse should assess the aide's technique for transferring a patient in other circumstances beyond transfer to a chair, such as transferring from a bed to bedside commode or to a shower chair.

We requested public comment on our proposed changes to allow virtual supervisory assessments of home health aides for patients receiving skilled care at § 484.80(h)(1)(i), and for the proposed changes to supervision, competency assessment, and retraining for aides providing care to patients receiving all levels of HHA care. We especially welcomed comments from patients and caregivers who have experienced virtual supervisory assessments of home health aides during the PHE.

Comment: Some commenters recommended that CMS eliminate the 14-day home health supervisory visit entirely. However, these commenters did not provide rationale for this recommendation.

Response: We did not propose any changes to the 14-day home health aide supervisory visit at § 484.80(h)(1) other than permitting this visit to be conducted virtually, via interactive telecommunications systems, in the rare circumstance that an onsite visit cannot be coordinated within the 14-day time period. The supervisory visits are conducted when patients are receiving aide services in conjunction with skilled home health services such as skilled nursing, occupational therapy, physical therapy, and speech language pathology services. These visits are the opportunity to verify the aide is following the patient's plan of care; effectively communicating with the patient; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights. We believe these visits are an important component to ensuring that aides furnish care in a safe and effective manner.

Comment: Commenters overwhelmingly supported the proposed change to permit the 14-day home health aide supervisory visit to be conducted virtually, via interactive telecommunications systems, in the rare circumstance that an onsite visit cannot be coordinated

within the 14-day time period. However, some of these commenters expressed concerns regarding the frequency that HHAs would be permitted to exercise this flexibility. Commenters indicated that it would be difficult, if not impossible, for home health agencies to track these visits at the agency level to ensure compliance. Many commenters recommended that CMS apply the frequency so that the virtual visits would be permissible at the patient-level rather than the agency-level. Some comments recommended a specific frequency for each patient, such as one or two per patient per 60-day episode.

Response: In proposing the limit on HHA utilization of virtual home health aide supervisory visits at § 484.80(h)(1), we sought to balance the need for in-person visits with flexibility for unplanned circumstances that may prevent an HHA from complying with this requirement. However, many commenters have indicated that the requirement, as proposed, would be difficult to track and monitor making it ineffective, especially for large agencies. We do believe it important to have this flexibility without creating additional burden for agencies. We are therefore revising the requirement to implement the change at the patient-level. However, we believe the in-person visits are an important component to ensuring that aides furnish care in a safe and effective manner. Therefore, we intend to limit this virtual nurse aide supervisory visit to one per patient per 60-day episode and only in the rare circumstance, from an unplanned occurrence, that an onsite visit cannot be coordinated within the 14-day time period. In our proposed rule, we stated such occurrences may be from items such as, but not limited to, severe weather, a patient requesting to change the date of the scheduled visit, or unexpected staff illness or absence on the planned day for the visit. We believe these examples still apply. However, if the HHA finds it necessary to utilize this virtual option, the HHA will need to document in the patients record the rationale for the virtual visit.

Comment: Several commenters recommended conducting all aide supervisory visits virtually. A commenter recommended removing any artificial cap the number and letting the HHA decide on which visits would be appropriate to be conducted in-person and which would

be appropriate for virtual supervision.

Response: We believe the home health services 14-day supervisory visit for aide services at § 484.80(h)(1) should be conducted in-person to ensure that patients are receiving care in a safe and effective manner. Replacing this requirement with completely virtual supervisory visits would reduce oversight of key aspects of care provided by aides.

Comment: A commenter opposed the changes in home health aide supervisory visits permitting a virtual visit in rare circumstances at § 484.80(h)(1), stating that the proposed change is inconsistent with the provision of quality care and limits the ability of HHAs to assess aides. This commenter suggested more evaluation and study be conducted before making the change permanent. Another commenter indicated that virtual visits are subject to numerous problems that may hinder effective home health aide supervision. This commenter indicated that there are frequently technical and economic barriers to virtual visits. They also indicated that many patients prefer in-person visits and that these forge a strong relationship with patients. Finally, the commenter indicated that virtual aide supervision would hinder the nurse from assessing for changes in the patient's condition that would otherwise be detected with an in-person visit.

Response: We appreciate these comments and the concern for patient safety and quality of care. However, we are proposing this flexibility to facilitate compliance with this requirement in the rare circumstance that an HHA cannot complete the requirement due to unplanned occurrences. Therefore, we expect HHAs to exercise this provision rarely and not more than once per patient every 60-day episode of care. Additionally, we do not expect to see this provision exercised for every patient during every 60-day period. We expect that home health surveyors would investigate such instances while conducting inspection of the home agency and seek supporting narrative in the home health patient record describing why a virtual visit was conducted in each instance. In instances when barriers prevent a virtual supervisory visit via a 2-way audio-visual telecommunications system, such as no internet service or the patient is unable to utilize the telecommunications system, the agency would be non-compliant with the

supervisory visit requirement and would need to complete an in-person visit as soon as possible. Finally, the primary purpose of the aide supervisory visit at § 484.80(h)(1) is to assess the aide care plan and services provided by the aide rather than an assessment of the patient that occurs during the skilled visit. The discussion that occurs between the nurse and the patient during this visit allows for open dialogue regarding the aide's services outlined in the plan of care and services carried out by the aide. If in the conversation the nurse notes a potential issue with the aide's care, a competency skills check will be triggered. Therefore, we believe the type and frequency of patient visits provided the necessary supervision to support quality care.

Comment: Several commenters recommended CMS remove the 2-way audio-visual requirement as part of the proposed virtual aide supervisory visit.

Response: We appreciate the requests to remove the proposed language regarding 2-way audio-visual requirement as part of the virtual aide supervisory visit. While we understand some patients may not have access to the internet or the ability to use such technology; we believe it is imperative for the clinician to be able to see the patient during these 2-way audio-visual communications. Utilizing only the phone for audio communications does not allow the clinician to visualize the patient and assess areas such as wounds, mobility and circulation. In regards to the patient using audio-visual technology, being able to visualize the clinician they are speaking with assists in fostering and maintaining the patient and clinician relationship. If the patient does not have access to 2-way audio-visual technology, the agency would be non-compliant with the supervisory visit requirement and would need to complete an in-person visit. Therefore, we are finalizing the use of interactive telecommunications systems as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. The use of interactive telecommunications systems for the aide supervisory assessment must not exceed 1 virtual supervisory assessment per patient in a 60-day period, regardless of the number of aides or patients associated with a given HHA.

Comment: Many commenters were supportive of the proposed provision at § 484.80(h)(2) revising the supervisory assessment requirements for aides providing care to patients who are not receiving skilled care services, indicating that the change would significantly reduce burden for HHAs. These commenters stated that the on-site and virtual visits would provide the appropriate balance of supervision for this requirement. However, these same commenters also recommended that CMS monitor the feasibility for HHAs to conduct a semi-annual onsite, aide present, supervisory visit on their non-skilled patients. They stated that they have concerns with the logistics of conducting a semi-annual onsite visit, aide present, for all home health aides.

Response: We appreciate the opportunity to clarify this requirement. CMS has previously received feedback that the prior requirement of an onsite visit every 60 days for each aide providing services to non-skilled patients was overly burdensome for the patient and the HHA if multiple home health aides provide care to the same patient. Retaining the 60-day frequency but changing the requirement for the in-person direct observation of the aide to biannually will decrease the amount of times the HHA must observe each aide in-person. For instance, over the course of 180 days, an HHA providing aide services to a patient receiving care from three aides would be required to coordinate and provide a total of nine supervisor visits with both the nurse and the aide present. Under the new requirement, the HHA would still be required to conduct nine supervisory visits but would only have to coordinate as few as three in-person supervisory with both the nurse and the aide present. Although this will require some coordination and planning on the part of the HHA, we believe this will provide for more efficient planning and scheduling for HHAs from the prior requirements while still maintaining oversight to ensure adequate supervision of the services provided.

Comment: A commenter opposed the proposed change to aide supervision at § 484.80(h)(2) for patients that are not receiving skilled services, permitting this supervisor visit to be conducted without the aide present. The commenter suggested that more evaluation and

study be conducted before making the change permanent. Another commenter stated the proposed change results in the RN's assessment and observation of a home health aide occurring three times less frequently. The commenter stated that lack of frequent direct assessment of the home health aide by an RN could jeopardize a patient's health, safety, and ability to recover their highest level of function.

Response: We appreciate these comments regarding the health and safety of patients and concerns for ensuring home health aides provide quality care. An important component to addressing these concerns is ensuring that home health aides enter the workforce meeting minimum qualifications that includes training and competency evaluation. We have extensive requirements specifying the content and duration of home health aide classroom and supervised practical training at § 484.80(b), competency evaluation requirements at § 484.80(c), annual in-service training requirement at § 484.80(d), qualifications for instructors conducting classroom and supervised practical training at § 484.80(e), and eligibility requirements for training and competency evaluation organizations at § 484.80(g). These aspects are critical components to ensuring the aide workforce is adequately trained and qualified to provide home health aide services. Aides are assigned to specific patients with written care instructions for the services they will be providing. Additionally, they will be provided periodic supervision by one of the HHA skilled professionals. Therefore, we do not believe the extensive direct supervision requirements for patients receiving non-skilled services only are necessary and believe these have been overly burdensome for HHAs. Regardless, we do believe that direct observation of the aide while providing services is an important component of supervision. However, we also believe that patients should also have the opportunity to speak with the skilled professional without the aide present to provide the patient the opportunity to speak freely about any concerns they may have. We believe this is also an important aspect of the supervision component in hearing directly from the patient where some patients may be more reserved in sharing concerns if the aide were present. However, we do acknowledge the commenters concerns regarding the

frequency of oversight that has been proposed. We had proposed that each aide receive one direct observation every 6 months for one non-skilled patients for which the aide is providing services. We are revising this requirement so that the aide receives a direct observation every 6 months for each patient to whom the aide is providing services. This is a significant decrease in the planning and coordination for HHAs from the previous requirement of a direct observation supervisory visit for each patient every 60 days. However, it provides an increase in supervisory visits over what was originally proposed. We believe this strikes a balance is reducing burden while providing necessary direct observation in ensuring the health and safety of patients receiving home health aide services.

Comment: Several commenters requested clarification on the skills that would be considered related when a deficient skill was assessed during an aide supervisory visit. While other commenters requested additional examples, to promote consistency for applying this requirement and that CMS align the requirements with the hospice requirements.

Response: We appreciate the commenters support on this issue and the request for clarification. We believe that when a deficient area(s) in the aide's care are assessed and verified by the RN, additional related competencies may reflect deficient practice areas that should be addressed. For example, if the patient informs the nurse that they almost fell when the aide was transferring them from bed to a chair, the nurse should assess the aide's technique for transferring a patient in other circumstances beyond transfer to a chair, such as transferring from a bed to bedside commode or to a shower chair. We believe this is not a one size fits all in determining what is related. Every patient and aide presents a unique dynamic. Ultimately it is the supervising nurse's clinical judgement on a case by case basis to determine what additional competency areas are related.

Final Decision: After consideration of the public comments received, we are finalizing the 14-day aide supervisor visit at § 484.80(h)(1) with modification. Based on public comment, we intend to apply the changes at patient-level rather than the agency-level. Therefore, we will

permit the one virtual supervisory visit per patient per 60-day episode. This visit must only be done in rare instances for circumstances outside the HHA's control and must have documentation in the medical record detailing such circumstances. At § 484.80(h)(2) we are finalizing the supervisory visit requirements for non-skilled patients with modification. We are modifying the semi-annual onsite visit to require that this visit be conducted on "each" patient the aide is providing services to rather than "a" patient. Lastly, after consideration of the public comments we received at § 484.80(h)(3), we are finalizing the assessment of deficient skills as proposed.

b. Permitting Occupational Therapists to Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

On December 27, 2020, the CAA, 2021 was signed into law. Division CC, section 115 of the CAA 2021 requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy and skilled nursing services are not initially on the plan of care. We proposed to conforming regulation text changes at § 484.55(a)(2) and (b)(3), respectively to implement this provision.

Currently, the requirement at § 484.55(a)(2) provide that when rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. We proposed to add new language that allows the occupational therapist to complete the initial assessment for Medicare patients when skilled nursing is not initially on the plan of care, but occupational therapy is ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility. This is necessary because a need for

occupational therapy alone cannot initially establish program eligibility under the Medicare home health benefit (see section 1814(a)(2)(c) and 1835(a)(2)(A) of the Act). Similarly, at § 484.55(b)(3), we proposed to modify our regulatory language to allow an occupational therapist to complete the comprehensive assessment for Medicare patients when ordered with another qualifying rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility and when skilled nursing is not initially part of the plan of care. It should be noted that the statutory requirements for establishing Medicare program eligibility have not changed. Therefore, only the need for skilled nursing, physical therapy or speech language pathology services can initially establish eligibility for Medicare home health care. However, occupational therapy can maintain eligibility for Medicare home health care after the need for skilled nursing, physical therapy, and speech language pathology services have ceased (see sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act).

Comment: Many commenters were appreciative of the change proposing to permit occupational therapists to conduct the initial assessment visit and the comprehensive assessment for home health services but questioned why occupational therapy alone does not establish program eligibility. A commenter stated that occupational therapists address a wide range of patient populations and diagnoses with a focus on individual patient goals. The commenter stated that occupational therapy is often the most appropriate discipline to assess and evaluate the patient in their home environment and provide interventions to ensure that the patient is able to safely perform the activities and routines they need and want to do while in their home. This commenter requested that CMS support any Federal legislation to make occupational therapy a qualifying service. Another commenter questioned why CMS did not modify the Social Security Act to allow the need for occupational therapy to establish eligibility for home health services.

Response: We appreciate the commenters' support. The eligibility requirements for the coverage of home health services is specified at sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act. The statute permits payment for home health services when a patient is confined to a home

and has a need for skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy. Additionally, payment may also be made when a patient no longer has a need for these services but continues to need occupational therapy. Therefore, occupational therapy alone does not establish initial program eligibility. CMS does not have the statutory authority to permit occupational therapy to be a qualifying service. An act of Congress would be needed to change the statute.

Comment: Many commenters recommended that all rehabilitation therapists (occupational therapists, physical therapist, and speech language pathologists) be permitted to conduct the initial assessment visit and the comprehensive assessment for home health services, even when ordered concurrently with skilled nursing services. Commenters stated that this change would facilitate more timely access to home health services.

Response: The requirements for conducting the initial assessment visit and the comprehensive assessment for home health services are based on sections 1814(a)(2)(c) and 1835(a)(2)(A) of the Act regarding eligibility and payment for home health services. The requirements for these assessments are based on the professional disciplines that will be involved in, and coordinating, care for the patient. Therefore, when nursing is assigned to the case, it is likely the patient will have a greater need for nursing services than other services so we believe that skilled nurses should conduct the initial assessment visit and initiate the comprehensive assessment. In therapy-only cases, it would be appropriate for the therapist to conduct the initial assessment visit and the comprehensive assessment. We did not propose changes beyond those authorized under Division CC, Section 115 of The Consolidated Appropriations Act of 2021, but will consider this issue in future rulemaking.

Comment: A commenter sought clarification on the sequence of services between qualifying services and other Medicare covered services, specifically occupational therapy. The commenter requested clarification on whether or not the sequencing of disciplines providing services, as described in the Medicare Benefits Policy Manual (CMS Pub 100-02), Chapter 7,

Section 30.2.11, would be irrelevant following the proposed changes permitting occupational therapists to conduct the initial assessment visit and comprehensive assessment. The commenter wanted to know if occupational therapists would be able to conduct these tasks before other therapy disciplines.

Response: We appreciate the opportunity to clarify this policy. The change implementing Division CC, Section 115 of The Consolidated Appropriations Act of 2021 permits occupational therapists to conduct the initial assessment visit and comprehensive assessment in “therapy-only” cases. This is when occupational therapy is on the home health plan of care along with physical therapy and/or speech therapy, but skilled nursing services are not initially on the plan of care. If the physician-ordered plan of care contains orders for a qualifying service other than skilled nursing services (physical therapy and/or speech language pathology services), then occupational therapy may conduct the initial assessment visit and comprehensive assessment prior to the visits from other therapy disciplines; however, the occupational therapist will be required to determine eligibility for the Medicare home health benefit, including homebound status, as part of the initial assessment and comprehensive assessment. In “therapy-only” cases for Medicare patients, the sequence in the delivery of the type of therapy is irrelevant as long as the need for a qualifying service is established during the initial assessment visit and when the comprehensive assessment of the patient is completed in accordance with the regulations at § 484.55.

Final Decision: After consideration of the public comments we received, we are finalizing this provision as proposed.

c. Adequacy of Aide Staffing

As stated earlier, ensuring that aide services are meeting the patient’s needs is a critical part in maintaining safe, quality care. However, in 2019 MedPAC reported that between 1998

and 2017 home health visits declined by 88 percent. We sought information about the adequacy of aide staffing and solicited comments on the following:

- Whether home health agencies employ or arrange for (under contract) home health aides to provide aide services.
- The number of home health aides per home health agency (both directly employed and under contract), and whether the number has increased or decreased over the past 5 to 10 years.
- The average number of aide hours per beneficiary with aide service ordered on the plan of care.
- The effect of the public health emergency on the ability of HHAs to employ home health aides or arrange for (under contract) the provision of home health aide services.

Comment: Several commenters provided feedback regarding the adequacy of aide staffing. Some of these commenters stated they are experiencing a severe shortage of nurses. While other commenters stated they are experiencing shortages in all disciplines, RN, PT, OT, ST, social worker, and aide staffing. A commenter noted that there had been a 50 percent decrease in the number of aides and professional staff applying for positions. The commenter also stated that “the pandemic has caused many professionals to change course to stay at home with families, look for remote work opportunities, and remain employed in facilities where they feel safer due to the controlled environment”. Commenters also stated that field safety has become more of concern because of recent social unrest and the pandemic leaving some of our most vulnerable patient service areas under-staffed. A commenter stated that “agencies are increasingly not staffing for home health aides (current COVID-related circumstances aside). Instead of providing home health aides, agencies refer patients to their non-Medicare, private pay “affiliates” for related services, or cost-shift home health aides for patients dually enrolled in Medicare and Medicaid to Medicaid. In the case of Medicare Advantage, many plans simply do not allow home health aide services to be delivered. Denying access to Medicare-covered home health aides for help with activities of daily living as critical as bathing, toileting, grooming, skin

care, walking, transferring, and assistance with self-administered medications, puts enrollees at risk of being hospitalized or entering a nursing home because they do not get the support they need to stay safely at home. These practices are costly for Medicare and detrimental to the enrollee's health and wellbeing". Other commenters suggested that CMS should ensure that Medicare home health agencies serving beneficiaries who require Medicare-covered home health aide services meet the statutorily defined limit of 28 to 35 hours a week and that robust oversight is necessary to ensure that agencies provide necessary care.

Response: We appreciate the robust comments in response to the adequacy of aide staffing questions. Ensuring home health workforce staffing adequacy is an important concern and we take reported shortages seriously. We will continue to review the information received as we consider ways to ensure that aide services are meeting the patient's needs as such services are a critical part in maintaining safe, quality care.

d. Technical Correction (§ 484.50(d)(5))

In the May 2020 COVID-19 IFC (85 FR 27550), we amended the home health regulations by adding "or allowed practitioner(s)" to the CoPs.

Comment: A commenter noted that the "allowed practitioner" language is missing from § 484.50(d)(5).

Response: We did not propose this change in the proposed rule. However, we believe making this change in the final rule constitutes a minor technical change to our regulation, which conforms our rule to the statutory language. Therefore, we are making the suggested correction to § 484.50(d)(5).

V. Home Infusion Therapy Services: Annual Payment Updates for CY 2022

A. Home Infusion Therapy Payment Categories

Section 5012 of the 21st Century Cures Act (“the Cures Act”) (Pub. L. 114-255), which amended sections 1834(u), 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit, effective January 1, 2021. The Medicare home infusion therapy services 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 furnished by a qualified home infusion therapy supplier.

Section 50401 of the Bipartisan Budget Act (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 in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. The temporary transitional payment began on January 1, 2019 and ended the day before the full implementation of the home infusion therapy services benefit on January 1, 2021.

For the full implementation of the home infusion therapy services benefit on January 1, 2021, we established a unit of single payment for each infusion drug administration calendar day in the individual’s home. In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment must be established for different 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 required that the single payment amount reflect factors such as patient acuity and complexity of drug administration. In the CY 2020 HH PPS final rule with comment period (84 FR 60628), we finalized our proposal to maintain the three payment categories that were utilized under the temporary transitional payments for home infusion therapy services. The three payment categories group home infusion drugs by J-code based on

therapy type. The single payment amount for each payment category varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, and; therefore, ultimately reflects variations in infusion drug administration services. Payment category 1 comprises 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 comprises subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions and other highly complex intravenous infusions. We did not propose to make any changes to the three payment categories in CY 2022.

The categories and associated J-codes can be found in the MLN Matters article entitled “Billing for Home Infusion Therapy Services on or After January 1, 2021” (MM11880).⁹² This list will be updated as new drugs and biologicals are added to the DME LCD and determined to be “home infusion drugs.” The list of home infusion drugs and their respective payment categories do not need to be updated through rulemaking when a new drug is added to the DME LCD for External Infusion Pumps (L33794).⁹³ The payment category may be determined by the DME MAC for any subsequent home infusion drug additions to the DME LCD for External Infusion Pumps (L33794)⁹⁴ as identified by the following NOC codes: J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified). Payment category 1 would include any appropriate subsequent intravenous infusion drug additions, payment category 2 would include any appropriate subsequent subcutaneous infusion drug additions, and payment category 3 would include any appropriate subsequent intravenous chemotherapy or other highly complex drug or biologic infusion additions.

⁹² Billing for Home Infusion Therapy Services on or After January 1, 2021 (MM11880). <https://www.cms.gov/files/document/mm11880.pdf>

⁹³ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794>

⁹⁴ Local Coverage Determination (LCD): External Infusion Pumps (L33794). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794>

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 (SAD) exclusion list. Division CC, section 117 of CAA 2021 amended section 1861(iii)(3)(C) of the Act so that the previously detailed SAD exclusion in the definition of home infusion drug would not apply to a self-administered drug or biological on a SAD exclusion list if such drug or biological was included as a transitional home infusion drug under subparagraph (A)(iii) of section 1834(u)(7), and was identified by a HCPCS code described in subparagraph (C)(ii) of such section.

In the CY 2021 HH PPS final rule (85 FR 70337), we stated that Hizentra®, a subcutaneous immunoglobulin, was not included in the definition of “home infusion drugs” under the benefit beginning January 1, 2021, because it was listed on a SAD exclusion list maintained by the Medicare Administrative Contractors (MACs). We also stated that if it is removed from all the SAD exclusion lists, Hizentra® could be added to the home infusion drugs list in the future. After publication of the CY 2021 HH PPS final rule on November 4, 2020, CAA 2021 was signed into law on December 27, 2020. Division CC, section 117 of CAA 2021 amended the definition of home infusion drugs in section 1861(iii)(3)(C) of the Act as previously noted.

Hizentra® was included as a transitional home infusion drug according to the definition of such drug in section 1834(u)(7)(A)(iii) of the Act, and was identified by a HCPCS code (J1559) described in subparagraph (C)(ii) of such section of the Act. Therefore, consistent with the statutorily amended definition of “home infusion drug”, the home infusion therapy services related to the administration of Hizentra® are covered under payment category 2 under both the temporary transitional payment from 2019 to 2020, and the permanent benefit beginning January 1, 2021. The DME MACs maintain and update the list of home infusion drugs and their

respective payment categories for purposes of the home infusion therapy services benefit under the DME LCD for External Infusion Pumps (L33794). For these routine updates, we will implement such changes through the subregulatory change request process.

B. Payment Adjustments for CY 2022 Home Infusion Therapy Services

1. 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 CY 2020 HH PPS final rule with comment period (84 FR 60629) we finalized the use of the geographic adjustment factor (GAF) to adjust home infusion therapy payments for differences in geographic area wages rates based on the location of the beneficiary. We reminded stakeholders that the GAFs are a weighted composite of each Physician Fee Schedule (PFS) localities work, practice expense (PE) and malpractice (MP) expense geographic practice cost indices (GPCIs) using the national GPCI cost share weights. The periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The GPCIs and the GAFs are updated triennially with a 2-year phase in and were last updated in the CY 2020 PFS final rule. The next full update to the GPCIs and the GAFs will be in the CY 2023 PFS proposed rule. For CY 2022, there will be changes to the GAF values for the majority of localities located in California because CY 2022 is the last year of a 5-year incremental transition for the majority of the California localities implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93) (PAMA 2014). The CY 2022 PFS proposed GAFs are available on the PFS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched>.

In the CY 2020 HH PPS final rule with comment period (84 FR 60628), we stated that the application of the GAF would be budget-neutral, therefore there is no overall cost impact by

applying a budget-neutrality factor. We proposed to continue this practice and apply the GAF budget-neutrality factor to the home infusion therapy service payment rates whenever there are changes to the GAFs in order to eliminate the aggregate effect of variations in the GAFs. For CY 2022, the GAF standardization factor would equal the ratio of the estimated national spending total using the CY 2021 GAF to the estimated national spending total using the CY 2022 GAF. Estimates of national spending totals would use home infusion therapy benefit utilization data for CY 2020. We did not receive any comments on the proposal to use the CY 2022 GAFs to wage adjust home infusion therapy payments nor the proposal to continue the application of the GAF standardization factor.

Final Decision: We are finalizing the proposal to use the CY 2022 GAFs to wage adjust home infusion therapy payments for CY 2022. We are also finalizing our proposal to continue the apply a GAF budget neutrality factor to home infusion therapy payments whenever there are changes to the GAFs in order to eliminate the aggregate effect of variations in the GAFs. The CY 2022 GAF standardization factor that will be used in updating the payment amounts for CY 2022 will be 1.0001. The final CY 2022 GAF values will be posted as an addendum on the PFS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched> under the supporting documentation section of the CY 2022 Medicare Physician Fee Schedule Final Rule and posted on the Home Infusion Therapy Billing and Rates webpage.⁹⁵

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 are required to increase the single payment amount from the prior year (that is, CY 2021) by the percentage increase in the Consumer Price Index for all

⁹⁵ Home Infusion Therapy Services Billing and Rates. <https://www.cms.gov/medicare/home-infusion-therapy-services/billing-and-rates>.

Urban Consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity. Section 1834(u)(3) of the Act further states that the application of the productivity adjustment may result in a percentage being less than 0.0 for 1-year, and may result in payment being less than such payment rates for the preceding year.

The CPI-U for the 12-month period ending in June of 2021 is 5.4 percent and the corresponding productivity adjustment is 0.3 percent. Therefore, the final home infusion therapy payment rate update for CY 2022 is 5.1 percent.

3. Initial and Subsequent Visit Adjustment

In the CY 2020 HH PPS final rule with comment period (84 FR 60627), we finalized our policy that 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 will be increased 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. We reminded stakeholders that effective January 1, 2021 there were changes to the office/outpatient E/M visit code set (CPT codes 99201,99215) used to calculate the initial and subsequent visit payment amounts for home infusion therapy. These changes were adopted from the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see <https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management>) and include the deletion of code 99201 (Level 1 office/outpatient visit, new patient), and new values for CPT codes 99202 through 99215. The initial visit percentage increase will still be calculated using the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year; however, only new patient E/M codes 99202 through 99205 were used in the calculation, as the final policy indicates that the calculation is based on the relative

difference between the average of the new and existing patient E/M codes. For CY 2021, the initial visit percentage increase was calculated using the average difference between the CY 2021 PFS amounts for office/outpatient E/M existing patient visits (99211 through 99215) and the CY 2021 PFS amounts for office/outpatient E/M new patient visits (99202 through 99205). In the CY 2021 HH PPS final rule (85 FR 70340), we estimated a 19 percent increase in the first visit payment amount and a 1.18 percent decrease in subsequent visit amounts based on the average difference between the CY 2021 proposed PFS E/M codes amounts for new and existing patients. The percent increase remained 19 percent for the first visit payment amount and the percent decrease remained 1.18 percent for subsequent visit amounts using the final PFS E/M rates for new and existing patients.

Division N, section 101 of CAA 2021 added section 1848(t)(1) of the Act applied a 3.75 percent increase in PFS payment amounts only for CY 2021.⁹⁶ Division CC, section 113 of CAA 2021 also delayed the implementation of an add-on E/M code G2211 until CY 2024. Because the PFS relative value units (RVUs) are budget neutral, this delay in the implementation of the add-on code changed the RVUs for all codes under the PFS, including the E/M codes used to calculate the home infusion therapy service payment initial visit percent increase. The updated RVUs and conversion factor after the changes implemented by the CAA 2021 were used to recalculate the CY 2021 payment amounts for home infusion therapy services, and the percent difference used to calculate the initial visit percentage increase. As a result, the initial home infusion therapy service visits increase was updated to 20 percent and the decrease for subsequent visits was updated to 1.33 percent. We noted that the change in the percent increase for initial visits was driven by the delay of the code G2211. While the updated payment amounts (after the changes implemented by the CAA 2021) for the office/outpatient E/M codes were used to recalculate the initial visit increase, removing the 3.75 percent does not impact the average

⁹⁶ Medicare Learning Network Connects “Special Edition: Physician Fee Schedule Update” (Jan 7, 2021). <https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf>.

difference between the office/outpatient E/M codes for new patient visits and existing patient because the increase was applied equally. Therefore, after removing the adjustment, the percent increase remains 20 percent for the initial visit payment amounts and a 1.33 percent decrease for all subsequent visit payment amounts.

In the CY 2021 HH PPS final rule (85 FR 70339) we also stated that we would increase 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. Section 1834 (u)(3) of the Act requires the rates from the previous year to be updated by the percentage increase in the CPI-U for the 12-month period ending in June of the preceding year reduced by a productivity adjustment beginning in 2022. Therefore, we are to update the established payment rates for CY 2021 by the percentage increase in the CPI-U reduced by the productivity adjustment without recalculating the percent difference each year using the updated values for the PFS E/M codes for CY 2022 payment purposes. For CY 2022, we proposed to maintain the 20 percent increase calculated for the initial home infusion therapy service visits and the 1.33 percent decrease calculated for subsequent visits after implementation of the changes mandated by the CAA 2021, which we previously noted did not impact these percentages. Table 34 shows the updated E/M visit codes and the final unadjusted PFS payment amounts (without the 3.75 percent increase implemented by the CAA 2021) for CY 2021, for both new and existing patients, used to determine the increased payment amount for the first visit. We invited comments on our proposal to maintain the percentages calculated for initial and subsequent home infusion therapy service visits calculated after implementing the changes mandated by the CAA 2021. We did not receive any comments on our proposal to maintain the percentages for the initial and subsequent visits.

TABLE 34: AVERAGE PERCENT DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS

New Patient E/M Code	Unadjusted CY 2021 PFS Rates	Existing Patient E/M Code	Unadjusted CY 2021 PFS Rates	Percent Difference
		99211	\$22.20	NA
99202	\$71.30	99212	\$54.82	30%
99203	\$109.64	99213	\$89.12	23%
99204	\$163.79	99214	\$126.46	30%
99205	\$216.25	99215	\$176.57	22%
Total	\$560.98		\$469.17	20%

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021. The RVUs used to calculate the unadjusted CY 2021 rates are taken from CY 2021 PFS Final Rule Addendum B, version dated December 29, 2020 (Available at: <https://www.cms.gov/files/zip/cy-2021-pfs-final-rule-addenda-updated-12292020.zip>; Accessed on 3/17/2021).

Final Decision: We are finalizing the proposal to maintain the 20 percent increase calculated for the initial home infusion therapy service visits and the 1.33 percent decrease calculated for subsequent visits after implementation of the changes mandated by the CAA 2021, which we previously noted did not impact these percentages.

C. CY 2022 Payment Amounts for Home Infusion Therapy Services

As noted previously, Division N, section 101 of CAA 2021 amended added section 1848(t)(1) of the Act, which applied and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payment amounts only for CY 2021.⁹⁷ For CY 2022, we will remove the 3.75 percent increase from the PFS amounts used to establish the CY 2021 home infusion therapy payment rates and use the unadjusted CY 2021 rates for the CY 2022 home infusion therapy services payment amounts. Table E2 shows the CY 2021 unadjusted payment rates after removing the 3.75 percent increase. The unadjusted CY 2021 rates will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the 5.4 percentage increase in the CPI-U for the 12-month period ending in June of 2021 reduced by the productivity adjustment of 0.3 percent, which results in a 5.1 percent increase.

The unadjusted CY 2021 national home infusion therapy rates are located in Table 35. The final CY 2022 national home infusion therapy services 5-hour payment amounts are located in Table 36.

TABLE 35: CY 2021 UNADJUSTED PAYMENT RATES

⁹⁷ Medicare Learning Network Connects “Special Edition: Physician Fee Schedule Update” (January 7, 2021). <https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf>.

HCPCS	Description	CY 2021 National Final Payment Rates	CY 2022 Rate Step Down Adjustment	CY 2021 National Unadjusted Payment Rates
G0068	Adm iv infusion drug in home	\$160.18	÷ 1.0375	\$154.39
G0069	Adm sq infusion drug in home	\$216.43	÷ 1.0375	\$208.61
G0070	Adm of chemo drug in home	\$269.25	÷ 1.0375	\$259.52
G0088	Adm iv drug 1st home visit	\$194.81	÷ 1.0375	\$187.77
G0089	Adm subq drug 1st home visit	\$263.21	÷ 1.0375	\$253.70
G0090	Adm iv chemo 1st home visit	\$327.46	÷ 1.0375	\$315.62

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021.

TABLE 36: FINAL CY 2022 NATIONAL HOME INFUSION THERAPY SERVICES 5-HOUR PAYMENT AMOUNTS

HCPCS	Description	CY 2021 National Unadjusted Payment Rates	GAF Standardization Factor	CPI-U Reduced by Productivity Adjustment	Final 2022 HIT Payment Amount
G0068	Adm iv infusion drug in home	\$154.39	X 1.0001	X 1.0510	\$162.28
G0069	Adm sq infusion drug in home	\$208.61	X 1.0001	X 1.0510	\$219.27
G0070	Adm of chemo drug in home	\$259.52	X 1.0001	X 1.0510	\$272.78
G0088	Adm iv drug 1st home visit	\$187.77	X 1.0001	X 1.0510	\$197.37
G0089	Adm subq drug 1st home visit	\$253.70	X 1.0001	X 1.0510	\$266.67
G0090	Adm iv chemo 1st home visit	\$315.62	X 1.0001	X 1.0510	\$331.75

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021.

The geographically adjusted home infusion therapy services payment rates will be released in a forthcoming change request CR and posted on the Home Infusion Therapy Services Billing and Rates webpage.⁹⁸ For more in-depth information regarding the finalized policies associated with the scope of the home infusion therapy services benefit and conditions for payment, we refer readers to the CY 2020 HH PPS final rule with comment period (84 FR 60544). While we did not include CY 2022 payment amounts in the proposed rule, we did not receive comments on the approach used to calculate these rates.

Final Decision: The unadjusted CY 2021 rates will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the 5.4 percentage increase in the CPI-U for

⁹⁸ Home Infusion Therapy Services Billing and Rates. <https://www.cms.gov/medicare/home-infusion-therapy-services/billing-and-rates>.

the 12-month period ending in June of 2021 reduced by the productivity adjustment of 0.3 percentage point, which results in a 5.1 percent increase.

VI. Medicare Provider and Supplier Enrollment Changes

A. Background – Provider and Supplier Enrollment Process

1. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help CMS confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet Federal and state requirements to do so. The process is, to an extent, a “gatekeeper” that helps prevent unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare.

Since 2006, we have taken various steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges. One such requirement (outlined in § 424.510) is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) (hereafter occasionally referenced as “Medicare contractor” or simply “contractor”) the appropriate enrollment application, typically the Form CMS-855 (OMB Control No. 0938-0685). The Form CMS-855, which can be submitted via paper or electronically through the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09-70-0532, Provider Enrollment, Chain, and Ownership System) collects important information about the provider or supplier; such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider’s or supplier’s initial enrollment application, CMS or the MAC will review and confirm the information thereon and determine whether the provider or supplier meets all applicable Medicare requirements. We

believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

The previously-referenced regulations we have issued since 2006 clarified and strengthened certain components of the enrollment process. Moreover, they enabled us to take further action against providers and suppliers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent therewith, and as further discussed in section VI.B. of this final rule, we proposed several changes to our existing provider enrollment regulations in the proposed rule.

2. Legal Authorities

There were two principal sources of legal authority for our proposed provider enrollment provisions. Section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

B. Provisions

1. Effective Dates

We proposed to codify in regulation certain effective date practices discussed in CMS Publication 100-08, Program Integrity Manual (PIM) (or in other subregulatory guidance). We believed that incorporating these topics into 42 CFR part 424 would furnish needed clarification and allow the provider community to furnish public comments thereon.

a. Effective Date of Billing Privileges

Section 424.520 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, non-physician practitioners (NPP), physician organizations, NPP organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy

suppliers. This effective date is the later of: (1) the date of filing of a Medicare enrollment application that a Medicare contractor subsequently approved; or (2) the date that the provider or supplier first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that the seven aforementioned provider and supplier types can retrospectively bill for services when they have met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to--

- Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 100-707, enacted November 23, 1988), 42 U.S.C. 5121-5206 (Stafford Act), precluded enrollment in advance of providing services to Medicare beneficiaries.

Under the applicable PIM guidance, CMS had applied the effective date policies in §§ 424.520(d) and 424.521(a) to the following additional supplier types: (1) Part B hospital departments; (2) Clinical Laboratory Improvement Amendment labs; (3) intensive cardiac rehabilitation facilities; (4) mammography centers; (5) mass immunizers/pharmacies; (6) radiation therapy centers; (7) physical therapists; (8) occupational therapists; and (9) speech language pathologists.

We proposed to add these nine supplier types to the scope of §§ 424.520(d) and 424.521(a). Our specific regulatory changes were as follows:

First, we proposed in the title and opening paragraph of § 424.520(d) to replace the current enumeration of all seven provider and supplier types therein with a simpler, more generic reference to the “provider and supplier types” identified in paragraph (d)(2). This proposed classification would include the aforementioned seven provider and supplier types as well as the nine we proposed to add to § 424.520(d). Consistent with this change, we further proposed to:

- Redesignate existing § 424.520(d)(1) and (2) as, respectively, new § 424.520(d)(1)(i) and (ii).

- List the 16 previously referenced provider and supplier types as new § 424.520(d)(2)(i) through (xvi).

Second, and similar to our change to § 424.520(d), we proposed to revise the title and opening language of § 424.521 to broadly encapsulate the 16 affected provider and supplier types (for example, the title would list them as “certain provider and supplier types”) rather than to individually list all 16 of them in the title and opening paragraph. As part of this, we also proposed to--

- Redesignate existing § 424.521(a)(1) and (2) as, respectively, new § 424.521(a)(1)(i) and (ii); and

- List the 16 previously discussed provider and supplier types as new § 424.521(a)(2)(i) through (xvi).

b. Effective Dates of Reassignments and Form CMS-855O Enrollments

(1) Reassignments

A Form CMS-855R application (OMB Control No. 0938-0685) must be completed for any individual supplier (reassignor) who wishes to reassign his or her Part B benefits to an eligible entity or individual (reassignee) under § 424.80. Under the applicable PIM guidance, CMS applied the basic principles of §§ 424.520(d) and 424.521(a) to Form CMS-855R reassignments when establishing the effective date of the latter. To codify this in regulation, we proposed to add a new § 424.522, the title of which would state: “Additional effective dates.” Paragraph (a) of § 424.522 would specify that a reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS-855R is submitted if all applicable requirements during that period were otherwise met.

(2) Practitioner Enrolling Solely to Order or Certify via Form CMS-855O

Under § 424.507, a physician or other eligible professional (as that term is defined in § 424.506(a)) who orders or certifies covered-- (1) imaging services; (2) clinical laboratory services; (3) durable medical equipment, prosthetics, orthotics, and supplies; and/or (4) home health services must be enrolled in or validly opted-out of Medicare for the resulting claim to be eligible for payment. There are situations where a physician or other eligible professional indeed wishes to enroll to order and/or certify these services and/or items but is not seeking Medicare billing privileges. In this scenario, he or she will complete the Form CMS-855O (“Medicare Enrollment Application: Enrollment for Eligible Ordering, Certifying and Prescribing Physicians and Eligible Professionals; OMB Control #: 0935-1135). CMS or MAC approval of this application does not grant billing privileges but only permits the individual to order/certify the aforementioned services and/or items.

The PIM states that a Form CMS-855O enrollment effective date is the date on which the Medicare contractor received the application (as opposed to, for instance, the date the contractor approves the application). This permitted the individual to order/certify these services and items for a limited period prior to enrollment. To incorporate this in regulation, we proposed to state in new § 424.522(b) that the effective date of a Form CMS-855O enrollment is the date on which the Medicare contractor received the Form CMS-855O application if all other requirements are met.

c. Comments on Effective Date Proposals

We did not receive specific comments on the foregoing effective date proposals and are therefore finalizing them as proposed and without modification.

2. Rejections and Returns

a. Background and Distinction

Per § 424.525(a), CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

- The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information.

- The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

- The prospective institutional provider (as defined in § 424.502) does not submit the application fee (in accordance with § 424.514) in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

The PIM outlines additional factual situations in which an application could have been rejected.

The return of provider enrollment applications, too, is discussed in the PIM. In general, an application has been returned when one of the return grounds outlined in the PIM applied. These grounds typically involve situations where the provider's or supplier's submission constitutes, in essence, a non-application. This is different from a rejected application in that the latter: (1) does not automatically involve an invalid submission yet the application, for instance, failed to include certain information or documentation or contains erroneous data; and (2) can be remedied prior to any rejection via the provider's or supplier's submission of a corrected, revised, supplemented, or complete application.

As there has been uncertainty within the provider community regarding the difference between application rejections and returns as well as the grounds for both actions, we proposed to revise § 424.525 and to add a new § 424.526.

b. Rejection and Return Policies

(1) Rejections

The three previously discussed reasons in § 424.525(a) for rejecting an application are currently designated as, respectively, paragraphs (a)(1), (2), and (3). We proposed to include the following ten rejection scenarios (almost all of which had been identified as reasons for rejection

in the PIM) within the larger § 424.525(a)(1) category. This means that rejection in these ten situations would only occur if the provider or supplier failed to comply with the requirements of paragraph (a)(1) (for instance, furnishing correct and complete data) within the 30-day period stated therein. The scenarios in question would be designated as § 424.525(a)(1)(i) through (x) and are as follows:

- The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, social security number, contact information, and practice location information).

- The application is unsigned or undated.

- The application contains a copied or stamped signature.

- The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.

- The application is signed by a person unauthorized to do so under 42 CFR part 424, subpart P.

- For paper applications, the required certification statement is missing.

- The paper application is completed in pencil.

- The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

- The provider or supplier failed to submit all of the forms needed to process a Form CMS-855 reassignment package within 30 days of receipt. (For example, a newly enrolling physician who will be reassigning her benefits to a group practice submits a Form CMS-855R application but fails to submit an accompanying Form CMS-855I application.)

- The provider or supplier submitted the incorrect Form CMS-855 application. (For example, the provider submitted a Form CMS-855B when a Form CMS-855A application (Medicare Enrollment Application; Institutional Providers; OMB # 0938-0685) was required.)

Existing § 424.525(b), (c), and (d) address various operational aspects of our rejection policy. We did not propose to revise them. However, and to clarify the scope of § 424.525, we proposed in new § 424.525(e) that § 424.525 applies to all CMS provider enrollment application submissions, including: (1) Form CMS-855 initial applications, change of information requests, changes of ownership (CHOWs), revalidations, and reactivations; (2) Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB # 0938-0626) submissions; (3) Form CMS-20134 submissions; and (4) any electronic or successor versions of the forms identified in § 424.525(e)(1) through (3). Concomitant with this change, we proposed to remove the word “prospective” from § 424.525(a)(1), (2), and (3) and (b). This would clarify that these three rejection grounds apply to enrolled providers and suppliers and not simply to prospective enrollees.

(2) Returns

We proposed in new § 424.526(a) that the following situations constitute grounds for CMS’ or the contractor’s return of the provider’s or supplier’s application to the provider or supplier. These grounds, which were discussed in the PIM, would be designated as § 424.526(a)(1) through (13)---

- The provider or supplier sent its paper Form CMS-855, Form CMS-588, or Form CMS-20134 application to the incorrect Medicare contractor for processing. (For example, the application was sent to Contractor X instead of Contractor Y.)
- The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. (This would not apply to: (1) providers and suppliers submitting a Form CMS-855A application; (2) ambulatory surgical centers; or (3) portable x-ray suppliers.)
- The seller or buyer in a change of ownership submitted its Form CMS-855A or Form CMS-855B application more than 90 days prior to the anticipated date of the sale.

- The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from: (1) a provider or supplier submitting a Form CMS-855A application; (2) an ambulatory surgical center; or (3) a portable x-ray supplier.

- The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

- The provider or supplier submitted an initial enrollment application prior to the expiration of their existing reenrollment bar under § 424.535 or reapplication bar under § 424.530(f).

- The application is not needed for (or is inapplicable to) the transaction in question.

- The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.

- A Medicare Diabetes Prevention Program (MDPP) supplier submitted an application with a coach start date more than 30 days in the future. (That is, the application lists an MDPP coach who will commence his or her services beginning at least 31 days after the date the Medicare contractor receives the application.)

- The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.

- The provider or supplier submits an application that is an exact duplicate of an application that: (1) has already been processed or (2) is currently being processed or is pending processing.

- The provider or supplier submits a paper Form CMS-855 or Form CMS-20134 application that is outdated and/or has been superseded by a revised version.

- The provider or supplier submits a Form CMS-855A or Form CMS-855B initial enrollment application followed by a Form CMS-855A or Form CMS-855B CHOW application.

If the Medicare contractor has done either of the following:

++ Not yet made a recommendation for approval concerning the initial application, both applications may be returned in this scenario.

++ Made a recommendation for approval concerning the initial application, the Medicare contractor may return the CHOW application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS-855A or Form CMS-855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS-855A or Form CMS-855B application.

We also proposed in § 424.526 to explain certain operational components of our return policy. First, we proposed in § 424.526(b) that a provider or supplier may not appeal a return of their enrollment application. (Section 424.525(d) contains a similar provision for rejections.) Second, we proposed to effectively duplicate proposed § 424.525(e) in new proposed § 424.526(c) in order to clarify the types of enrollment applications and transactions to which § 424.526 would apply.

(3) Comments on Rejection and Return Proposals

We did not receive specific comments on the foregoing rejection and return proposals and are therefore finalizing them as proposed and without modification.

3. Deactivation

(a) Background

Regulatory policies regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or "reactivated") upon the submission of information required under § 424.540. As stated in § 424.540(c), deactivation is intended to protect the provider or supplier from the misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. A deactivated provider or supplier is not revoked from Medicare and remains enrolled in the program; also, per § 424.540(c), deactivation does not impact the

provider's or supplier's existing provider or supplier agreement. However, the provider's or supplier's ability to bill Medicare is halted pending its compliance with § 424.540's requirements for reactivation.

There are currently three grounds for deactivation under § 424.540(a), listed as, respectively, paragraphs (a)(1), (2), and (3):

- The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months.
- The provider or supplier does not report a change in its enrollment information within 90 calendar days of the change. (Changes in ownership or control must be reported within 30 calendar days.)
- The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit a revalidation application in accordance with § 424.515. (In addition, § 424.550(b) permits deactivation if the prospective new owner in a CHOW fails to submit a new enrollment application containing information concerning the new owner within 30 days of the CHOW. CMS may also deactivate in a CHOW situation if: (1) an incomplete CHOW application is submitted containing material omissions; or (2) CMS has information that makes it question whether the provider agreement will be transferred to the new owner.)

To reactivate one's billing privileges, § 424.540(b) states that the provider or supplier must: (1) recertify that their enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate; or (2) submit a complete Form CMS-855 application if required by CMS.

We constantly examine the effectiveness of our deactivation processes from both a program integrity and a provider impact perspective. Based on this monitoring, we proposed several changes to § 424.540 that we believed were necessary.

(b) Deactivation Grounds, Deactivation Effective Dates, and Reactivations

First, existing § 424.540(a) contains an opening clause followed by the three existing deactivation reasons, codified as paragraphs (a)(1), (2), and (3). We proposed to add several new deactivation grounds as paragraphs (a)(4) through (8); respectively, they would be as follows:

- The provider or supplier is not in compliance with all enrollment requirements in title 42.
- The provider's or supplier's practice location is non-operational or otherwise invalid.
- The provider or supplier is deceased.
- The provider or supplier is voluntarily withdrawing from Medicare.
- The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

Second, we proposed to revise § 424.540(b)(1) to state that for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in title 42.

Third, and consistent with existing policy, we proposed in new paragraph (d)(1)(i) to specify that, except as provided in § 424.540(d)(1)(ii), the effective date of a deactivation is the date on which the deactivation is imposed. In paragraph (d)(1)(ii), we proposed that CMS may apply a retroactive deactivation effective date--based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)--in the following instances (which would include our proposed new deactivation grounds, discussed previously):

++ For deactivation reasons § 424.540(a)(2), (3), and (4), the effective date would be the date on which the provider or supplier became non-compliant (for example, the expiration of the period in which the provider was required to report a change in its enrollment information).

++ For deactivation reason § 424.540(a)(5), the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

++ For deactivation reason § 424.540(a)(6), the date of death of the provider or supplier.

++ For deactivation reason § 424.540(a)(7), the date on which the provider or supplier voluntarily withdrew from Medicare.

++ For deactivation reason § 424.540(a)(8), the date of the sale.

(c) Payment Prohibition

We also proposed in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). We recognize that the PIM has permitted retroactive payment (once the provider or supplier is reactivated) for services furnished during the period of deactivation; current subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation. After careful reflection, however, we believed that the most sensible approach from a program integrity perspective is to prohibit such payments altogether. In our view, a provider or supplier should not be effectively rewarded for its non-adherence to enrollment requirements (for example, failing to respond to a revalidation request or failing to timely report enrollment information changes) by receiving payment for services or items furnished while out of compliance. We stated that proposed § 424.540(e) would not only be an important payment safeguard in this regard but also would: (1) clarify this important issue (which has created some confusion within the provider community); and (2) allow the public to furnish feedback on the topic.

(d) Additional Revisions

We also proposed three additional clarifications to the deactivation provisions in § 424.540.

First, the opening sentence of § 424.540(c) states that deactivation is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments. We believed this sentence was too restrictive in that it did not address other reasons for our deactivation policy. Therefore, we

proposed to delete it. (The existing second sentence of § 424.540(c) was to remain intact and comprise the whole of revised paragraph (c).)

Second, and as alluded to previously, the concluding sentence of existing § 424.540(a)(2) states that changes in ownership or control must be reported within 30 calendar days as specified in §§ 424.520(b) and 424.550(b). We proposed to clarify that our existing deactivation authority under § 424.540(a)(2) applies to both the changes that must be reported within 90 days and those within 30 days. Thus, we proposed to delete the existing version of this paragraph and stated that deactivation is permitted if the provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under Title 42.

Third, under the applicable PIM guidance, the effective date of a reactivation is generally the date on which the Medicare contractor received the application that was processed to completion. To clarify this policy in regulation, we proposed to add it as new § 424.540(d)(2) with one modification, in that the word “completion” would be replaced with “approval.” This would make clear that the contractor would have to actually approve the application (rather than merely complete the processing thereof) in order for the reactivation to become effective.

(e) Comments on Deactivation Proposals

We did not receive specific comments on the foregoing deactivation proposals and are therefore finalizing them as proposed and without modification.

4. HHA Capitalization

Under §§ 489.28(a) and 424.510(d)(9), an HHA entering the Medicare program - including a new HHA resulting from a change of ownership if the latter results in a new provider number being issued - must have sufficient funds (known as initial reserve operating funds) available: (1) at the time of application submission; and (2) at all times during the enrollment process, to operate the HHA for the 3-month period after the Medicare contractor conveys billing privileges (exclusive of actual or projected accounts receivable from Medicare). This means that

the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

To enable CMS or the MAC to verify compliance with the requirements of §§ 489.28(a) and 424.510(d)(9), the HHA must submit adequate proof of the availability of initial reserve operating funds. Section 489.28(d) states that such proof must include, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA. With respect to borrowed funds, § 489.28(e) states that if such funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a statement similar to the bank/financial institution officer attestation referenced in § 489.28(d).

CMS has recently learned that several national bank chains are no longer providing these attestation statements, thus hindering the ability of HHAs to comply with § 489.28(d) or (e). To remedy this, we proposed to insert the phrase “(if the financial institution offers such attestations)” after the term “financial institution” as used § 489.28(d) and (e).

We did not receive specific comments on this proposal and are therefore finalizing it as proposed and without modification.

5. HHA Changes of Ownership

Section 424.550(b) states that if there is a change in majority ownership of an HHA by sale within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the HHA's provider agreement and Medicare billing privileges do not convey to the new owner (hereafter occasionally referenced as the “36-month rule”). Instead, the prospective provider/owner of the HHA must: (1) enroll in Medicare as a new (initial) HHA; and (2) obtain a state survey or accreditation.

Section § 424.550(b) contains several exceptions to the previously referenced requirement to enroll as a new HHA. One exception (identified in § 424.550(b)(2)(i)) is that the HHA has submitted 2 consecutive years of full cost reports. There has been uncertainty within the provider community as to whether this particular exception applies only to the 2-year cost report period after initial enrollment or also to 2-year cost report periods after the HHA's previous change in majority ownership. To clarify this, we proposed to revise the first sentence of § 424.550(b)(2)(i) to specify that the HHA submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. (The second sentence of § 424.550(b)(2)(i), which clarifies that low utilization or no utilization cost reports do not qualify as full cost reports for purposes of § 424.550(b)(2)(i), would remain intact.)

We did not receive specific comments on this proposal and are therefore finalizing it as proposed and without modification.

C. Miscellaneous Comments

We received the following three comments from stakeholders concerning our proposed enrollment provisions as a whole.

Comment: A few commenters expressed support for the codification into regulation of the previously-discussed sub-regulatory guidance. However, one of these commenters requested that CMS: (1) update the paper enrollment forms to mirror the PECOS system; and (2) explain when paper forms are required instead of submission via Internet-based PECOS.

Response: We appreciate the commenters' support for our proposed codifications. However, we believe that the commenter's two requests are outside the scope of this rule.

Comment: A commenter requested that CMS permit hospitals to update their Form CMS-855A enrollment to furnish home infusion therapy (HIT) and to provide durable medical equipment (DME) to support HIT. The commenter did not believe that hospitals should have to separately enroll as a HIT supplier or DME supplier to provide these services and items.

Response: We appreciate this comment but believe it is outside the scope of this rule.

VII. Survey and Enforcement Requirements for Hospice Programs

A. Background

Hospice care, as referenced in our regulations at § 418.3, means a comprehensive set of services described in section 1861(dd)(1) of the Act. These services are identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care that is individualized and person-centered. Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for the relief of pain and symptom management. Medicare regulations at § 418.3 define “palliative care” as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. Palliative care that is patient-centered and individualized is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice program uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, to make the beneficiary as physically and emotionally comfortable as possible.

As referenced in hospice program regulations at § 418.22(b)(1), to be eligible for Medicare hospice program services, the patient’s attending physician (if any) and the hospice program medical director must certify that the individual is “terminally ill,” as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3. Under this definition, an individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. Under the Medicare hospice program benefit, the election of hospice program

care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group (IDG) is essential in the seamless provision of primarily home-based services.

As noted in § 489.10(b), in order to be certified in the Medicare program, hospice programs must comply with applicable civil rights laws,⁹⁹ including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at: <http://www.hhs.gov/ocr/civilrights>.

1. Medicare Participation and Survey Activity

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and the implementing regulations in 42 CFR part 418, establish eligibility requirements, payment standards, and procedures; define covered services; and delineate the conditions a hospice program must meet to be approved for participation as a provider in the Medicare program. Part 418, subpart G, provides for a per diem payment based on one of four prospectively-determined rate categories of hospice care (routine home care, continuous home care, inpatient respite care, and general inpatient care), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is meant to cover all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act.

Section 1864(a) of the Act authorizes the State survey agencies (SAs) or other appropriate local agencies, under an agreement with CMS, to perform surveys of health care

⁹⁹ Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

providers and suppliers to assess their compliance with the applicable Medicare conditions.

There are several types of surveys conducted, including initial surveys (to receive initial certification), recertification surveys (to maintain certification), complaint surveys (to investigate complaints), and surveys for validation of the results of accrediting organization (AO) surveys.

Only the SA or we may survey certain provider types because a CMS-approved AO option does not exist for their type, while others cannot be surveyed by SAs in accordance with the statute but can only be accredited by a CMS-approved AO (such as providers of the technical component of advanced diagnostic imaging). Based on the SA recommendations from survey findings, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

2. CMS Requirements for AOs Approved to Deem Hospice Programs

Section 1865(a) of the Act allows most health care facilities to demonstrate their compliance with the Medicare conditions through accreditation by a CMS-approved program of an AO, instead of being surveyed by SAs for certification. Currently, CMS-approved accreditation programs for facilities under section 1865(a) of the Act include ambulatory surgical centers (ASCs); hospitals; critical access hospitals (CAHs); home health agencies (HHAs); hospices; outpatient physical therapy (OPT) facilities; end-stage renal disease (ESRD) facilities; and rural health clinics (RHCs). This is referred to as “deeming” accreditation. This is because CMS-approved AOs are recognized by the Secretary as having programs with accreditation standards that meet or exceed those of Medicare. Therefore, any provider or supplier that is accredited by an AO under a CMS-approved accreditation program is deemed by CMS to have also complied with the applicable Medicare conditions or requirements. Accreditation by an AO is generally voluntary on the part of the providers and suppliers, as they have the choice to seek accreditation from an approved AO or seek Medicare certification through the SA.

CMS is responsible for—(1) providing continuous oversight of the AOs’ accreditation programs to ensure that providers or suppliers accredited by the AOs meet the required Medicare

conditions or requirements; (2) ensuring that the AOs have formalized procedures to determine whether the health care facilities deemed under their accreditation programs meet the AO's accreditation standards (which must meet or exceed the applicable Medicare program requirements); and (3) ensuring that the AO's accreditation standards and practices for surveying providers and suppliers meet or exceed the Medicare conditions and practices for approving.

The current regulations at §488.4 set forth the general provisions for CMS-approved accreditation programs for providers and suppliers. The requirements at § 488.5 set out application and re-application procedures for national AOs that seek to obtain CMS approval of their accreditation programs, often called "deeming authority." These regulations task CMS with the responsibilities of approval and oversight of the AOs' accreditation programs.

As of March 2021, there are three AOs with CMS-approved hospice accreditation programs: Accreditation Commission for Health Care, Inc. (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). These three AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half.

B. Regulatory Provisions

1. Overview

Division CC, section 407 of the CAA 2021, amended Part A of Title XVIII of Act to add a new section 1822 to the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. There are nine new survey and enforcement provisions. The law requires public reporting of hospice program surveys conducted by SAs and AOs, as well as enforcement actions taken as a result of these surveys, on the CMS website in a manner that is prominent, easily accessible, searchable, and presented in a readily understandable format. It also removes the prohibition at section 1865(b) of the Act of public disclosure of hospice surveys performed by AOs, requiring that AOs use the same survey deficiency reports as SAs (Form CMS-2567, "Statement of Deficiencies" or a successor form) to

report survey findings. The law requires programs to measure and reduce inconsistency in the application of survey results among all surveyors. The law requires the Secretary to provide comprehensive training and testing of SA and AO hospice program surveyors, including training with respect to review of written plans of care. The statute prohibits SA surveyors from surveying hospice programs for which they have worked in the last 2 years or in which they have a financial interest, requires hospice program SAs and AOs to use a multidisciplinary team of individuals for surveys conducted with more than one surveyor (to include at least one registered nurse (RN)), and provides that each SA must establish a dedicated toll-free hotline to collect, maintain, and update information on hospice programs and to receive complaints. Finally, the law directs the Secretary to create a Special Focus Program (SFP) for poor-performing hospice programs, sets out authority for imposing enforcement remedies for noncompliant hospice programs, and requires the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. These enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program. These remedies include civil money penalties (CMPs), suspension of all or part of payments, and appointment of temporary management to oversee operations.

The provision requiring a new hospice program hotline is effective 1 year after the CAA 2021 enactment (that is, December 27, 2021). Most other provisions are effective on October 1, 2021, including the following—the requirement to use multidisciplinary survey teams, the prohibition of conflicts of interest, expanding CMS-based surveyor training to AOs, and the requirement for AOs with CMS-approved hospice accreditation programs to begin use of the Form CMS-2567 (or a successor form). The public disclosure of survey information and the requirement to develop and implement a range of enforcement remedies is effective no later than October 1, 2022. The other provisions in the legislation were effective upon enactment of the CAA 2021.

In the proposed rule, we proposed a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public. Our goals include: (1) maintaining the public trust through addressing conflicts of interest and improving survey transparency; (2) addressing inconsistency within the survey process through training and survey team composition and use of common hospice program deficiency reporting mechanisms; and (3) ensuring hospice programs are held accountable for addressing identified health and safety issues. The statutory requirements outlined in the CAA 2021 will address CMS' goals and are in the best interest of patients who receive care in Medicare-participating hospice programs.

We proposed to add new subparts M and N to 42 CFR part 488 to implement the CAA 2021 requirements. Subpart M would provide survey and certification processes while subpart N would provide the enforcement remedies for hospice programs with deficiencies that are not in compliance with Medicare participation requirements. The proposed enforcement remedies for hospice programs with deficiencies are similar to the alternative enforcement sanctions available for HHAs with deficiencies. We proposed to amend §§ 488.2 and 488.28, where appropriate, to include the reference to a hospice program. In addition, we proposed to amend termination and appeal requirements in 42 CFR parts 489 and 498 based on the proposed enforcement remedies.

We received 35 timely pieces of correspondence from hospice industry associations, patient advocacy organizations, AOs with hospice programs, and individuals.

Comment: Multiple commenters expressed support for the steps Congress and CMS are taking to ensure high-quality hospice care and consistent hospice program survey process throughout the nation.

Response: We appreciate the support from the public and agree that ensuring high-quality, safe care for all patients in Medicare-certified hospice programs is paramount and that a consistent survey and enforcement process will help ensure quality.

2. Subpart A--General Provisions

a. Statutory Basis (§§ 488.2 and 498.1)

The CAA 2021 amended Part A of title XVIII of the Act to add section 1822 of the Act on hospice program survey and enforcement procedures. We proposed to amend the requirement at §§ 488.2 and at 498.1 to include this statutory reference to hospice program services. We received no public comments on these provisions, and we are finalizing the regulations at § 488.2 and at § 498.1 as proposed.

b. Application and Re-Application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require the AOs, as part of a hospice program AO's application and reapplication process, to submit a statement acknowledging that the AO will include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document findings of the hospice program Medicare CoPs under section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

Currently, the regulations under § 488.5 do not require AOs to utilize the same forms as SA surveyors when documenting survey findings of noncompliance. Specifically, § 488.5(a)(4)(ii) in part states that AOs with CMS-approved programs must submit documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting Federal Medicare surveys for the same provider or supplier type. Therefore, AOs are not required to and do not utilize the Form CMS-2567 to report their survey findings, nor do they use the same software system used by SAs to capture the information. Each of the three AOs with CMS-approved hospice program deeming authority has a unique software system that is proprietary to the organization and develops a unique survey report for their deemed hospice organizations. These systems are platforms for AO/client communication as well as document storage and are unique to the AOs standards and process, which may meet or exceed those of CMS. The AO's survey

reports, provided to hospice program clients, set out the deficiencies related to CMS requirements, as well as any additional AO standards combined into one report.

The Form CMS-2567 Statement of Deficiencies and Plan of Correction¹⁰⁰ is the legal, documentary basis for how SAs and CMS Federal surveyors note findings of compliance or noncompliance (deficiencies) resulting from an inspection of Medicare-participating providers and suppliers. Our regulations at § 488.18 require that SAs document all deficiency findings on a statement of deficiencies, which is the Form CMS-2567.

Additionally, §§ 488.26 and 488.28 further delineate how findings must be recorded and that CMS prescribed forms must be used. The Form CMS-2567 is used to state concisely and in a standard format, whether or not any deficiencies were identified during a survey, including the evidence to support each finding. Following the survey, the provider/supplier will use the form to document their plan for correcting the identified deficiencies.

The completed Form CMS-2567 exists in PDF format and is also compiled by the CMS Automated Survey Processing Environment (ASPEN) survey software, which is the current national database, designed to help SAs collect and manage healthcare provider data. CMS is in the process of transitioning the ASPEN software system to a new, web-based Internet Quality Improvement and Evaluation System (iQIES).¹⁰¹ In mid-2021, CMS began transitioning to the new software system on a program-specific implementation schedule, starting with HHAs. It may take several years to fully transition all programs to the new technology platform, and CMS will continue to evaluate documentation needs, make necessary system adjustments with each program that transitions, and train surveyors on system use.

Currently, AOs are able to access the online PDF version of the Form CMS-2567 but do not have access to the CMS ASPEN system, as this software was only designed and distributed for use by SAs and CMS employees. CMS and the AOs must therefore determine the systems

¹⁰⁰ CMS-2567 available at: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2567.pdf>

¹⁰¹ iQIES is available at: <https://iqies.cms.gov/>

process for the inclusion and subsequent collection of the Form CMS-2567 as part of all deemed hospice program surveys completed by AOs. CMS already requires all AO survey reports to identify the comparable Medicare CoPs for each finding of noncompliance with accreditation standards (§ 488.5(a)(4)(iv)). Therefore, in order to meet the new statutory requirement for hospice program AOs to also use the Form CMS-2567 (or a successor form), each of the three CMS-approved hospice program AOs must now develop a way to incorporate this form into their data systems.

As required by § 488.5(a)(11)(ii), AOs submit their survey findings to CMS. The database, *Accrediting Organization System for Storing User Recorded Experiences* (ASSURE), is currently used by AOs to provide CMS with survey data from its deemed facilities. The ASSURE system requires the AO to match its specific survey findings and comparable AO standards to the Medicare conditions or requirements by uploading a spreadsheet text file, designed based on the data fields in the system, or by manually inputting the information. At this time, the ASSURE system does not and cannot develop a statement of deficiencies Form CMS-2567, as ASPEN does for SA surveyors because ASSURE was designed to capture survey details and findings based on the requirements for AOs at § 488.5.

CMS is continuing to assess the systems revisions needed for each of the three database options (ASPEN, ASSURE, and iQIES) to determine if one of the systems could be a future vehicle for hospice program AOs to document their survey findings in the same manner as SAs and subsequently have those forms easily captured by CMS for reporting purposes. Since ASPEN and ASSURE are nearing the end of their lifecycle, as CMS transitions to iQIES, it may not be prudent for CMS to invest resources and redistribute funding intended to update the future system to update legacy systems. At this time, it is most important for AOs to develop a way of incorporating the Form CMS-2567 into their documentation systems. As their systems are proprietary, CMS is unable to tell the AOs exactly how to incorporate the Form CMS-2567, but

we will work with the AOs to determine how their version can be submitted to CMS via electronic data exchange.

Separately from the systems issues, the existing format of the Form CMS-2567 must be modified, as it does not currently have a place for the name of the AO that is performing the survey as this form was historically only used by SAs. Consequently, the form directions do not refer to AOs. Since this is a public document that is frequently used by consumers, advocacy groups, and the public as a source of information about the quality of care and facility compliance, CMS must make updates to the form to include AO information so it is clear who performed the survey. CMS sought Office of Management and Budget (OMB) approval of this revised form for information collection, in accordance with provisions of the Paperwork Reduction Act (PRA). For further discussion on PRA implications and timeline, see the collection of information requirements in section XI of this final rule.

We sought public comment on how AOs can customize their proprietary systems to incorporate a version of the Form CMS-2567 and then submit it to CMS via electronic data exchange.

Comment: Several commenters supported the requirement for AOs to utilize the same forms as SA surveyors when documenting survey findings of noncompliance and noted it will promote consistency and standardization.

Response: We thank the public for their support and believe this is one step to ensuring consistency and transparency for the survey process.

Comment: Several commenters asked that CMS engage stakeholders when revising the Form CMS-2567. A suggestion was also made that CMS create and offer an electronic version of the form to all states and AOs.

Response: Given the timeline mandated by the CAA 2021 and the timing of this final rule, CMS needed to quickly revise the existing Form CMS-2567 in order for AOs to integrate it into their documentation systems for use. As required by the Paperwork Reduction Act of 1995

(PRA) requirements, CMS posted public notice of the proposed form changes for a 30-day comment period beginning July 13, 2021. 86 FR 36751. We received one comment on the Form CMS-2567 which was outside the scope of the information collection request. We made the necessary minimal updates to the form, that were needed for AO use, which we described in the proposed rule, 86 FR 35969, 35988, and in the public notice of proposed form changes, 86 FR 35874. If CMS decides to make further revisions to the form, it will go through public notice process again as required by the PRA.

Additionally, as noted in the proposed rule discussion, CMS has begun transitioning to the new software system on a program-specific implementation schedule, starting with HHAs. While it may take several years to fully transition all programs to the new technology platform, SAs and AOs will have access to this system. The Form CMS-2567 is currently generated electronically through the CMS software system and will continue to be as we transition systems and provide additional user access. As the rule notes, the requirement is for the inclusion of a statement of deficiencies, which means the Form CMS-2567 or a successor form. CMS will communicate with stakeholders if we move away from the Form CMS-2567 to a different format.

Comment: A few commenters noted that AO standards contain requirements that exceed those of CMS. The commenters believe that CMS should only require Medicare CoP requirements on the Form CMS-2567 because any additional AO requirements that exceed Medicare CoPs are proprietary standards. In addition, commenters believed it could be confusing to the public if different requirements were listed for each AO and reported on for hospices. Similar to the comment regarding AO standards that exceed CMS requirements, a commenter also questioned whether Form CMS-2567s would also include state licensure requirements.

Response: We explained in the proposed rule that changes to the Form CMS-2567 would require OMB approval via notice and comment, and that process would be separate from the

rulemaking for this rule. 86 FR 35988. As noted above, CMS has recently updated the Form CMS-2567 pursuant to the process required by the PRA, including posting the proposed changes for public comment. We made minimal changes to the form, and we have no plans to update the form again to include any AO- or State-specific requirements.

We note that including the Form CMS-2567 in AO reports of survey findings is required by the statute and is one step towards providing hospice patients and families information needed to make decisions on where they wish to receive care, and we want that information to be as clear and useful as possible. Since Medicare participation is partially based on the findings of compliance surveys, which are used to determine whether a hospice program meets the Medicare CoPs, we noted in the proposed regulation, that AOs must include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document survey findings for the hospice Medicare CoPs. Although AOs are required to include the Form CMS-2567 in their reports to CMS, this regulation does not require AO surveyors to use the form. For example, while one AO may require its surveyors to use the Form CMS-2567 to record survey findings, another AO may continue to allow its surveyors to use its proprietary survey forms and then translate the survey findings to Medicare CoPs on the Form CMS-2567.

Section 1865(a)(1) of the Act requires that for most provider entities, including hospices, if the Secretary finds that the requirements for accreditation from an AO demonstrate that a provider entity meets or exceeds all applicable conditions, the Secretary must deem such requirements to be met. The statutory language of “meets or exceeds” currently allows AOs to develop additional standards that differ from those of Medicare. When an AO applies for “deeming authority,” we determine whether its standards meet or exceed ours. With the required inclusion of the Form CMS-2567, we are not restricting AOs from using accreditation standards that exceed the Medicare CoPs. However, including the AO findings of the Medicare hospice CoPs on the Form CMS-2567 allows CMS to post hospice program survey reports from SAs and AOs in a manner that is standardized across both types of surveying entities. We believe that

including only CMS requirements, and not state-specific licensure or AO-specific requirements that vary across states and AOs, provides for consistency and avoids confusion. AOs may still use additional standards that exceed the Medicare CoPs, but documentation of whether hospice programs meet those additional standards would not be on the Form CMS-2567.

Comment: A commenter expressed concern that incorporation of the Form CMS-2567 into AO data systems could result in the duplication of data.

Response: AO data systems are proprietary and therefore CMS is not able to address specifics of how AOs will implement the Form CMS-2567 into their systems. However, as part of the existing regulations at §488.5(a)(4)(iv), AO survey reports must identify for each finding of non-compliance with accreditation standards, the comparable Medicare CoP, conditions for coverage, conditions for certification, or requirements. Therefore, this data already exists in some form with each AO survey report. Adding the requirement to include the Form CMS-2567 (or a successor form) only changes the format and not the data included. Additionally, we are not restricting the AO from reporting survey findings in their existing AO format to their accredited facilities. AOs would only need to extract the data related to the Medicare CoPs into the Form CMS-2567 (or a successor form) for our purposes. Ultimately, the information will align and be mirrored, but not duplicative.

Comment: A commenter asked if there would be an opportunity for hospice programs to preview the forms before they are submitted to CMS to verify the accuracy of the reported information and to use internally to act to correct the issues. Additionally, the commenter asked what would happen if a deficiency is corrected during the survey process.

Response: We thank the commenter for their clarifying questions and note that this rule does not change the existing survey process outlined in the State Operations Manual at Chapter 2 and Appendix M related to completing the statement of deficiencies and submitting it to the facility for review and response.

Comment: A few commenters requested that CMS clarify if AOs were required to also have facilities use the form to submit their plan of correction (POC) for identified non-compliance. They stated the Form CMS-2567 formatting is antiquated and that AOs have electronic or customer portal POC formats that guide the hospice to create a strong POC, inclusive of all specific actions to be taken, date correction to be completed, and individual responsible for correction process to prevent recurrence with monitoring of corrective actions to ensure they effectively prevent a recurrence. Commenters encouraged CMS to allow AOs to continue the use of their electronic POCs and not require POC documentation on the Form CMS-2567 itself.

Response: The Form CMS-2567 has a section for listing the deficiencies and another section for providers to document their POC. In 2017, CMS indicated that providers may document POCs in a separate document instead of on the form itself. Stakeholders may refer to CMS memorandum S&C:17-34-ALL which can be found at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-34.pdf>.

Hospice programs have the flexibility to document their POCs in their preferred format, including the format currently used by an AO. It is important to note that all elements of an acceptable POC, as outlined in the State Operations Manual, Chapter 2, Section 2728B, are still required regardless of which format or document is used.

Comment: Most commenters expressed serious concerns about the October 1, 2021, statutory deadline and urged CMS to provide enough time for AOs to adapt their technology systems to include the use of the Form CMS-2567. Specifically, AOs with hospice programs stated that the proposed rule did not provide critical information on the process and timing for submitting the Form CMS-2567 and therefore they do not have the information necessary to build their data systems for reporting purposes. AOs reported their need to analyze specifications, design solutions, create new processes, and then perform testing on their systems.

Several commenters also noted the need to provide training to familiarize surveyors and other staff with any new processes and procedures that allow for completion and submission of the Form CMS-2567 to CMS. The AOs and several commenters stated CMS should either ask Congress for an extension of the October 1, 2021, statutory deadline or delay at least 3 to 6 months for inclusion and use of the form.

Response: We appreciate the concern and understands that it takes time for AOs to adapt their systems to include the requisite form and then submit it in a manner specified by CMS. We thank commenters for their detailed feedback and note that CMS will develop associated guidance to address many of the concerns raised by commenters regarding the October 1, 2021, deadline, submission, and formatting/reporting. In accordance with §488.8(b), CMS specifies in a written notice any changes that affect accrediting organizations and provides a timeframe to submit its proposed equivalent changes.

Final Decision: After consideration of the public comments we received, we are finalizing the regulation at § 488.5(a)(4)(x) as proposed.

c. Release and Use of Accreditation Surveys (§ 488.7)

We proposed to add a new § 488.7(c), which would require the posting of the Form CMS-2567 in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates. Prior to the CAA 2021, CMS did not have the authority to publish AO surveys for deemed hospice programs except to the extent that the AO survey and its survey information are related to an enforcement action taken by CMS against the provider. However, CMS may post State agency complaints or validation survey results of deemed hospice providers; CMS utilizes the Quality, Oversight, and Certification Reports (QCOR)¹⁰² public website for this purpose.

As mentioned in section VII.B.1.b of this final rule, CMS recognizes there are challenges related to the system implications for use of the Form CMS-2567 by the AOs. However,

¹⁰² Quality, Certification and Oversight Reports (QCOR)

Congress removed the prohibition that previously allowed AO hospice program survey reports to be considered confidential and proprietary. We proposed to require that AOs release deficiency reports for hospice program surveys conducted under their respective deeming authority to increase transparency among the hospice beneficiary community.

CMS will need to address various system integrations and updates to integrate AO survey results on the Form CMS-2567 as mentioned in section VII.B.2.b of this final rule. Furthermore, CMS recognizes there are limitations and additional data system changes to consider for survey results from the Form CMS-2567 to be displayed in a meaningful and useful format.

We sought public comments as to how data elements from the Form CMS-2567 may be utilized and displayed, and other recommendations of relevant provider information, to assist the public in obtaining a more comprehensive understanding of a hospice program's overall performance. The CAA 2021 requires that CMS publish survey information from the Form CMS-2567 in a way that is readily understandable and useable by the public in a meaningful way. We anticipate the need for us to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices' performance. We recognize that the implications of releasing national survey data would require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.

Comment: Many commenters recommended that CMS establish a Technical Expert Panel (TEP) that focuses on the display of survey findings, which should include a wide array of stakeholders. Furthermore, they believe this TEP should be responsible for identifying a comprehensive algorithm to include salient Form CMS-2567 findings related to the scope and severity of deficiencies and additional metrics that will provide a more comprehensive overview of the hospice provider.

Response: The CAA 2021 mandates that survey findings be “prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely

updates.” CMS recognizes that a metric or algorithm would help to accomplish this goal, which could integrate salient findings from the Form CMS-2567 that may be utilized by the general public to adequately compare hospice providers’ services. CMS considers the publication of the Form CMS-2567 to be a first step in meeting the intent of this provision. CMS remains committed to continuing collaboration with hospice stakeholders after this rule is finalized; we appreciate and are considering commenters’ suggestion to convene a TEP or other vehicle for gathering stakeholders’ input on ways to define a more comprehensive metric or algorithm for public display in guidance.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal at § 488.7(c) with one technical change. We are modifying the regulatory text at § 488.7(c) by changing “accreditation organization” to “accrediting organization” for internal consistency within § 488.7.

d. Providers or Suppliers, Other than SNFs, NFs, HHAs, and Hospice Programs with Deficiencies (§ 488.28)

Currently, the regulation at § 488.28 states that if a provider or supplier is deficient in one or more of the standards set out in such provider’s or supplier’s CoPs, it must submit an acceptable plan of correction (POC) for achieving compliance. An acceptable POC must be received within a reasonable time acceptable to CMS to continue Medicare participation. If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards in the CoPs, it is granted a “reasonable time” to achieve compliance. The amount of time depends upon the nature of the deficiency and the survey agency’s judgment as to whether the facility can provide adequate and safe care. Ordinarily, a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies. However, the SA may recommend additional time be granted based on individual situations if it is not reasonable to expect compliance within 60 days. The regulation exempts SNFs, NFs, and HHAs from this requirement; instead, similar provisions are separately set out in

the regulations relating to those specific provider types.

Section 1822(c) of the Act authorizes the Secretary to take actions to ensure the removal and correction of condition-level deficiencies in a hospice program through an enforcement remedy or termination or both. The enforcement remedy requirements for hospice programs are outlined in the proposed new subpart N. Regardless of which remedy is applied, a non-compliant hospice program must still submit a POC for approval by the SA or CMS. The POC is a plan developed by the hospice program and approved by the SA or CMS. However, only CMS can impose an enforcement remedy or termination or both. It is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and the hospice program specifies the date by which those deficiencies will be corrected. We proposed revising the heading for § 488.28 to indicate that hospice programs would also be exempt from the requirements set out in that section because we proposed POC provisions for hospice programs with deficiencies in new subpart N, as discussed in section VII.B.4 of this final rule.

Final Decision: We did not receive comments on this proposal and therefore are finalizing this provision without modification.

3. New Subpart M – Survey and Certification of Hospice Programs

a. Basis and Scope (§ 488.1100)

We proposed at § 488.1100 to specify the statutory authority and general scope of the hospice program. As stated in the proposed rule, this rule is generally based on the rulemaking authority in section 1822 of the Act as well as specific statutory provisions identified in the preamble where appropriate. We received no public comments on this provision and we are finalizing it as proposed.

b. Definitions (§ 488.1105)

We proposed to add definitions at § 488.1105 for survey and enforcement terms for hospice programs. The definitions proposed for hospice programs include the following:

- *Abbreviated standard survey* would mean a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or CoPs. An abbreviated standard survey may be based on complaints received or other indicators of specific concern. Examples of other indicators include media reports or findings of government oversight activities, such as OIG investigations.

- *Complaint survey* would mean a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.

- *Condition-level deficiency* would mean noncompliance as described in § 488.24.

- *Deficiency* would mean a violation of the Act and regulations contained in 42 CFR part 418, subparts C and D, is determined as part of a survey, and can be either standard or condition-level.

- *Noncompliance* would mean any deficiency found at the condition-level or standard-level.

- *Standard-level deficiency* would mean noncompliance with one or more of the standards that make up each condition of participation for hospice programs.

- *Standard survey* would mean a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by a hospice program.

- *Substantial compliance* would mean compliance with all condition-level requirements, as determined by CMS or the State.

Comment: An AO commenter stated that they do not conduct what CMS references as a standard level survey, but all initial and renewal reviews are comprehensive surveys.

Response: We acknowledge that the terminology of "standard survey" may vary with AOs and that the AOs are still required under Section 1865 of the Act to meet or exceed Medicare requirements and survey procedures. We also note that the new requirement at § 488.1110(a) requires a hospice standard survey (initial, recertification, or renewal) to be

conducted not later than 36 months after the date of the previous standard survey. While the regulation at § 488.5(a)(4)(i) provides a timeframe for AOs of no later than 36 months after the prior accreditation effective date, or shorter if there is a statutorily mandated survey interval of fewer than 36 months, we expect hospice AOs to follow the new requirement for hospice surveys at § 488.1110(a) to be comparable with the requirements outlined for SAs. Therefore, the new hospice requirement at § 488.1110(a) would supersede the AO requirement at § 488.5(a)(4)(i) for hospice surveys.

After consideration of the public comments we received, we are finalizing this section as proposed.

c. Hospice Program Surveys and Hospice Program Hotline (§ 488.1110)

At proposed § 488.1110(a), a standard survey would have to be conducted not later than 36 months after the date of the previous standard survey, as specified in section 1822(a)(1) of the Act. A survey could be conducted more frequently than 36 months to assure that the delivery of quality hospice services complies with the CoPs and confirm that the hospice program corrected deficiencies that were previously cited. At proposed §488.1110(b)(1), a standard or abbreviated standard survey would have to be conducted when complaint allegations against the hospice program were reported to CMS, the State, or local agency. Additionally, we recognize that for AOs with hospice deeming programs, the proposed 36-month surveys would mirror the requirements for AOs to describe the frequency of surveys as part of the AO application process at existing § 488.5(a)(4)(i). That provision requires AOs to agree to survey and re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, or shorter if there is a statutorily mandated survey interval of fewer than 36 months.

Prior to the amendments made by CAA 2021, section 1864(a) of the Act required that agreements between the Secretary and the State, under which SAs carry out the Medicare certification process, shall provide for the appropriate State or local agency to establish and

maintain a toll-free hotline for HHAs. The CAA 2021 amended this requirement to include hospice programs. The provision now requires that a hotline must be maintained: (1) to collect, maintain, and continually update information on HHAs and hospice programs located in the State or locality that are certified to participate in the program established under this title; and (2) to receive complaints (and answer questions) with respect to HHAs and hospice programs in the State or locality. Section 1864(a) of the Act also provides that such agreements shall provide for the State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1865 of the Act, and consumer medical records (but only with the consent of the consumer or his or her legal representative). We proposed to build on these same requirements for hospice programs consistent with the amendments made to section 1864(a) of the Act by CAA 2021.

Therefore, at § 488.1110(b)(2) we proposed that the State or local agency is responsible for establishing and maintaining a toll-free hotline to receive complaints (and answer questions) with respect to hospice programs in the State or locality and for maintaining a unit to investigate such complaints. The requirement for the hotline would be described in the annual CMS Quality, Safety and Oversight Group's Mission and Priority Document (MPD) that serves as the scope of work to which State Agencies are bound contractually via section 1864 of the Act (42 U.S.C. 1395aa).

As we plan for the implementation of the hospice toll-free hotline to streamline and enhance the complaint process for hospice program beneficiaries, we sought public comment on current experiences with the HHA toll-free hotline as required by section 1864(a) of the Act. We sought this information to inform CMS of potential future enhancements to the toll-free hotline. Specifically, what data elements and processes should be included to assure confidentiality and immediate communication with relevant SAs in order to permit them to respond promptly.

Comment: Several commenters were in support of the CAA 2021, which makes permanent the requirement that hospice programs receive recertification surveys no less frequently than once every 36 months. A commenter recommended that CMS clarify the implementation dates related to the hospice surveys.

Response: *The Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT Act) (Pub. L. 114-185) initially amended section 1861(dd)(4) of the Act to provide that hospice programs will be subject to a standard survey every 36 months beginning six months from enactment through September 2025. The CAA 2021 amends Title XVIII of the Act to permanently continue this provision. CMS is codifying this mandate into regulation. Hospice programs will continue to be surveyed not later than 36 months after the date of the previous survey.

Comment: A commenter stated that CMS should establish a 6-month timeframe in which surveyors must conduct complaint surveys once an allegation is reported.

Response: We currently maintain a national complaint tracking and prioritization system which prioritizes complaints according to the level of risk for a hospice program's patients. Complaints that indicate the possibility of an immediate jeopardy situation are given the highest priority and investigated by the State as soon as possible. The State Operations Manual, chapter 5, specifies the timeframes and procedures by which all types of complaints should be investigated.

Comment: A commenter stated serious concerns about the ability of SAs and AOs to increase staffing to support more frequent surveys. The commenter states that the Department of Health and Human Services and the Office of the Inspector General (OIG) have documented a substantial backlog of standard surveys, with roughly 71 percent of nursing homes that have gone at least 16 months without a standard survey as of May 31, 2021.

Response: The requirement to survey hospice programs every three years was initially established in the *Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT

Act) and the CAA 2021 establishes permanency of the continuation of this requirement. We are codifying this mandate into regulation. The AOs are currently required in regulations to survey hospice programs every three years, which is the same as the legislative requirement. Hospice programs will continue to be surveyed not later than 36 months after the date of the previous survey by the SA or AO.

The comment regarding the substantial backlog of nursing home surveys referenced is outside the scope of this rule.

Comment: Several commenters support codifying and making uniform throughout the United States a dedicated toll-free hospice hotlines, each maintained by the appropriate State or local agency. The commenters supported the proposed use of hotlines to collect, maintain, and continually update information, as well as to receive complaints, on hospice programs located in the State or locality that are certified to participate in the Medicare program. Commenters noted that the State or local agency must also maintain a unit for investigating such complaints and that many State or local agencies have existing hotlines for home health agencies.

Response: We appreciate the support. State or local agencies that have existing toll-free hotlines for home health agency complaints can utilize this hotline to also collect and maintain information on hospice programs. However, the State or local agency may decide to establish a separate toll-free hotline specific to hospice programs.

Comment: A commenter recommends that the State or local agency staff the hospice hotline with individuals who are appropriately trained on hospice care and the hospice philosophy.

Response: We believe that the hospice hotline staff decision should be left to the State or local agency. The State or local agency follows the MPD that discusses survey and certification functions as well as the Medicare funding allocation process for states, which directly impacts the work prioritization and planning for the required survey workload in the fiscal year the MPD is issued.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

Section 1822(a)(4)(C) of the Act requires the Secretary to provide training for State and Federal surveyors, and any surveyor employed by an AO, including a training and testing program approved by the Secretary, no later than October 1, 2021. Further, no surveyor can conduct hospice program surveys until they complete training and testing. Currently, AOs are required by § 488.5(a)(8) to provide training to their surveyors. As the AO requirements outlined in § 488.5 also allow for standards and processes that exceed those of CMS, the AO's training may differ from what CMS provides to SA surveyors, thereby creating a potential disparity in overall survey performance. At § 488.1115, we proposed that all SA and AO hospice program surveyors would be required to take CMS-provided surveyor basic training currently available, and additional training as specified by CMS. As part of the AO application and reapplication process under § 488.5(a)(8), the AO is required to submit a description of the content and frequency of the organization's in-service training it provides to survey personnel. Under proposed § 488.1115, AO surveyors would be required to complete the online CMS hospice program basic training. CMS proposed that until the rule is finalized, that it accepts the current AO training, that was previously reviewed and approved by CMS during the AO application process. State agency surveyors should already be in compliance with this requirement.

AOs already have voluntary access to our Quality, Safety & Education Portal (QSEP), which contains the CMS training. Currently, the trainings are available free of charge through the QSEP website at <https://qsep.cms.gov>, to providers and all entities conducting surveys, including AOs, and the public at large. QSEP training is accessible on an individual, self-paced basis.

The basic training online courses provide surveyors with the key knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare conditions and assure an adequately trained, effective surveyor workforce. The online courses also help develop and refine surveying skills, promote critical thinking skills, and enhance surveyors' overall ability to conduct and document surveys. Users may access the online courses at any time. This allows surveyors to refresh knowledge regarding Medicare conditions and processes whenever necessary. The number of learners trained in online courses has steadily increased since the courses' inception.

We are updating the hospice program basic training and including enhanced guidance for surveyors. The updated training will emphasize the assessment of quality of care. Specifically, we would emphasize four "core" hospice program CoPs in revisions to the CMS State Operations Manual (SOM) (Pub. 100-07). The four core CoPs (identified in the preamble of the final rule, Medicare and Medicaid Programs; Hospice Conditions of Participation (73 FR 32088, June 5, 2008)) are §418.52 Condition of Participation: Patient's rights; §418.54 Condition of Participation: Initial and comprehensive assessment of the patient; §418.56 Condition of Participation: Interdisciplinary group, care planning and coordination of care; and, §418.58 Condition of Participation: Quality assessment and performance improvement. The revised training, which we expect to be implemented soon, emphasizes the requirements for establishing individualized written plans of care, which are integral to the delivery of high quality care, and regularly updating these plans with the full involvement of the interdisciplinary team, patients, and their families. Despite the emphasis placed on these core CoPs, hospice programs must comply with all CoPs to achieve successful certification.

We invite commenters to review the trainings by signing up for a free account on the homepage of the CMS website, or by choosing the "Public Access" button on the upper right-hand corner of the website homepage. We sought comments on the requirement for continued SA and AO surveyor training as CMS releases additional basic course updates.

In addition to training requirements for surveyors, we proposed to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with section 1822(a)(4)(B) of the Act. While the statute specifically addresses SA surveyors, CMS takes prohibiting violations of public trust for those representing the Medicare program very seriously and therefore we proposed to include hospice AO surveyors under this requirement as well.

In 2012, as part of an effort to mitigate conflicts of interest in the HHA survey process, CMS established requirements at § 488.735(b) to outline circumstances that disqualify a surveyor from performing HHA surveys. For example, if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the HHA undergoing the survey, they would be disqualified for a conflict of interest.

Chapter 4, Section 4008 of the SOM states, “conflicts of interest may arise within the Medicare/Medicaid certification program when public employees utilize their position for private gain or to secure unfair advantages for outside associates. The gain involved may or may not be monetary. Abuses of privileged information, abuses of influence, and other abuses of trust are included, regardless of whether a monetary advantage is gained or sought.”¹⁰³

Individual health care professionals, such as physicians or nurses, commonly have concurrent employment relationships with more than one health care setting. Many health care professionals, such as physicians, physician assistants, and nurse practitioners have multi-setting practices or are employed at more than one health care facility. For example, an RN may work on staff at a hospital but also work at other hospitals through a medical staffing agency. In addition, as employees of a health care facility, these health care professionals could gain a financial interest in the health care facility through means such as being a contributor to the construction costs of a new wing of the facility or buying stock in the facility or its parent

¹⁰³ CMS State Operations Manual, Chapter 4 Medicare State Operations Manual (cms.gov) (Internet Only Manual, Pub. 100-07).

corporation. Management employees could be awarded stock or stock options for the facility or its parent corporation as part of their compensation and benefits package.

SAs and AOs often hire surveyors that are also employed at one or more outside health care settings because the professional associations, expertise, knowledge, and skills held by these health care practitioners make them an asset as a surveyor. Longstanding CMS policy noted in section 4008 of the SOM describes examples of scenarios that would be conflicts of interest for SA surveyors of any provider or supplier type, including surveyors who have an outside relationship with a facility that is surveyed by the SA. However, the SOM generally applies only to SA surveyors, not AO surveyors. Therefore, we proposed to codify these long-standing policies for both SA and AO surveyors to ensure there is no conflict of interest between the organization and the surveyor.

We proposed that a surveyor would be prohibited from surveying a hospice program if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the hospice program undergoing the survey. Specifically, the surveyor could not have been a direct employee, employment agency staff at the hospice program, or an officer, consultant, or agent for the surveyed hospice program regarding compliance with the CoPs. A surveyor would be prohibited from surveying a hospice program if he or she has a financial interest or an ownership interest in that hospice. The surveyor would also be disqualified if he or she has an immediate family member who has a financial interest or ownership interest with the hospice program to be surveyed or has an immediate family member who is a patient of the hospice program to be surveyed.

In regards to the definition of “immediate family member” in the previous statement, we would utilize the definition of “immediate family member” located at § 411.351, which was also used for the development of similar HHA regulations (see 77 FR 67140). This definition includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law,

brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

(1) Surveyor Qualifications

Comment: While commenters notably agreed that requiring all surveyors (AOs, State, and CMS Location surveyors) to take the training offered by CMS provides greater consistency, several expressed concern that the timeline would have the effect of needing to pull surveyors without training from the field by October 1, 2021, contributing to further backlogs in surveys, already large due to COVID restrictions. They requested that CMS allow a period beyond October 1, 2021, the current date for implementation of this provision.

Response: We anticipate that the revised Hospice Basic Training will be available at the time of the implementation of this rule. Surveyors should take the training that is available when their individual need for training arises (that is, upon hiring, or if beginning to survey a provider they have not previously been trained to survey). CMS will post a training update of changes in the new version for surveyors who used the older version of the CMS training so that they will not have to take the new training in its entirety.

Comment: Commenters made several suggestions related to surveyor training. Additional training content areas were suggested such as addressing psychosocial, emotional, and spiritual components of hospice care, that surveyors be trained to cite based on evidence of trends rather than a single violation, and requiring a minimum number of surveys as well as ongoing eligibility via competency evaluation and continuing education.

Response: These comments are outside of the scope of this rule, which focuses on the universality of CMS training. We note that the training suggestions are already included in CMS' hospice training (for example, citing deficiencies based on severity and frequency, and not just a single occurrence, unless it is severe) and among the experiential requirements for surveyors (minimum number of monitored/supported surveys prior to surveying independently). Regarding ongoing training and competency, we rely on the managerial oversight of state

agencies, with the assistance of state training coordinators to monitor surveyor abilities, and direct access to the many additional training opportunities available through the CMS Quality, Safety & Education Portal (QSEP-<https://qsep.cms.gov/>).

Comment: Some commenters suggested that surveyors should have “real-world experience” or have worked in hospice care to qualify to be hospice surveyors.

Response: We are confident that given the appropriate professional background as a licensed physician, RN, social worker, or chaplain, surveyors’ professional training, along with CMS training, that surveyors are fully prepared to conduct accurate field assessments of compliance with the Medicare Conditions of Participation (CoPs). Additionally, surveys are reviewed at multiple levels—through validation surveys and managerial oversight—to corroborate the interpretation of findings and citing of deficiencies.

Comment: A commenter stated that we should include emergency preparedness (EP) in hospice training as well as address patient safety in the comprehensive assessment.

Response: Though not expressly addressed in the comprehensive assessment, safety is addressed throughout the CoPs. EP is addressed in hospice training and references the dedicated State Operations Manual appendix and training related to EP.

Final Decision: After consideration of the public comments we received, we are finalizing the surveyor qualification provisions as proposed.

(2) Prohibition of Conflicts of Interest

Comment: A few commenters expressed appreciation of CMS’ proposals to implement conflict of interest provisions as they believe it is an important element of ensuring fairness in the survey process.

Response: We appreciate the support for our prohibition of conflicts of interest proposals.

Comment: A commenter suggested that CMS develop a code of ethics for surveyors instead of trying to list out every potential conflict of interest. Additionally, it was suggested the

code of ethics be tied to online training where surveyors would take the training and then sign the code of ethics.

Response: We appreciate the suggestion. Addressing conflicts of interest can be challenging because it is not possible to list all situations which could be construed as potential conflicts. CMS takes the responsibility of public trust very seriously and as such has a long-standing policy in the State Operations Manual, Chapter 4, which outlines the process for abuses of influence, privileged information, or trust arising through conflicts of interest. We believe these provisions address the most common scenarios where conflicts arise nationally. While we believe a code of ethics for surveyors is valuable, we will consider this suggestion for future policy changes that would affect all surveyors and all programs as this is out of scope for the current hospice program rule. We also appreciate the idea of adding it to a CMS training course and will consider this in the future.

Comment: A commenter suggested that CMS consider requiring surveyors to professionally attest that they are aware and will comply with the prohibition on conflicts of interest. Furthermore, they expressed support for a provision requiring surveyors to attest that they intend to judge providers objectively, within the bounds of the CoPs, and refrain from relying on any personal convictions about what end-of-life care should be or ought to entail.

Response: Similar to the suggestion for CMS to consider developing a code of ethics for surveyors, we appreciate the idea of attestation and will consider this in future policy changes for surveyors of all programs.

Comment: A few commenters stated CMS should develop materials to help guide surveyors and survey entities regarding potential conflicts of interest.

Response: We agree that surveyors benefit from training materials related to conflicts of interest. Currently, CMS has training in the Quality Safety and Education Portal (QSEP) related to surveying for non-long term care (non-LTC) that aids learners in developing surveyor skills and proficiency by establishing a foundational understanding of the non-LTC survey process.

This training addresses roles and responsibilities of surveyors, including conflicts of interest.

CMS will review the existing training and will make updates as needed.

Comment: Multiple commenters suggested additional conflicts of interest for consideration including: prohibiting anyone who has a family member using hospice services; surveyors with prior work history, including termination from, a hospice being surveyed; or work history with a hospice's competitor. Specifically, commenters expressed concern with conflicts of interest arising out of a work history that includes an employment arrangement with a hospice's competitor and a suggestion was made that CMS consider a 2-year ban on staff from competing hospices surveying each other. However, a few commenters acknowledged addressing such a conflict through regulation may be challenging as it would be difficult to determine how far such a prohibition could extend. Several commenters also noted that adding additional conflicts could create challenges in small, rural communities but encouraged CMS to provide surveyors with the opportunity to recuse themselves if needed.

Response: We appreciate the additional considerations and concerns that commenters have raised. We are particularly interested in the comments raised regarding competition between hospices and the potential conflict of interest if surveyors work for one hospice and participate in survey activity of known competitors. CMS has considered this potential conflict of interest and agrees with commenters that it would be challenging to address through rulemaking as it could be said that all hospices in certain geographic locations are considered competitors. We also agree with the concerns raised regarding small, rural communities and limiting surveyor availability. CMS, SAs, and AOs are all responsible for evaluating the need for preventive measures to protect the integrity of the survey process. All relevant circumstances that may exist beyond the benchmarks given in regulations should be considered to ensure that the integrity of the survey process is preserved. As noted in the current CMS State Operations Manual policy, SA administrators should require employees to make a declaration of any such

outside interests and update this declaration periodically. Therefore, we believe surveyors are responsible for disclosing and recusing themselves as needed.

Final Decision: After consideration of these comments, we are revising § 488.1115 to add a requirement that surveyors must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves as necessary.

e. Survey Teams (§ 488.1120)

The CAA 2021, adding section 1822(a)(4)(A) of the Act, calls for the use of multidisciplinary survey teams when the survey team comprises more than one surveyor, with at least one person being a RN. Currently, the SOM, Appendix M – Guidance to Surveyors requires that each hospice program survey team include at least one RN, and, if the team is more than one surveyor, the additional surveyors should include other disciplines with the expertise to assess hospice program compliance with the conditions of participation. We proposed at § 488.1120 under a new subpart M to require that all survey entities—SA or AOs—include diverse professional backgrounds among their surveyors to reflect the professional disciplines responsible for providing care to persons who have elected hospice care. Such multidisciplinary teams should include professions included in hospice core services at 42 CFR 418.64—physicians, nurses, medical social workers, pastoral or other counselors—bereavement, nutritional, and spiritual. To fulfill CAA 2021 requirements, SAs and AOs might need time to reconstruct their workforce to accommodate the new requirements for hospice program surveys to utilize multidisciplinary teams. We recognize that SAs and AOs may incur additional costs, given the varying, and potentially higher rates of average pay for some disciplines. Surveying entities may need up to 1 year to hire and train surveyors from the needed disciplines, depending on the timing of the attrition of current staff and workforce availability of the appropriately experienced professionals. In addition, we seek to better understand the current professional makeup of survey entities' workforces. In order to track compliance with this provision, we

proposed to establish a baseline knowledge by asking survey entities to tell us: (1) the extent to which their surveys are conducted by one professional, who by regulation must be an RN; (2) the professional makeup of their current workforce; and (3) estimate a timeframe in which they could effectuate multidisciplinary teams if not already in place. We would provide additional guidance with instruction for the survey entities regarding the submission of this information to CMS.

Our rules at § 418.56 require that hospice programs use interdisciplinary teams or groups to determine a holistic plan of care for the hospice program patient and family. The interdisciplinary group or IDG, must include, but not be limited to a physician, an RN, a medical social worker, and pastoral or other counselor. Therefore, we proposed that when the survey team comprises more than one surveyor, the additional slots would be filled by professionals from among these disciplines, and we sought comments on this approach. Similarly, section 1819(g)(2)(E) of the Act and 42 CFR 488.314 require that long-term care (LTC) facility surveys be conducted by a multidisciplinary team of professionals, at least one of whom must be a RN.

Our certification guidance in Chapter 2 of the SOM provides details as to how the survey agency might select the appropriate disciplines for a survey team. SOM, Chapter 2 states that various professional disciplines should represent the expertise needed to determine compliance with the CoPs, standards, or requirements for that provider/supplier group. In establishing multidisciplinary teams under new section 1822(a)(4)(A) of the Act, we would consider, as a model, our current CMS guidance for LTC facilities, which uses specialty surveyors with expertise not typically included in a survey team (for example, a pharmacist, physician, or registered dietitian), who may not be needed for the entire survey, but must be onsite at some time during the survey.

Comment: Several commenters provided feedback on the makeup of survey teams, in response to the proposed provision that survey teams should be multi-disciplinary. Commenters suggested that a licensed practical nurse should be included on the survey team.

Response: We proposed that the survey teams be multidisciplinary and that at least one member of the survey team must be an RN. These are statutory requirements, and they are consistent with the current guidance in the SOM, Appendix M. Because an RN will be on every survey team, to ensure that the survey team is multidisciplinary, if there is more than one surveyor, then the additional team members must be selected from other disciplines included in the interdisciplinary group.

Comment: Several commenters suggested that the survey team members be required to have prior experience in the hospice field.

Response: We do not require that surveyors have actual hospice experience, nor target particular types of hospice expertise (that is, former hospice administrators). It is at the discretion of the hiring state survey agencies to identify individuals whose background is suitable. All surveyors must successfully complete CMS-based training to ensure that they are capable of conducting accurate and complete surveys. CMS's training includes substantial detail in content and interactive learning in the hospice philosophy of care and all hospice regulatory requirements, as well as guidance in survey technique and procedures specific to the CoPs. With the appropriate professional background (that is, credentialing in one of the disciplines included in the IDG) and CMS's hospice-specific training, we believe surveyors will have the expertise needed to conduct surveys for compliance with Medicare's well-prescribed requirements.

Final Decision: After consideration of the public comments we received, the proposed policy is being finalized without modification.

f. Consistency of Survey Results (§ 488.1125)

New section 1822(a)(3) of the Act requires that each State and the Secretary implement programs to measure and reduce inconsistency in the application of hospice program survey results among surveyors. In addition to ensuring consistency of hospice survey results across SAs, we believe that this also applies to reducing discrepancies between SA and AO surveys of hospice providers. Survey consistency has been a longstanding concern for CMS at multiple

levels—interstate and intrastate, as well as Federal to State. While there are multiple strategies currently in place, as described in this section, to directly address the matters presented in the CAA 2021, we proposed at § 488.1125 to enhance the requirements of the State Performance Standards System (SPSS) to direct States to implement processes to measure the degree or extent to which surveyors’ findings and determinations are aligned with Federal regulatory compliance and with an SA supervisor’s determinations. Given the variation among State agencies with respect to the number of surveyors deployed for a particular survey, or the distribution of surveyor professional backgrounds, in the proposed rule we noted that we expected to promulgate objective measures of survey accuracy, and sought public opinion on what measures would be feasible for States. We desired measures that are both specific and utilize currently collected data, if possible. Accuracy could include whether a survey finding aligns with the selected regulatory deficiency, as well as failing to cite such findings. When applied to survey findings, the measures should allow CMS to determine the need for corrective action or education for individual surveyors or for a group of surveyors. If systemic issues were found, CMS would be prepared to enhance its training to address systemic issues found as a result of interstate analysis.

CMS monitors the consistency of SA surveys through a review of an SA’s Form CMS-2567s (the Statement of Deficiencies and Plan of Correction), which is conducted by its assigned CMS Survey Operations Group (SOG) Location, and consistency among AOs through validation surveys conducted by SAs. The SAs perform validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, Hospice Programs, and HHAs) accredited by the AOs. Validation surveys report disparate findings as the percentage of validation surveys that have conditions identified by the SA but missed by the AO survey team. This percentage is referred to as the “disparity rate” and is tracked by CMS as an indication of the quality of the surveys performed by the AO. This is reported annually in a report to Congress (QSO-19-17-AO/CLIA). The most recent report can be found at

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-and-Regions-Items/AdminInfo-20-02-ALL>.

Using the disparity rate approach used with AOs, where surveys are reviewed for condition-level deficiencies the AO fails to identify, we proposed to analyze trends in the disparity rate among States, as well as among AOs. State surveys results would be reviewed to identify findings that were potentially worthy of condition-level citation but were not cited.

We believe that the disparate deficiency citations between AO surveyors and SA surveyors may, in part, be attributed to differences in surveyor training and education. This variation may be due to inconsistencies in AO training with the CMS-provided SA basic surveyor training. We believe that uniform surveyor training would increase the consistency between the results of the surveys performed by SAs and AOs, and have a positive impact on the high disparity rates. We also want to align our processes more closely to those CMS has found effective for other provider types. For instance, what we proposed for hospice programs is similar to what is done with nursing homes, where validation surveys are described at section 1819(g)(3)(A) of the Act as “...a representative sample...in a sufficient number to allow inferences about the adequacies of each State’s surveys...(B)...each year concerning at least 5 percent of the number of skilled nursing facilities...” Even though AOs are not currently included in the CMS SPSS, we expect that a similar methodology would be applied to all hospice surveying entities, including AOs with an approved hospice program. Just as CMS monitors disparate results across States in their adherence to Federal processes for determining deficiencies, investigating, and reporting complaints, it requires States to monitor the quality of its surveyors’ survey activity and actions. Performance measures are applied to all surveying entities to assess consistency. If CMS finds that surveying entities—SAs and AOs—do not meet the performance standards, they must develop and implement a corrective action plan.

The SPSS, established annually, provides for oversight of SA performance when conducting surveys to ensure that Medicare and Medicaid certified providers and suppliers are compliant with Federal CoPs, to improve and protect the health and safety of Americans. This oversight allows CMS to determine that surveyors are thorough, accurate, and consistent when they determine if a hospice program provider is complying with the Medicare CoPs. Survey findings with respect to a hospice program can include: (1) standard level deficiency—where the hospice program is not complying fully with CoPs, which need corrective action; (2) condition-level deficiencies—which require remediation and could lead to termination of the hospice program; or, (3) immediate jeopardy (IJ) level—where beneficiaries are present in situations where significant harm could occur and which need to be addressed without delay. SA supervisors are responsible to ensure that surveyors’ findings (from observations, interviews, and document reviews) are consistent with their determination of IJ, and standard- or condition-level deficiency where a hospice program is not compliant with a condition of participation.

To reduce inconsistencies in survey results among surveyors, we proposed to require agencies that review other entities’ survey findings for missed condition-level deficiency citations (disparities) (SAs for AOs, and CMS SOG locations for SAs) to notify each survey entity of its disparity rate annually and to require a formal corrective plan as part of the survey entity’s (SA or AO) Quality Assurance program. A disparity rate above 10 percent in 2 consecutive cycles would trigger remedial activity such as implementing corrective action through education, mentoring, or other processes to align surveyors’ actions, and determinations of deficiencies with regulatory requirements.

Comment: Commenters supported our plans to create more opportunities for consistency between survey entities as well as between surveyors within the same surveying entity. They noted CMS’ plan to require universal use of CMS hospice training as a key element of this effort. A commenter suggested that in this effort, CMS should provide AO surveyors with access to

QSEP at the same level as state surveyors, so that all content and not just Basic Training is available to the AO surveyors as a means of greater consistency across agencies.

Response: We will modify access to QSEP for AO surveyors on the same basis as for state surveyors, so that all appropriate content is available, though only Hospice Basic will be required by the AO surveyors.

Final Decision: After consideration of the public comments we received, the proposed policy is being finalized without modification.

g. Special Focus Program (SFP) (§ 488.1130)

Section 1822(b) of the Act requires the Secretary to conduct a Special Focus Program for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of the Act. We proposed at § 488.1130 to develop a hospice Special Focus Program (SFP) to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight, and/or technical assistance. We proposed that specific criteria would be used to determine whether a hospice program participates in the SFP. The proposed criteria are as follows: a history of condition-level deficiencies on two consecutive standard surveys, two consecutive substantiated complaint surveys, or two or more condition-level deficiencies on a single validation survey (the validation survey with condition-level deficiencies would be in addition to a previous recertification or complaint survey with condition-level deficiencies). A subset of hospice programs that meet the proposed criteria would be selected to be in the SFP, and those hospice programs would be surveyed every 6 months, which may result in additional enforcement remedies and/or termination. CMS uses a similar program with LTC facilities and outlined the following protocol for a hospice SFP in the proposed rule:

- The SA and CMS SOG location would receive a list from CMS of all hospice programs that meet the established criteria at proposed § 488.1130(b) for placement in the SFP (Candidate List). The SA would work with the CMS SOG location to select hospice programs from the list provided by CMS that would be selected for the SFP based on State priorities. In

the event that no hospice programs in a State meet the established criteria, then the State SA would not have a hospice program in the SFP at that time.

- While a hospice program is in the SFP, the SA would survey the facility at least once every 6 months, as required by the CAA 2021, and may include progressively stronger enforcement actions in the event of a hospice program's continued failure to meet the requirements for participation with the Medicare and Medicaid programs.

- Once an SFP hospice program has completed 2 consecutive 6-month SFP surveys with no condition-level deficiencies cited, the facility would graduate from the SFP. If the hospice program did not meet the requirements to graduate, it would be placed on a termination track.

We sought public comment regarding the SFP, specifically the following issues:

- Should CMS utilize a similar criteria, process, or framework for the SFP as outlined in the current Special Focus Facility Program used for LTC facilities? What if any differences should CMS consider to enhance the overall impact of the hospice SFP?

- Are there additional selection criteria that CMS should consider for the identification and participation in the SFP? This may include use of current or future data elements that could be incorporated into a more comprehensive algorithm.

- Should we utilize a Technical Expert Panel (TEP) to enhance the SFP in terms of selection, enforcement and technical assistance criteria while a hospice is in the program? A TEP may assist CMS by identifying contextual data and relevant information that would help the public in obtaining a more comprehensive understanding of the Form CMS-2567 survey data and the overall performance of a hospice provider, in addition to what data to include, how to make this information useful and meaningful on a CMS website.

Comment: Many commenters believe that CMS should not implement this provision until a comprehensive framework can be established that focuses on a targeted approach in the identification and enrollment of hospice programs to the SFP. Some commenters stated that the criteria outlined in the proposed rule are subjective and may lead to inconsistencies across State

Agencies in hospice identification and enrollment in the SFP, without addressing the most non-compliant hospices for not delivering quality care and putting patients at risk. Given the complexities associated with this proposal, commenters agreed that CMS should use a TEP that includes a wide array of stakeholders to assist CMS in the development of a comprehensive algorithm that would include relevant findings from the Form CMS-2567 and other metrics related to hospice performance. Commenters also thought that CMS should include relevant tools and education to assist hospice providers that participate in the SFP to improve quality and compliance prior to termination.

Response: The CAA 2021 mandates that a SFP be established to identify poor-performing hospice programs and enhance the quality of care. CMS recognizes that to accomplish the intent of this provision elements, in addition to the Form CMS-2567, may be needed to develop a comprehensive structure and methodology for a targeted approach to identify, select, and remove a hospice program for inclusion in the SFP. Given the intent of this provision to identify the poorest performing hospice programs and the need to define a comprehensive structure and methodology for selection into the SFP, CMS intends to review the public comments received and collaborate with hospice stakeholders to further develop the SFP that was initially proposed.

Taking into account the comments that we have received on this proposal, we are not finalizing the proposed SFP requirements at proposed § 488.1130. We intend to work on a revised proposal and will seek additional collaboration with stakeholders to further develop the structure and methodology for implementing the SFP, which we hope to include in a proposal for FY 2024 rulemaking.

4. New Subpart N – Enforcement Remedies for Hospice Programs with Deficiencies
 - a. Statutory Basis (§ 488.1200)

We proposed to set out the statutory basis for the proposed new subpart at § 488.1200, which is new sections 1822(c)(1) through 1822(c)(5) of the Act. The requirements under this

new subpart would expand the Secretary's options to impose additional enforcement remedies for hospice programs failing to meet Federal requirements. These additional enforcement remedies may be used to encourage poor-performing hospice programs to come into substantial compliance with CMS requirements before CMS is forced to terminate the hospice program's provider agreement. This process is currently afforded to HHAs at § 488.745.

Prior to the enactment of section 1822(c)(5)(A) of the Act, the only enforcement action available to CMS to address hospice programs that are determined to be out of compliance with Federal requirements was the termination of their Medicare provider agreement. In accordance with section 1866(b)(2) of the Act and § 489.53(a)(3), CMS may terminate a hospice program provider agreement if that hospice program is not in substantial compliance with the Medicare requirements (that is, the failure to meet one or more CoPs is considered to be a lack of substantial compliance).

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

b. Definitions (§ 488.1205)

We proposed to add § 488.1205 to define the terms "directed plan of correction," "immediate jeopardy," "new admission," "per instance," "plan of correction," "repeat deficiency," and "temporary management." Although section 1891 of the Act uses the term "intermediate sanctions," with respect to HHA enforcement, and other rules use "alternative sanctions," we proposed to use "remedies" or "enforcement remedies," which we consider to have the same meaning and are closer to the language in section 1822 of the Act.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

c. General Provisions (§ 488.1210)

We proposed at § 488.1210 general rules pertaining to enforcement actions against a hospice program that is not in substantial compliance with the CoPs. Under section 1822(c)(1)

of the Act, if CMS determines that a hospice program is not in compliance with the Medicare hospice programs CoPs and the deficiencies involved may immediately jeopardize the health and safety of the individual(s) to whom the hospice program furnishes items and services, then we may terminate the hospice program's provider agreement, impose the one or more enforcement remedies described in section 1822(c)(5)(B) of the Act, or both. We proposed that our decision to impose one or more remedies, including termination, would be based on the degree of noncompliance with the hospice program Federal requirements. With the proposed provisions, CMS would be able to impose one or more remedies for each discrete condition-level deficiency constituting noncompliance.

As noted in the proposed rule, it is also important to note that hospice programs can acquire initial certification for participation in Medicare via an SA survey or via accreditation by a CMS-approved AO. Accreditation by a CMS-approved AO is voluntary and not necessary to participate in the Medicare program. If an AO finds deficiencies during an accreditation survey, it communicates any condition-level findings to the applicable CMS SOG location. Based on the survey findings, CMS makes any determinations regarding the imposition of Federal enforcement remedies. An AO cannot recommend or implement enforcement remedies. In accordance with SOM Chapter 2, section 2005B, CMS may temporarily remove deemed status of an accredited hospice program due to condition-level findings found by the SA or Federal survey team during a complaint or validation survey. If the deficiencies remain uncorrected, oversight of that hospice program is transferred to CMS, through the SA, until the hospice program either demonstrates substantial compliance or CMS terminates its Medicare participation. In such a case where "deemed status" is removed, CMS will follow the usual procedures for oversight, as indicated in sections 3254 and 5100 of the SOM. Once an enforcement remedy is imposed on a formerly accredited hospice program and deemed status is removed, oversight and enforcement of that hospice program will be performed by the SA until

the hospice program achieves compliance and the condition(s) causing the noncompliance are removed or until the hospice program is terminated from the Medicare program.

At proposed § 488.1210(e), we proposed that a hospice program would be required to submit an acceptable POC to the SA or CMS within 10 calendar days from receipt of the statement of deficiencies. This plan is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and the date by which those deficiencies would be corrected. CMS would determine if the POC was acceptable based on the information presented.

At proposed § 488.1210(e), we proposed the notification requirements for enforcement remedies for hospice programs that will be issued by CMS. CMS would provide a notice of intent to the hospice program that would include the intent to impose a remedy, the statutory basis for the remedy, the nature of the noncompliance, the intent to impose a payment suspension and which payments would be suspended (if applicable), the intent to proposed a CMP and the amount being imposed (if applicable), the proposed effective date of the sanction, and appeal rights.

We proposed that for all remedies imposed, except for CMPs, when there is IJ the notice period is at least 2 calendar days before the effective date of the enforcement action and when there is no IJ, that the notice period is at least 15 calendar days before the effective date of the enforcement action. As discussed later in this section, we proposed to codify these proposals at §§ 488.1225(b) and 488.1230(b), respectively.

With respect to CMPs, we proposed that once the administrative determination to impose the CMP is final, CMS would send a final notice to the hospice program with the amount of the penalty assessed, the total number of days of noncompliance (for CMPs imposed per day), the total amount due, the due date of the penalty, and the rate of interest to be charged on unpaid balances. We proposed to codify these proposals at § 488.1245(e).

We proposed that the hospice program could appeal the determination of noncompliance leading to the imposition of a remedy under the provisions of 42 CFR part 498. A pending hearing would not delay the effective date of the remedy against the hospice program and remedies will be in effect regardless of any pending appeals proceedings. Civil money penalties would accrue during the pendency of an appeal, but would not be collected until the administrative determination is final, as we note in proposed § 488.1245(f).

Comment: Several commenters recommended the incorporation of the informal dispute resolution (IDR) process to also align with the process available for HHAs.

Response: We thank the commenters for their suggestion about incorporating an informal dispute resolution (IDR) process, but because the IDR process was not proposed in this rule, we are not including it at this time. We will consider the commenter's suggestions for future rulemaking.

Final Decision: After consideration of the public comments received, we are finalizing this provision with one modification based on changes to proposed § 488.1240, which are discussed in section VII.B.4.i of this final rule. Because payment suspensions will apply only to new patient admissions, there will be no ambiguity as to which payments are being suspended. Accordingly, we are removing the requirement at § 488.1210(e) that the notice to hospice providers identify which payments are being suspended.

d. Factors to be Considered in Selecting Remedies (§ 488.1215)

Section 1822(c) of the Act provides that if a hospice program is found to be out of compliance with the requirements specified in section 1861(dd) of the Act, CMS may impose one or more specified enforcement remedies. In the proposed rule, we proposed to establish requirements for enforcement remedies that may be imposed when hospice programs are out of compliance with Federal requirements. At CMS' discretion, these enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program, for a period not to exceed 6 months. The choice of any enforcement remedy

or termination would reflect the impact on patient care and the seriousness of the hospice program's patterns of noncompliance and would be based on the factors proposed in § 488.1215. CMS may impose termination of the provider agreement (that is, begin termination proceedings that would become effective at a future date, but no later than 6 months from the determination of noncompliance), and impose one or more remedies for hospice programs with the most egregious deficiencies, on a hospice program that was unwilling or unable to achieve compliance within the maximum timeframe of 6 months, whether or not the violations constituted an immediate jeopardy (IJ) situation. We proposed at § 488.1215, consistent with section 1822(5)(B)(i) of the Act, to establish procedures for selecting the appropriate enforcement remedy, including the amount of any CMP and the severity of each remedy, which have been designed to minimize the time between the identification of deficiencies and the final imposition of remedies, as required under section 1822(c)(5)(A)(ii) of the Act. To determine which remedy or remedies to apply, we proposed to consider the following factors that are consistent with the factors for HHA alternative sanctions:

- The extent to which the deficiencies pose IJ to patient health and safety.
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.
- The presence of repeat deficiencies (defined as condition-level), the hospice program's compliance history in general, and specifically concerning the cited deficiencies, and any history of repeat deficiencies at any of the hospice program's additional locations.
- The extent to which the deficiencies are directly related to a failure to provide quality patient care.
- The extent to which the hospice program is part of a larger organization with documented performance problems.
- Whether the deficiencies indicate a system-wide failure of providing quality care.

Comment: Several commenters requested that CMS provide staff in the CMS locations (formerly CMS Regional Offices) training in the factors to be used in making determinations on when remedies should be applied and develop processes to ensure these remedies are consistently applied. A commenter stated that this guidance and training should also be made available to hospice providers.

Response: We will develop associated guidance and provide training to CMS location and SA staff, as appropriate, that will address the concerns raised by the commenters regarding the procedures that will be followed to apply and implement the enforcement remedies while also allowing for surveyor judgment. Developed guidance and training will be made publicly available.

Comment: A few commenters recommended a step-wise approach to enforcement remedies for hospice programs that consider the seriousness and prevalence of the deficiency beginning with more targeted education remedies (for example, directed plan of correction and directed in-service training) to more stringent remedies for more severe deficiencies.

Response: We have set forth the factors upon which we will base our choice of remedy or remedies. Those factors include the extent to which the deficiencies are directly related to a failure to provide quality care and pose an immediate threat to patient health and safety, as well as the nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

e. Available Remedies (§ 488.1220)

Section 1822(c)(5)(A)(ii) of the Act provides that we “shall develop and implement specific procedures for the conditions under which each of the remedies developed under clause (i) is to be applied, including the amount of any fines and the severity of each of these remedies.”

Section 1822(c)(5)(B) of the Act explicitly provides for the following enforcement remedies to be included in the range of remedies: (1) CMPs in an amount not to exceed \$10,000 for each day

of noncompliance by a hospice program with the requirements specified in section 1861(dd) of the Act; (2) suspension of all or part of payments, , on or after the date on which the Secretary determines that remedies should be imposed; and (3) appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made to bring the program into compliance with all such requirements. In addition to those specified in the statute, we proposed to add a directed POC and directed in-service training as additional enforcement remedies at § 488.1220.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

f. Action when Deficiencies Pose Immediate Jeopardy (§ 488.1225) and Termination (§ 489.53)

For situations involving IJ, if we determine based on a standard survey or otherwise that a hospice program's deficiencies involve IJ to the health and safety of the individuals to whom the program furnishes items and services, it shall take immediate action to ensure the removal of the IJ and to correct the deficiencies or terminate the certification of the program. We proposed at § 488.1225(a) to implement the statutory requirement of 1822(c)(1) of the Act by specifying that if the IJ situation is not addressed and resolved within 23 days from the last day of the survey because the hospice program is unable or unwilling to correct the deficiencies, we will terminate the hospice program's provider agreement. In addition, we could impose one or more enforcement remedies including a CMP, temporary management, and/or suspension of Medicare payments before the effective date of termination.

We proposed § 488.1225(b), that for a deficiency or deficiencies that pose IJ, we would provide the hospice program with at least 2 days advance notice of any proposed remedies, except CMPs (discussed at proposed § 488.1245). The requirements for a notice of intent are set forth at proposed § 488.1210(e). Under our existing survey process, providers are informed of any IJ findings upon discovery of the IJ situation during the survey or as part of the exit

conference at the end of the survey. This would give a hospice program time to remove the IJ and correct the deficiencies that gave rise to the IJ finding. To assure a hospice program achieves prompt compliance, we expect that we will give hospice programs written notice of an impending enforcement actions against them as quickly as possible following the completion of a survey of any kind.

For terminations, we proposed that we would give notice of the termination within 2 days before the effective date of the termination, to hospice programs consistent with the requirement for HHAs. We also proposed to amend § 489.53(a)(17) to indicate that we would terminate a hospice program's (as well as an HHA's) provider agreement if the hospice program failed to correct a deficiency or deficiencies within the required time frame.

Finally, at proposed § 488.1225(c), we proposed to require a hospice program whose provider agreement is terminated to appropriately and safely transfer its patients to another local hospice program within 30 days of termination, unless a patient or caregiver chooses to remain with the hospice program as a self-pay or with another form of insurance (for example, private insurance). In addition, the hospice program would be responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients.

Comment: Several commenters recommended that CMS clarify the notice period in calendar days for action imposed when deficiencies pose immediate jeopardy or are at the condition-level but do not pose immediate jeopardy.

Response: We appreciate the comments and in this final rule added "calendar" days for the notice period in the titles at §§ 488.1225(b) and 488.1230(b). Additionally, we are making a technical correction in § 488.1225(b) to reflect the notice requirements are outlined in § 488.1210(e), not § 488.1225(e).

Comment: Several commenters recommended that CMS consider the method that will be used to deliver the notices and whether 2 days is reasonable. Commenters stated situations where the statement of deficiencies has exceeded the 10-business day delivery requirement to the

provider and they are concerned that delays will occur when enforcement remedies are applied. Commenters recommended that for delays in the statement of deficiencies that the hospice provider should be granted an extension for the plan of correction submission equivalent to the number of delinquent days, and commenters also believed that in situations where enforcement remedies are applied, the implementation date of the remedy should be delayed for the same number of days that the notice is delinquent. One commenter recommended that CMS investigate the reasons for these delays and implement processes to remedy the situation.

Response: The 2-day calendar notice is to inform the hospice program of the immediate jeopardy situation and that the hospice program will be terminated in 23 days unless the immediate jeopardy is corrected and for all imposed remedies, except for CMPs. This policy is consistent with the current HHA requirements and has been used in immediate jeopardy situations for other providers. The written notice will be delivered in hard copy by mail or in an electronic format, such as e-mail. The 2-day calendar notice of termination with an immediate jeopardy finding is prudent considering the short 23-day time frame to attain compliance and also given the serious risk to patient health and safety. For remedies imposed when there is immediate jeopardy, the notice will be given at least 2 calendar days before the effective date of the enforcement action. The notice will include the requirements finalized in § 488.1210(e) that includes the proposed effective date of the remedy. The recommendation for us to investigate delays in notices and implement processes to remedy the situation is beyond the scope of this rule.

Final Decision: After consideration of the public comments we received, we are adding the word “calendar” to the 2-day notice at § 488.1225(b) and fixing a technical error in that same paragraph, in the reference to notice requirements, to accurately reflect § 488.1210(e).

g. Action when Deficiencies are at the Condition-level but do not Pose Immediate Jeopardy (§ 488.1230)

In section 1822(c)(2) of the Act, if the Secretary determines based on a survey or otherwise that a hospice program is no longer in compliance with the requirements specified in section 1861(dd) of the Act and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose remedies developed under section 1822(c)(5)(A) of the Act, in lieu of terminating the hospice program's participation in the Medicare program. If, after such a period of remedies, the program is still not in compliance with all requirements, the Secretary shall terminate the hospice program's participation in the Medicare program.

In the proposed rule, we specified that enforcement remedies, such as those proposed in § 488.1220, would be imposed before the termination becomes effective, but cannot continue for a period that exceeded 6 months. In addition, to protect the health and safety of individuals receiving services from the hospice program, enforcement remedies would continue in effect until the hospice program achieves compliance or has its Medicare participation terminated, whichever occurs earlier. For example, the suspension of payment remedy would end when the hospice program corrects all condition-level deficiencies or is terminated from the Medicare program.

We proposed at § 488.1230, that for a deficiency or deficiencies that do not pose IJ, we would provide the hospice program at least 15 days advance notice of any proposed remedies, except for CMPs (discussed at proposed § 488.1245). Such remedies would remain in effect until the effective date of an impending termination (at 6 months) or until the hospice program achieves compliance with CoPs, whichever is earlier. This 15-day period is consistent with the general rule for providers and suppliers in § 489.53(d)(1).

Comment: Several commenters recommended that for enforcement remedies at the condition level that do not pose immediate jeopardy, CMS clarify that the notice period is in calendar days.

Response: We appreciate the comments and in this final rule we have included “calendar” in the title at § 488.1230(b).

Final Decision: After consideration of the public comments we received, we are adding the word “calendar” to the 15-day notice at § 488.1230(b).

h. Temporary Management (§ 488.1235)

Section 1822(c)(5)(B)(iii) of the Act specifies the use of appointment of temporary management as an enforcement remedy to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made in order to bring the program into compliance with all such requirements. As we proposed at § 488.1205, “temporary management” means the temporary appointment by us or an authorized agent, of a substitute manager or administrator, who would be under the direction of the hospice program’s governing body and who would have authority to hire, terminate or reassign staff, obligate hospice program funds, alter hospice program procedures, and manage the hospice program to correct deficiencies identified in the hospice program’s operation. The substitute manager or administrator would be appointed based on qualifications described in §§ 418.100 and 418.114 and would be under the direction of the hospice program’s governing body.

We proposed at § 488.1235 to set out the circumstances under which we would utilize our authority under section 1822(c)(5)(C)(iii) of the Act to place a hospice program under temporary management. We proposed to specify the duration and effect of this enforcement remedy, and the payment procedures for temporary managers’ salaries and other additional costs. We would provide the hospice program with written notice of our intent to impose a temporary management remedy in accordance with proposed § 488.1210(e).

At § 488.1235(a), we proposed that temporary management would be imposed when a hospice program is determined to have condition-level deficiencies and that the deficiencies or the management limitations of the hospice program are likely to impair the hospice program’s

ability to correct the deficiencies and return the hospice program to compliance with all of the CoPs within the required timeframe. We proposed at § 488.1235(c) to impose temporary management to bring a hospice program into compliance with program requirements within 6 months of the date of the survey identifying noncompliance.

We proposed at § 488.1235(b) if the hospice program refuses to relinquish authority and control to the temporary manager, we would terminate the hospice program's provider agreement. If a temporary manager was appointed, but the hospice program failed to correct the condition-level deficiencies within 6 months from the last day of the survey, the hospice program's Medicare participation would be terminated. Additionally, if the hospice program resumes management control without CMS's approval, we would impose termination and could impose additional enforcement remedies. The appointment of a temporary manager would not relieve the hospice program of its responsibility to achieve and maintain compliance with the participation requirements. We proposed at § 488.1235 that temporary management would end when--

- We determine that the hospice program has achieved substantial compliance and has the management capability to remain in compliance;
- The hospice program provider agreement is terminated; or
- The hospice program resumes management control without CMS approval.
- Temporary management would not exceed a period of 6 months from the date of the survey identifying noncompliance.

At § 488.1235, we proposed that temporary management would be required to be provided at the hospice program's expense. Before the temporary manager was installed, the hospice program would have to agree to pay his/her salary directly for the duration of the appointment. We believe that the responsibility for the hospice program to pay the expenses of the temporary manager is an inherent management responsibility of the hospice agency for which Medicare regularly reimburses the hospice program and through such temporary outside

management might be necessary in some cases to bring the hospice program back into compliance with the CoPs. We proposed that the salary for the temporary manager would not be less than the amount equivalent to the prevailing salary paid by providers in the geographic area for positions of this type, based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates. In addition, the hospice program would have to pay for any additional costs that the hospice program may have incurred if such person had been in an employment relationship, and any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State. We would consider a hospice program's failure to pay the salary of the temporary manager to be a failure to relinquish authority and control to temporary management.

Comment: Several commenters stated that when the temporary management enforcement remedy is imposed, the individual acting as the temporary manager should complete the basic CMS hospice surveyor training before beginning their assignment.

Response: Although not an explicit requirement, we encourage the temporary manager to complete the basic CMS hospice surveyor training. The training is available free of charge on the QSEP website at <https://qsep.cms.gov>, to providers and all entities conducting surveys, and the public at large. QSEP training is accessible on an individual, self-paced basis. The basic training courses provide surveyors with the key knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare CoPs and assure an adequately trained, effective surveyor workforce.

Comment: Several commenters recommended that we clarify whether a temporary manager is required to be external to the hospice organization.

Response: The temporary manager must have the experience and education that qualifies the individual to oversee the hospice program. The temporary manager can be either internal or external to the hospice program, and will be appointed by CMS or the SA based on qualifications

described in §§ 418.100 and 418.114. Additionally, the temporary manager would be under the direction of the hospice program's governing body.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

i. Suspension of Payment for all New Patient Admissions (§ 488.1240)

We proposed in § 488.1240 provisions describing when and how we would apply a suspension of payment for all new patient admissions on or after the date on which the Secretary determines that remedies should be imposed under § 488.1225 or § 488.1230. We proposed that if a hospice program has a condition-level deficiency or deficiencies (regardless of whether or not an IJ exists), we may suspend payments for all or part of the payments to which a hospice program would otherwise be entitled for items and services furnished by a hospice program on or after the effective date of the enforcement remedy. We proposed to determine whether to impose a suspension of all or part of the payments on or after the effective date of the enforcement remedy. We proposed to determine whether to impose a suspension of payment based on the factors outlined in proposed § 488.1215 that are considered when selecting remedies. The suspension of payment was proposed at § 488.1240 to be for a period not to exceed 6 months and would end when the hospice program either achieved substantial compliance or was terminated. We proposed to provide the hospice program with written notice of our intent to impose a payment suspension remedy at least 2 calendar days before the effective date of the remedy in IJ situations, per proposed § 488.1225(b), or 15 calendar days before the effective date of the remedy in non-IJ situations, per proposed § 488.1230(b). The proposed notice of intent for all remedies, described at § 488.1210(e), would be used to notify a hospice program of a suspension of all or part of the payments to which the hospice program would otherwise be entitled. .

Additionally, section 1822(c)(5)(C)(ii) of the Act provides that a suspension of payment remedy shall terminate when we find that the hospice program is in substantial compliance with the requirements specified in, or developed in accordance with, section 1861(dd) of the Act.

That is, the suspension of payment remedy would end when the hospice program is determined to have corrected all condition-level deficiencies, or upon termination, whichever is earlier. We proposed to codify that duration of the remedy at § 488.1240(c).

Comment: Several commenters expressed concerns and requested that CMS consider limiting the suspension of all or part of payments to new hospice admissions only. The commenters stated that a suspension of payment not limited to new hospice admissions would result in a disproportionate financial burden on hospice providers and would affect access to care. Commenters also stated that limiting the suspension of all or part of payments to new hospice admissions only would be consistent with existing HHA enforcement sanctions, Congressional intent, and OIG recommendations. A commenter recommended we consider suspension of all or part of payments to new hospice admissions only in the case of an immediate jeopardy situation.

Response: We have considered the commenters' suggestions and agree that limiting the payment suspension to all new patient admissions would help avoid disproportionate financial burdens on hospice programs. In addition, for poor performing hospice programs, CMS continues to have the option to terminate.

Final Decision: After consideration of the public comments we received, we are finalizing this provision with modifications to limit the suspension of payments to all new patient admissions. As noted elsewhere, we have made conforming edits to §§ 488.1210(e), 488.1220(b), and 488.1260(a)(1)(i).

j. CMPs (§ 488.1245)

We proposed at § 488.1245 requirements for the imposition of CMPs. Section 1822(c)(5)(C) of the Act outlines the requirements for CMP procedures. Additionally, section 1822(c)(5)(C)(i)(I) of the Act requires that the CMP provisions under section 1128A (other than subsections (a) and (b)) of the Act shall be applied to the hospice CMPs, which also must be considered when establishing the amount. We proposed to impose a CMP against a hospice

program that is determined to be out of compliance with one or more CoPs, regardless of whether the hospice program's deficiencies pose IJ to patient health and safety. We could also impose a CMP for the number of days of IJ. Under section 1822(c)(5)(B)(i) of the Act, the CMP amount cannot exceed \$10,000 for each day of noncompliance. Our proposals align with the imposition of CMPs authorized by section 1891(f) of the Act as set out for HHAs at § 488.845, which we may impose against an HHA that is determined to be out of compliance with one or more CoPs, regardless of whether the HHA's deficiencies pose IJ to patient health and safety.

In this section, we proposed both "per day" and "per instance" CMPs at § 488.1245(a). The per day CMPs would be imposed for each day of noncompliance with the CoPs. Additionally, should a survey identify a particular instance or instances of noncompliance during a survey, we proposed to impose a CMP for that instance or those individual instances of noncompliance. We proposed to define "per instance" in § 488.1205 as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes that we impose a remedy.

While there may be a single event that leads to noncompliance, there can also be more than one instance of noncompliance identified and more than one CMP imposed during a survey. For penalties imposed per instance of noncompliance, we proposed penalties from \$1,000 to \$10,000 per instance. Such penalties would be assessed for one or more singular events of condition-level noncompliance that were identified at the survey and where the noncompliance was corrected during the onsite survey.

Since the range of possible deficiencies is great and depends upon the specific circumstances at a particular time, it would be impossible to assign a specific monetary amount for each type of noncompliance that could be found. Thus, we believe that each deficiency would fit into a range of CMP amounts.

We proposed that, in addition to those factors that we would consider when choosing a type of remedy proposed in § 488.1215, we would consider the following factors when determining a CMP amount:

- The size of the hospice program and its resources.
- Evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the CoPs and to ensure patient health and safety. When several instances of noncompliance would be identified at a survey, more than one per-day or per instance CMP could be imposed as long as the total CMP did not exceed \$10,000 per day. In addition, a per-day and a per-instance CMP would not be imposed simultaneously for the same deficiency in conjunction with a survey.

At proposed § 488.1245, we would have the discretion to increase or reduce the amount of the CMP during the period of noncompliance, depending on whether the level of noncompliance had changed at the time of a revisit survey. However, section 1822(c)(5)(B)(i) of the Act specifies that the remedies shall include a CMP in an amount not to exceed \$10,000 for each day of noncompliance. Therefore, we proposed at § 488.1245(b)(2)(iii) that no CMP assessment could exceed \$10,000 per day of noncompliance. To comply with sections 1822(c)(5)(B)(i) and 1822(c)(5)(C)(i) of the Act, we proposed to establish a three-tier system with subcategories that would establish the amount of a CMP.

In proposed § 488.1245(b)(3), (4), and (5), we proposed ranges of CMP amounts based on three levels of seriousness—upper, middle, and lower:

- Upper range—For a deficiency that poses IJ to patient health and safety, we would assess a penalty within the range of \$8,500 to \$10,000 per day of condition-level noncompliance.

- Middle range—For repeat and/or a condition-level deficiency that did not pose IJ, but is directly related to poor quality patient care outcomes, we would assess a penalty within the range of \$1,500 up to \$8,500 per day of noncompliance with the CoPs.

- Lower range—For repeated and/or condition-level deficiencies that did not constitute IJ and were deficiencies in structures or processes that did not directly relate to poor quality patient care, we would assess a penalty within the range of \$500 to \$4,000 per day of noncompliance.

The proposed CMP amounts would be subject to annual adjustments for inflation in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74). Annually adjusted amounts are published at 45 CFR part 102.

Under the proposed provisions, if we imposed a CMP, we would send the hospice program written notification of the intent to impose it, including the amount of the CMP being imposed and the proposed effective date of the sanction, under proposed §§ 488.1210(e) and 488.1245(c). Once the administrative determination is final, we proposed to send a final notice to the hospice program with the amount of the penalty that was assessed; the total number of days of noncompliance (for per day CMPs); the total amount due; the due date of the penalty; and the rate of interest to be charged on unpaid balances.

Whether per instance or per day CMPs are imposed, once the hospice program has received the notice of intent to impose the CMP, it would have 60 calendar days from the receipt of the written notice of intent to either request an administrative hearing in accordance with § 498.40 or to provide notice to CMS of its intent to waive its right to an administrative hearing, in accordance to the procedures specified in proposed § 488.1245(c)(2), to receive a 35 percent reduction in the CMP amount. The CMP would be due within 15 calendar days of hospice programs' written request for waiver. If the hospice program did not respond to the notice of

intent to impose a CMP within 60 calendar days of receipt, it would waive its right to a hearing. In such cases, the CMP would not be reduced by 35 percent because a hospice program must follow the procedures specified at proposed § 488.1245(c)(2) to receive the reduction.

A per-day CMP would begin to accrue as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance and would end on the date of correction of all deficiencies, or the date of termination. We proposed at § 488.1245(d) that in IJ cases, if the IJ is not removed, the CMP would continue to accrue until we terminated the provider agreement (within 23 calendar days after the last day of the survey which first identified the IJ). Under proposed § 488.1245(d)(4), if IJ did not exist, the CMP would continue to accrue until the hospice program achieved substantial compliance or until we terminated the provider agreement.

As noted elsewhere, in no instance would a period of noncompliance be allowed to extend beyond 6 months from the last day of the survey that initially determined noncompliance. If the hospice program has not achieved compliance with the CoPs within those 6 months, we would terminate the hospice program. The accrual of per-day CMPs would stop on the day the hospice program provider agreement was terminated or the hospice program achieved substantial compliance, whichever was earlier. The total CMP amounts would be computed and collected after an administrative determination is final and a final notice sent to the hospice program as described in § 488.1245(e).

We also proposed that for a hospice program being involuntarily terminated and for which a civil money penalty had been imposed and was still due, we would include the final notice, also known as a due and payable notice, as part of the termination notice. In other words, the information in a final notice, as described in § 488.1245(e), would be included in the termination notice.

At proposed § 488.1245(f), a CMP would become due and payable 15 calendar days from--

- The time to appeal had expired without the hospice program appealing its initial determination;
- We received a request from the hospice program waiving its right to appeal the initial determination;
- A final decision of an Administrative Law Judge or Appellate Board of the Departmental Appeals Board upheld CMS's determinations; or
- The hospice program was terminated from the program and no appeal request was received.

A request for a hearing would not delay the imposition of the CMP, but would only affect the collection of any final amounts due to us.

Comment: Commenters recommended CMS develop specifications for penalties collected at the national and/or state level for hospice program improvements.

Response: Determinations on whether to impose an enforcement remedy and the specific remedy to be imposed will not be left to the sole discretion of the hospice surveyor. All final decisions regarding whether or not to impose a remedy and what type of remedy to be imposed will be made by the applicable CMS Location. Any funds collected as a result of CMPs imposed upon a hospice are distributed to the State Medicaid Agency and to the US Treasury under section 1128A(f) of the Act. Additionally, the CAA 2021 included a provision at section 1822(c)(5)(C) that allows the Secretary to use a portion of the CMPs collected to support activities that benefit individuals receiving hospice care, including education and training programs to ensure hospice program compliance. We will consider using this authority to support improvement activities in hospices in the future and will consider developing interpretive guidance for clarification as needed.

Comment: Many commenters recommended that CMS consider a hospice provider-initiated improvement plan to achieve positive outcomes and sustained compliance over a "look back" period in determining whether to impose the CMP remedy for previous noncompliance.

Response: We disagree that a hospice provider-initiated improvement plan should be a determination on whether to impose the CMP remedy for previous noncompliance. The hospice program is expected to be in continuous compliance with the health and safety CoPs. When we determine the amount of the CMP penalty, one factor that is considered is evidence that the hospice program has an internal quality assessment and performance improvement system to ensure patient health and safety and compliance with the CoPs. We are finalizing as proposed the requirement at § 488.1245(b)(1)(iii) that CMS take into account that the hospice program has evidence of a self-regulating quality assessment and improvement plan when determining the amount of the penalty. We can also decrease the CMP penalty amount from the upper range to the middle or lower range if a condition-level deficiency exists and the hospice program shows an earnest effort to correct systemic causes of the deficiencies and sustain improvement. We are finalizing as proposed the requirement at § 488.1245(b)(7) to allow CMS to shift the CMP amount imposed per day from the upper range to the middle or lower range.

Comment: Commenters recommended that CMS use a scaled approach to CMPs based on deficiency scope and severity and a commenter noted that CMS proposes criteria that also include factors that account for the size of the hospice program and its resources in order to provide some relief for small hospice programs.

Response: We will factor in the size of the hospice program and its resources when considering the amount of the CMP as proposed in § 488.1245(b)(1)(ii). CMPs may be adjusted based on revisit survey findings and after a review of the provider's attempted correction of deficiencies as proposed in § 488.1245(b)(2). Additionally, CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or uncorrected deficiencies from a prior survey as proposed in § 488.1245(b)(8)(iii).

Comment: Commenters encouraged CMS to provide a standardized, transparent process regarding the calculation of CMPs.

Response: The proposed CMP regulations at § 488.1245 provide a transparent process regarding CMP application, penalty amounts and adjustments, and appeal procedures consistent with requirements standardized for HHAs. CMS will also consider developing interpretive guidance for clarification as needed.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

k. Directed Plan of Correction (§ 488.1250)

We proposed at § 488.1250 to include a directed plan of correction as an available remedy. This remedy is a part of the current HHA and nursing home alternative sanction procedures and has been an effective tool to encourage the correction of deficient practices. Specifically, we proposed that we may impose a directed POC on a hospice program that is out of compliance with the CoPs. A directed POC remedy would require the hospice program to take specific actions to bring the hospice program back into compliance and correct the deficient practice(s). As indicated in § 488.1250(b)(2) a hospice program's directed POC would be developed by us or by the temporary manager, with CMS approval. The directed POC would set forth the outcomes to be achieved, the corrective action necessary to achieve these outcomes, and the specific date the hospice program would be expected to achieve such outcomes. The hospice program would be responsible for achieving compliance. If the hospice program failed to achieve compliance within the timeframes specified in the directed POC, we could impose one or more additional enforcement remedies until the hospice program achieved compliance or was terminated from the Medicare program. Before imposing this remedy, we would provide appropriate notice to the hospice program under § 488.1210(e).

Comment: Commenters were in support of the proposed directed POC and directed in-service training enforcement remedies that align with the available home health alternative sanctions. A commenter recommended that the directed POC be developed by CMS or by the temporary manager, with CMS approval. The commenter also recommended that the directed

POC include follow-up reports to CMS or the SA and/or a resurvey to ensure continued progress and compliance with the directed POC. Additionally, the commenter recommended that directed POCs ultimately be publicly reported and delineate between and among deficiencies, especially regarding the scope and severity of such deficiencies.

Response: We appreciate the support for the proposed directed POC and directed in-service training enforcement remedies that align with the available home health alternative sanctions. Similar to HHAs, a directed POC can be guided by CMS, the SA, or a temporary manager (with CMS/SA approval) to ensure that the underlying cause of the cited deficiency or deficiencies does not recur. Follow-up reports to the directed POC and/or a resurvey to ensure compliance with the directed POC will be at the discretion of CMS or the SA. The public reporting of directed POCs and delineation of deficiencies is beyond the scope of this rule.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

1. Directed In-Service Training (§ 488.1255)

We proposed at § 488.1255, to outline the requirements for conducting directed in-service training for hospice programs with condition-level deficiencies. At proposed § 488.1255(a), directed in-service training would be required where staff performance resulted in noncompliance and it was determined that a directed in-service training program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

At § 488.1255(a)(3), we proposed that hospice programs use in-service programs conducted by instructors with an in-depth knowledge of the area(s) that would require specific training so that positive changes would be achieved and maintained. Hospice programs would be required to participate in programs developed by well-established education and training services. These programs would include, but not be limited to, schools of medicine or nursing, area health education centers, and centers for aging. We would only recommend possible

training locations to a hospice program and not require that the hospice program utilize a specific school/center/provider. In circumstances where the hospice is subject to the SFP, additional technical assistance and/or resources could be made available. The hospice program would be responsible for payment for the directed in-service training for its staff. At proposed § 488.1255(b), if the hospice program did not achieve substantial compliance after such training, we could impose one or more additional remedies. Before imposing this remedy, we would provide appropriate notice to the hospice program under proposed § 488.1210(e).

Comment: Commenters were in support of the proposed directed plan of correction and directed in-service training enforcement remedies that align with the available home health alternative sanctions.

Response: We appreciate the support for the proposed directed plan of correction and directed in-service training enforcement remedies that align with the available home health alternative sanctions.

Final Decision: After consideration of the public comments we received, we are finalizing this section as proposed.

m. Continuation of Payments to a Hospice program with Deficiencies (§ 488.1260)

We proposed at § 488.1260, the continuation of Medicare payments to hospice programs not in compliance with the requirements specified in section 1861(dd) of the Act over a period of no longer than 6 months in accordance with section 1822(c)(4) of the Act. The continuation of Medicare payments would continue for 6 months if –

- An enforcement remedy or remedies (with the exception of suspension of all payments) have been imposed on the hospice program and termination has not been imposed;
- The hospice program has submitted a POC which has been approved by CMS; and
- The hospice program agrees to repay the Federal Government the payments received under this arrangement should the hospice program fail to take the corrective action as outlined in its approved POC in accordance with the approved plan and timetable for corrective action.

We proposed these three criteria at § 488.1260(a). If any of these three requirements outlined in the Act were not met, a hospice program would not receive any Federal payments from the time that deficiencies were initially identified. We would also terminate the agreement before the end of the 6-month correction period, which begins on the last day of the survey, in accordance with § 488.1265 if the requirements at § 488.1260(a)(1) were not met. If any remedies were also imposed, they would stop accruing or end when the hospice program achieved compliance with all requirements, or when the hospice program's provider agreement was terminated, whichever was earlier.

Finally, if a hospice program provided an acceptable POC but could not achieve compliance with the CoPs upon resurvey within 6 months of the last day of the survey, we proposed at § 488.1230(d) that we would terminate the provider agreement.

Comment: A commenter recommended that CMS modify the proposed regulatory text at § 488.1260(a) by replacing “may” with “will” to ensure continuity of the continuation of payments to a hospice program with deficiencies.

Response: We respectfully disagree with the commenter's suggested change of “may” to “will” at § 488.1260(a). The language for continued payments is consistent with the language in the HHA regulation at § 488.860. Therefore, the language at § 488.1260(a) for continued payments will read “CMS *may* continue payments to a hospice program with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.”

Final Decision: After consideration of the public comments we received, we are finalizing this section with one modification. Because we are finalizing § 488.1240 to apply only to payments for all new patient admissions, we are removing the parenthetical in proposed § 488.1260(a)(1)(i) that excepted the suspension of all payment.

n. Termination of Provider Agreement (§ 488.1265)

At § 488.1265(a), we proposed to address the termination of a hospice program's Medicare provider agreement, as well as the effect of such termination. Termination of the provider agreement would end all payments to the hospice program, including any payments that were continued at the proposed § 488.1260. Termination would also end enforcement remedies imposed against the hospice program, regardless of any proposed timeframes for the remedies originally specified. At proposed § 488.1265(b), we would terminate the provider agreement if-- (1) the hospice program failed to correct condition-level deficiencies within 6 months unless the deficiencies constitute IJ; (2) the hospice program failed to submit an acceptable POC; (3) the hospice program failed to relinquish control of the temporary manager (if that remedy is imposed); or (4) the hospice program failed to meet the eligibility criteria for continuation of payments. At § 488.1265(d) we proposed using the procedures for terminating a hospice program at § 489.53 and providing appeal rights in accordance with 42 CFR part 489. Additionally, we proposed using the procedures for payments 30 days post termination for hospice programs at § 489.55. Payment is available for up to 30 days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination (§ 489.55(a)(2)).

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

VIII. Requests for Information

A. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality

Measurement in Post-Acute Care Quality Reporting Programs – Request for Information

In the proposed rule, we sought input on the following steps that would enable transformation of our quality measurement enterprise to be fully digital (86 FR 19765):

1. What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?
2. How do you currently share information with other providers and are there specific industry best practices for integrating SDOH screening into EHR's?
3. What ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to HHAs?
4. What additional resources or tools would post-acute care settings, including but not limited to HHAs and health IT vendors, find helpful to support testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?
5. Would vendors, including those that service post-acute care settings, including but not limited to HHAs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?
6. What could be the potential use of FHIR dQMs that could be adopted across all QRPs?

Most commenters supported the use and adoption of Fast Healthcare Interoperable Resources (FHIR) Application Programming Interfaces (APIs). Many commenters stressed the need for further work in standardizing data that are part of clinical documents to exchange

information based on high-value use. Another requirement suggested by commenters is to specify the defined set of FHIR-APIs and HL7 messages that each health IT vendor must support to meet interoperability standards of practice or both. Many commenters shared that we need to consider providing incentives to working with EHR vendors that promote practices that support interoperability. Commenters supported the meaningful use framework and how it relates to promoting dQMs. They note that HHAs and other PAC providers were not included in the HITECH Act and therefore did not have the incentives as other provider communities that are needed to support providers and vendors. A commenter suggested that incentives need not be financial and that they could be in the form of points via a value-based purchasing program. Other incentives suggested included training and technical assistance for providers with the lowest adoption of technology infrastructure. Commenters requested there be a robust trial period before any dQM adoption nationally. Ideally, commenters would prefer 6 months to 1 year from whenever final specifications around dQMs are made before implementation. A commenter noted that family or caregivers play an important role in older patients care and need to be included and supported in any transition to more digital records as they support patients. Some commenters also provided responses to questions about their EHR systems and capabilities. We appreciate commenters' input on this very important work.

While we are not responding to comments in response to this Request for Information, we intend to use this input to inform future policy related to Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs.

B. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs – Request for Information

In the proposed rule, we sought public comment on the following:

- As finalized in the HH PPS final rule (84 FR 60597 through 60608), HHAs will be required to report Standardized Patient Assessment Data Elements on certain SDOH, including race, ethnicity, preferred language, interpreter services, health literacy,

transportation and social isolation.¹⁰⁴ We sought guidance on any additional Standardized Patient Assessment Data Elements that could be used to assess health equity in the care of HHA patients, for use in the HH QRP.

- Recommendations for how we can promote health equity in outcomes among HHA patients. We are also interested in feedback regarding whether including HHA-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow HHAs to identify gaps in the quality of care they provide (for example, methods similar or analogous to the *CMS Disparity Methods*¹⁰⁵ which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmission Reduction Program (84 FR 42496 through 42500).

- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.

- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges HHAs encounter for effective capture, use, and exchange of health information include data on ethnicity and other social determinants of health to support care delivery and decision-making.

Commenters consistently supported our focus on closing health equity gaps in post-acute care, including under the HH QRP. Many commenters shared that relevant data collection and appropriate stratification are very important in addressing any health equity gaps. Stratification of health outcomes would be very helpful to organizations and some commenters supported providing home health agencies with confidential reports that report quality measures stratified

¹⁰⁴ In response to the COVID-19 PHE, CMS released a May 8, 2020 interim final rule with comment period (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least 2 full fiscal years after the end of the PHE.

¹⁰⁵ <https://qualitynet.cms.gov/inpatient/asures/disparity-methods/methodology>

by social risk factors. Many commenters shared their strategies for addressing health disparities, noting that this was an important commitment for many health provider organizations. Some commenters who worked for HHAs note that they collect SDOH elements to develop comprehensive and individualized care plans. Commenters also shared that HHAs currently use OASIS data on payer information, race/ethnicity, zip code, and age.

Commenters had recommendations for additional SDOH elements that could strengthen data collection efforts. Many commenters suggest capturing information related to food insecurity, income, education, transportation, and housing. Other commenters suggested the data collection and measurement of demographic characteristics such as sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status. Numerous commenters suggested that for any data elements introduced, we need to ensure the format align with other Federal agency best practices, such as indicators used by the U.S. Census Bureau. Commenters also suggested that we need to consider adopting the use of Z codes for SDOH on home health claims. Some commenters emphasized balancing the need to have targeted new data elements that capture necessary information on non-clinical patient characteristics without introducing undue burden with too many new, untested items. Some commenters proposed working with existing efforts in the public and private sector that promote health equity by addressing social determinants of health. A commenter cautioned we from the inclusion of social risk factors without careful methodological considerations into risk adjustment models. They note inclusion of some social risk factors could perpetuate low performance expectations. Commenters noted that the COVID-19 PHE promoted use of more digital health tools and that this expansion need to be made permanent to help support the reduction in the equity gap. Some also highlighted how the PHE underscores the need for better data collection and analysis of demographic data to aid in addressing disparities in outcome and care. Some commenters are against indirect estimation methods and suggest that we need to work on a timeline for introducing any SDOH data elements needed and to focus on direct estimation. A commenter

shared that it is important to consider the needs of American Indian/Alaska Natives in any data collection strategy.

While we are not responding to specific comments submitted in response to this Health Equity request for information (RFI) in this final rule, we appreciate all of the comments and interest in this topic. We will continue to take all concerns, comments, and suggestions into account as we continue work to address and develop policies on this important topic. It is our hope to provide additional stratified information to HHAs related to race and ethnicity if feasible. The provision of stratified measure results will allow HHAs to understand how they are performing with respect to certain patient risk groups, to support these providers in their efforts to ensure equity for all of their patients, and to identify opportunities for improvements in health outcomes.

IX. Revised Compliance Date for Certain Reporting Requirements Adopted for Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) and Long-Term Care Hospital (LTCH) QRP

A. Revised Compliance Date for Certain Inpatient Rehabilitation Facility (IRF) QRP Reporting Requirements

1. Background

In IFC-2 (85 FR 27550), we delayed the compliance date for certain reporting requirements under the IRF QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for IRFs to begin reporting the Transfer of Health (TOH) Information to Provider-PAC and the TOH Information to Patient-PAC measures and the requirement for IRFs to begin reporting certain Standardized Patient Assessment Data Elements from October 1, 2020, to October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. We also delayed the adoption of the updated version of the IRF Patient Assessment Instrument (PAI) V4.0 with which IRFs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements.

Under IFC-2, IRFs must use the IRF-PAI V4.0 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. IRFs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the IRF-PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. The delay to begin collecting data for these measures was intended to provide relief to IRFs from the added burden of implementing an updated instrument during the COVID-19 PHE. We wanted to provide maximum flexibilities for IRFs to respond to the public health threats posed by the COVID-19 PHE, and to reduce the burden in administrative efforts associated with attending

trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC-2, we believed that the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements would not have a significant impact on the IRF QRP. However, the COVID-19 PHE showed the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the HH QRP. The PHE's disproportionate impact demonstrates the importance of analyzing this impact and the needs for these populations in order to improve quality of care within IRFs especially during a public health emergency.

2. Current Assessment of IRFs

To accommodate the COVID-19 PHE, we provided additional guidance and flexibilities, and as a result IRFs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID-19 PHE. For example, we held regular "Office Hours" conference calls to provide IRFs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting and billing. We also supported PAC providers, including IRFs, by providing flexibilities in the delivery of care in response to the PHE, such as modifying the required face-to-face visits in IRF to be completed by telehealth (42 CFR 412.622(a)(3)(iv) and 412.29(e)) during the PHE for COVID-19, and waiving the post-admission physician evaluation requirement at § 412.622(a)(4)(ii). In the FY 2021 IRF PPS final rule (85 FR 48445 through 48447),¹⁰⁶ we removed the post-admission physician evaluation requirement permanently beginning October 1, 2021. In addition, as of June 9, 2021, 63.8 percent of the adult population has received at least one vaccination, and COVID-19 cases and deaths have steadily declined over the last 30 days.¹⁰⁷ We also believe that much more is known about COVID-19 than we did at the time IFC-2 was

¹⁰⁶ In the FY 2022 HH proposed rule (86 FR 35874), CMS provided an incorrect citation and is correcting that error here and throughout this final rule.

¹⁰⁷ CDC COVID Data Tracker. Retrieved from: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

finalized.^{108,109,110,111}

Based upon other flexibilities such as the previous examples, the increase in knowledge IRF providers have about treating patients with COVID-19¹¹² since finalizing IFC-2, and the trending data on COVID-19, IRFs are in a better position to accommodate reporting of the TOH measures and certain (Social Determination of Health) Standardized Patient Assessment Data Elements. Also, recent reports (that were not available at the time the IFC-2 was finalized) suggest that IRFs have the capacity to begin reporting the TOH measures and certain Social Determinant of Health (SDOH) Standardized Patient Assessment Data Elements.¹¹³

After evaluating the impact of the revised compliance date under IFC-2, feasibility around data collection by IRFs, and support needs of providers during the COVID-19 PHE, we have determined that IRFs now have the administrative capacity to attend training, train their staff, and work with their vendors to incorporate the updated assessment instruments, the IRF-PAI V4.0 into their operations.

We now believe that based upon the advancement of information available about COVID-19 vaccination and treatments described previously, and the importance of the data in the IRF QRP, it would be appropriate to modify the compliance date finalized in IFC-2. This may support future activities under Executive Order 13985, entitled “Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government,” issued January 20, 2021 (<https://www.federalregister.gov/documents/2021/01/25/2021->

¹⁰⁸ Here’s Exactly Where We are with Vaccine and Treatments for COVID-19. Healthline. May 11, 2021. Retrieved from: <https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-for-covid-19>.

¹⁰⁹ COVID research: a year of scientific milestones. Nature. May 5, 2021. Retrieved from: <https://www.nature.com/articles/d41586-020-00502-w>.

¹¹⁰ Clinical trial of therapeutics for severely ill hospitalized COVID-19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from: <https://www.nih.gov/news-events/news-releases/clinical-trial-therapeutics-severely-ill-hospitalized-covid-19-patients-begins>.

¹¹¹ COVID-19 Treatment Guidelines. National Institutes of Health. Updated April 21, 2021. Retrieved from: <https://www.covid19treatmentguidelines.nih.gov/whats-new/>.

¹¹² Ehsanian R, Workman J, Jones D, et al. Free-standing acute inpatient rehabilitation hospital enhanced practices and policies in response to the COVID-19 outbreak. *Future Sci OA*. 2021 Feb; 7(2): FSO667. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745654/>.

¹¹³ <https://www.healthaffairs.org/doi/10.1377/hblog20201214.543463/full/>.

[01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government](https://www.federalregister.gov/documents/2021/07/01/2021-12811/01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government)).

3. Collection of the Transfer of Health Information to Provider-PAC measure, the Transfer of Health Information to Patient-PAC measure, and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2022

We proposed to revise the compliance date from IFC-2 to October 1, 2022. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the IRF-PAI assessment instrument referred to as IRF-PAI V4.0. This revised date of October 1, 2022, which is a 2-year delay from the original compliance date finalized in the FY 2020 IRF PPS final rule (84 FR 39054 through 39173), balances the support that IRFs needed during much of the COVID-19 PHE as we provided flexibilities to support IRFs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and TOH Information measures have been shown to be even more pressing with issues of inequities the COVID-19 PHE laid bare. This data that includes addressing SDOH provides information expected to improve quality of care for all. Consequently, we proposed to revise the compliance date to reflect this balance and assure that data collection begins on October 1, 2022.

As stated in the FY 2020 IRF PPS final rule, we will provide the training and education for IRFs to be prepared for this implementation (84 FR 39119 through 39147). In addition, if we adopt an October 1, 2022 compliance date, we would release a draft of the updated version of the IRF-PAI, IRF-PAI V4.0, in early 2022.

Based upon our evaluation, we proposed that IRFs collect the Transfer of Health Information to Provider-PAC measure, the TOH Information to the Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning October 1, 2022.

Accordingly, we proposed that IRFs begin collecting data on the two TOH measures

beginning with discharges on October 1, 2022. We also proposed that IRFs begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the IRF-PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

We invited public comment on these proposals.

Comment: Many commenters raised concerns with revising the compliance date from October 1st of the year that is at least 1 full fiscal year after the end of the PHE to October 1, 2022, given the current increase in the number of COVID-19 cases across the nation. Several commenters also stated CMS was too optimistic about the COVID-19 data and IRFs' readiness to train staff on the IRF-PAI V4.0. They point to the CDC's Daily Tracker which shows a 7-day average of new COVID-19 cases having increased by >100,000 since the CY 2022 HH PPS proposed rule (86 FR 35874) was published on July 7, 2021.

Response: As stated in section IX.A. 2 of the CY 2022 HH PPS proposed rule (86 FR 35983 through 35984), CMS has provided IRFs a number of flexibilities to accommodate the COVID-19 PHE, including delaying the adoption of the updated version of the IRF Patient Assessment Instrument (PAI) V4.0 with which IRFs would have used to report the TOH measures and Standardized Patient Assessment Data Elements (85 FR 27595 through 27596). We also waived the IRF QRP reporting requirements for Q1 (January 1, 2020 through March 31, 2020) and Q2 (April 1, 2020 through June 30, 2020) and modified the required face-to-face visits in IRF such that they could be completed by telehealth (42 CFR 412.622(a)(3)(iv) and 412.29(e)) during the PHE for COVID-19. Additionally, we also made the waiver on the post-admission physician evaluation requirement permanent beginning October 1, 2021, in the FY 2021 IRF PPS final rule (85 FR 48445 through 48447). We believe we have provided a number of flexibilities to provide relief to IRFs throughout the PHE. We have also previously provided IRFs with the necessary tools they would need to implement the new IRF PAI 4.0, including

release of the item set in 2019 and draft data specifications in early 2020. If this proposal is finalized, we will continue to provide IRFs with the tools they need well in advance of the implementation of the IRF PAI V4.0.

Despite the COVID-19 PHE, we must maintain its commitment to the quality of care for all patients, and we continue to believe that the collection of the Standardized Patient Assessment Data Elements and TOH Information measures will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies^{114,115,116,117,118,119} and improving the quality of care in IRFs through a reduction in preventable adverse events. 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.^{120,121,122,123,124,125} Poor

¹¹⁴ Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.

¹¹⁵ Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf>.

¹¹⁶ Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

¹¹⁷ https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf

¹¹⁸ www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm

¹¹⁹ Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327

¹²⁰ 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.

¹²¹ 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.

¹²² 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.

¹²³ 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.

¹²⁴ 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.

¹²⁵ Boling, P. A., “Care transitions and home health care,” *Clinical Geriatric Medicine*, 2009, Vol. 25(1), pp. 135-48.

communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits and medication errors.^{126,127,128,129,130,131,132,133,134,135} While we understand that there are concerns related to the timeline proposed, we do not believe that further delaying the data collection is an actionable solution to these concerns.

Comment: A commenter stated that CMS' original postponement from IFC-2 would likely have called for full adoption by October 1, 2023 and they believe this is still an appropriate adoption date.

Response: We interpret the commenter's reference to "full adoption" to refer to the adoption of the IRF-PAI V4.0, which includes the items for the TOH-Patient measure, the TOH-Provider measure, and the Standardized Patient Assessment Data Elements. We believe that as the healthcare community continues to learn about the enormous impact that social determinants of health (SDOH) and social risk factors (SRFs) have on patient health and health outcomes,¹³⁶ it

¹²⁶ Barnsteiner, J. H., "Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,"

¹²⁷ 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

¹²⁸ 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.

¹²⁹ 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>.

¹³⁰ 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.

¹³¹ 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.

¹³² 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>.

¹³³ 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.

¹³⁴ 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.

¹³⁵ King, B. J., Gilmore- Bykovsky, 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.

¹³⁶ Hood CM, Gennuso KP, Swain GR, Catlin BB. County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *Am J Prev Med*. 2016 Feb;50(2):129-35. Available at: <https://pubmed.ncbi.nlm.nih.gov/26526164/>. Accessed 9/1/21.

becomes more critical to collect this in order to better understand the impact of the PHE on our healthcare system, as well as how to improve the inequities that the PHE has made so visible. We believe it will help IRFs, physicians, and other practitioners caring for patients in IRFs better prepare for the complex and resource-intensive care needs of patients with COVID-19, which will be particularly important during continued surges of this virus or new and emerging viruses. If finalized, this proposal would effectively grant a 2-year delay to the originally planned release of the IRF-PAI V4.0, a delay we granted due to the PHE. We believe that there has been a sufficient timeframe for IRFs to adjust to the change in care patterns associated with the PHE.

Comment: A commenter stated that the Delta variant, and the potential for other variants, has undermined the knowledge and experience gained by IRFs earlier in the pandemic. Commenters stated a continued delay would provide IRFs the necessary capacity to accommodate additional surges.

Response: We understand the conditions under which IRFs are working to address the number of new COVID-19 cases resulting from the Delta variant. We disagree with the commenter, however, that the knowledge and experience IRFs have gained since the beginning of the pandemic has been undermined by the Delta variant. The Delta variant is a mutation of the original SARS-CoV-2 strain, rather than a novel virus as COVID-19 was when it emerged in January of 2020. While the CDC has described the Delta variant as more transmissible than the Alpha COVID-19 virus,¹³⁷ many of the symptoms are similar.¹³⁸ The methods of reducing transmission of the Delta variant are also similar, that is indoor masking, social distancing, and vaccination.¹³⁹ Currently, there are multiple treatments^{140,141} for COVID-19 and vaccines that

¹³⁷ Delta Variant: What We Know about the Science. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html> Accessed 9/1/2021.

¹³⁸ What Are the Symptoms of the COVID-19 Delta Variant? Available at: https://www.emedicinehealth.com/what_are_the_symptoms_of_covid19_delta_variant/article_em.htm. Accessed 9/1/2021.

¹³⁹ 5 Things to Know About the Delta Variant. Available at: <https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid>. Accessed 9/1/2021.

¹⁴⁰ National Institutes of Health COVID-19 Treatment Guidelines. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed 9/9/2021.

¹⁴¹ FDA Approves First Treatment for COVID-19. October 22, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>. Accessed 9/9/2021.

are either authorized under a Food and Drug Administration's (FDA) Emergency Use Authorization^{142,143} or have approval from FDA.¹⁴⁴

Comment: A commenter stated that if the PHE was a valid reason to delay implementation of the TOH measures and certain Standardized Patient Assessment Data Elements a year ago, the recent surge is a valid reason to maintain the delay.

Response: We disagree with the commenter. As described in section XI.A.1 of the CY 2022 HH PPS proposed rule (86 FR 35983 through 35984), at the time we finalized the policy in the IFC-2 (85 FR 27550), we were in the initial months of the COVID-19 PHE and very little was known about the COVID-19 virus. We believed the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements was necessary in order to allow IRFs to focus on patient care and staff safety during a time when very little was known about COVID-19. However, the COVID-19 PHE has illustrated the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the IRF QRP. The PHE's disproportionate impact among black, Latino, and American Indian and Alaska Native (AI/AN) persons^{145,146} demonstrates the importance of analyzing this impact in order to improve quality of care within IRFs especially during a crisis. As stated in section VII.F of the FY 2022 IRF PPS proposed rule (86 FR 19110 through 19112), one important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies, and the data collected will support future activities under Executive Order 13985, entitled "Advancing Racial

¹⁴² U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download>. Accessed 9/9/2021.

¹⁴³ U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download>. Accessed 9/9/2021.

¹⁴⁴ FDA Approves First COVID-19 Vaccine | FDA, available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>. Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Accessed 9/28/2021.

¹⁴⁵ <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf>

¹⁴⁶ Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>

Equity and Support for Underserved Communities Throughout the Federal Government,” issued January 20, 2021 (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>).

Currently, there are multiple treatments^{147,148} for COVID-19, and vaccines that are either authorized under FDA’s Emergency Use Authorization^{149,150} or have approval from FDA.¹⁵¹ As of August 13, 2021, 82.2% of the population 65 years of age or older and 64.4% of the population 18 years of age or older have been fully vaccinated.¹⁵²

Comment: Several commenters stated implementing the IRF-PAI V4.0 would divert critical patient care resources at a time when IRFs are struggling to keep up with current documentation requirements. They raised concerns that having to train nursing staff to collect and report these data would divert their attention away from direct patient care. A commenter stated that hospitals are still requiring social distancing and limiting large group gatherings, so the logistics of training would be challenging. A commenter stated that implementing the new assessment tool at this time may increase the risk for patient-care errors, while another commenter stated they would have no means to dedicate staff to the task of training which would defeat the purpose of collecting the information.

Response: As described in section IX.A.2. of this final rule, we granted IRF providers several waivers related to documentation in order to ease burden during the PHE, and many of

¹⁴⁷ National Institutes of Health COVID-19 Treatment Guidelines. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed 9/9/2021.

¹⁴⁸ FDA Approves First Treatment for COVID-19. October 22, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>. Accessed 9/9/2021.

¹⁴⁹ U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download>. Accessed 9/9/2021.

¹⁵⁰ U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download>. Accessed 9/9/2021.

¹⁵¹ FDA Approves First COVID-19 Vaccine. FDA. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>. Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Accessed 9/28/2021.

¹⁵² COVID-19 Vaccinations in the United States. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed 9/9/2021.

these are still in effect. We are very mindful of burden that may occur from the collection and reporting of data. Both the TOH-Patient measure and TOH-Provider measure are comprised of one item, and further, the activities associated with the measure align with existing requirements related to transferring information at the time of discharge to safeguard patients (84 FR 51882 and § 482.43). Additionally, TEP feedback and pilot testing of the items did not find the burden of reporting to be significant.¹⁵³

The new Standardized Patient Assessment Data Element items in the IRF-PAI 4.0 are also reflective of patient characteristic that providers are likely already gathering in order to meet hospital conditions of participation, such as patient's preferred language, race, ethnicity, hearing, vision, health literacy, pain, high-risk drug classes and cognitive function.

We also understand provider's concerns with developing training materials for the TOH-Patient measure and TOH-Provider measure items and the Standardized Patient Assessment Data Elements. We plan to provide multiple training resources and opportunities for IRFs to take advantage of, reducing the burden to IRFs in creating their own training resources. These training resources may include online learning modules, tip sheets, questions and answers documents, and/or recorded webinars and videos, and would be available to providers in early 2022, allowing IRFs several months to ensure their staff take advantage of the learning opportunities. Having the materials online and on-demand would also eliminate the need for large group gatherings, a concern raised by some commenters. The IRF QRP Helpdesk would also be available for providers to submit their follow up questions by email, further enhancing the educational resources.

Comment: We received a comment stating that implementing the IRF-PAI 4.0 would require additional staffing, specifically nursing staff, at a time when there is a pandemic-induced nursing staff shortage, which in some areas is so critical that IRF beds have been reduced. A

¹⁵³ Transfer of Health Information TEP Meeting 4 – June 2018. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf>. Accessed 9/9/2021.

commenter noted that although there are multiple positions open at their IRF, they have had no applicants. This same commenter reported they have had to reinstitute COVID emergency staffing registered nurse (RN)-to-patient ratios, and without a foreseeable end in the surge in cases, staff leadership cannot turn their resources and attention to the task of training. They suggested that not finalizing the proposal would minimize administrative and reporting requirements and provide an opportunity to recover from the pandemic's effects on the workforce.

Response: We interpret the commenter's concern to be associating the nursing shortage with the COVID-19 pandemic. According to the Centers for Disease Control and Prevention's (CDC) COVID Data Tracker Weekly review on October 1, 2021,¹⁵⁴ the current 7-day moving average of daily cases has decreased 13.3% compared to the previous 7-day moving average. Additionally, COVID-19 cases have been steadily declining since January 2021. Despite an uptick in weekly reported cases in September, the height of new cases at that time was still 36% less than the numbers reported in January 2021.¹⁵⁵ According to the CDC's forecast modeling, new cases are estimated to continue to decline another 30% in the next four weeks. The impacts of the COVID-19 PHE on the healthcare system, including staffing shortages, make it especially important now to monitor quality of care.¹⁵⁶ Still, we are mindful of burden that may occur from the collection and reporting of our measures. We emphasize, however, that that TOH Information Provider – PAC and TOH Information Patient – PAC measures consist of one item each, and further, the activities associated with the measures align with the existing requirements related to transferring information at the time of discharge to safeguard patients. Additionally, as stated in the FY 2020 IRF PPS final rule (84 FR 39054 through 39173), we convened a

¹⁵⁴ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

¹⁵⁵ Centers for Disease Control and Prevention. COVID-19 Forecasts: Cases. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/forecasts-cases.html>. Accessed September 27, 2021.

¹⁵⁶ Nursing and Patient Safety. Agency for Healthcare Research and Quality. April 21, 2021. Available at: <https://psnet.ahrq.gov/primer/nursing-and-patient-safety>. Accessed 10/4/2021.

Technical Expert Panel (TEP)¹⁵⁷ and conducted a pilot test.¹⁵⁸ Both the TEP feedback and the pilot participants found the burden of reporting not to be significant.

We have strived to balance the scope and level of detail of the data elements against the potential burden placed on IRFs. We plan to provide multiple training resources and opportunities for IRFs to take advantage of, which will reduce the burden to IRFs. We plan to make these training resources available to IRFs in early 2022.

Comment: Several commenters pointed out the lack of Information Systems (IT) personnel as a barrier to being able to implement the IRF-PAI V4.0 on October 1, 2022. They state that implementing the IRF-PAI V4.0 would require new flowsheets, interfaces, and reports to inform the new version of the assessment instrument, and they are limited in their resources. They state that IT systems and personnel had to quickly pivot to developing virtual platforms for care during the PHE, and/or develop platforms and reports to implement mandatory and time-sensitive COVID-19-related tracking requirements. A commenter noted that there are also 2020 “maintenance releases” that have been delayed due to the PHE and staffing shortages. As a result, these commenters do not believe they have the operational resources to dedicate to the investment of retooling their electronic health record for the IRF-PAI V4.0.

Response: While we acknowledge there will be some updates required of IT vendors and systems, we believe a significant portion of the work has already been completed. For example, we posted a change table in November 2019 illustrating the changes that would occur to the IRF-PAI with the transition from the IRF-PAI 3.0 to 4.0. In March 2020, we posted the IRF-PAI Draft Technical Data Submission Specifications. The IRF-PAI 4.0 was not postponed due to the PHE until June 17, 2020, fewer than 4 months before it was to be implemented October 1, 2020.

¹⁵⁷ Transfer of Health Information TEP Meeting 4 – June 2018. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf>. Accessed 9/1/2021.

¹⁵⁸ Transfer of Health Information 2018 Pilot Test Summary Report. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-Pilot-Test-Summary-Report_Final_Feb2018.pdf. Accessed 9/1/2021.

Therefore, we believe that most IRFs would have already made the necessary enhancements to their electronic medical records and flowsheets in preparation for the transition. We plan to provide the final draft specifications and release that to providers and vendors in late 2021 or when technically feasible, which would give providers just under 1 year to build their necessary IT programs.

Comment: Several commenters stated that if CMS finalized the October 1, 2022, date for the collection of the TOH Information to the Patient-PAC measure, the TOH Information to the Patient-Provider measure, and the Standardized Patient Assessment Data Elements, they would have to divert resources away from the tasks associated with patient care and instead put the resources in training nursing staff to complete the new assessment. A commenter stated they believe the benefit to CMS of having this information to study is significantly outweighed by the burden imposed on IRFs.

Response: We would like to clarify that CMS proposed to begin collecting the TOH Information to the Patient - PAC measure, the TOH Information to the Patient-Provider measure and the Standardized Patient Assessment Data Elements to support our responsibility to monitor and ensure quality of care for patients. Additionally, this information will provide actionable data on which IRFs can improve health care outcomes.

We disagree that the benefit of having this information is outweighed by the burden. As stated earlier, we plan to provide multiple training resources and opportunities for IRFs to take advantage of, which will reduce the burden to IRFs. We plan to make these training resources available to IRFs in early 2022, allowing IRFs several months to ensure their staff take advantage of the learning opportunities, and to allow IRFs to spread the cost of training out over several quarters.

Comment: A commenter stated that proposing the implementation of the IRF-PAI V4.0 so soon after CMS' request for information (RFI) on creating new standardized data collection elements across the continuum of care (not just post-acute care) in the IRF PPS proposed rule (86

FR 19110 through 19112) created confusion for providers. They believe it would create confusion and unnecessary administrative burden for CMS to add data elements to the IRF-PAI V4 because they are available, only to replace them with more reliable elements based on the feedback received to the FY 2022 IRF RFI.

Response: To clarify, the Standardized Patient Assessment Data Elements that would be collected in the IRF-PAI V4.0 were finalized in the FY 2020 IRF PPS final rule (84 FR 4 FR 39109 through 39161). The request for information published in section VII.F. of the FY 2022 IRF PPS proposed rule (86 FR 19110 through 19112) requested public comment on recommendations for quality measures or measurement domains that address health equity as well as additional items that could be used to assess health equity in the care of IRF patients, which may or may not include Standardized Patient Assessment Data Elements. Therefore, we do not anticipate unnecessary administrative burden as a result of the feedback received to the FY 2022 IRF RFI.

Comment: A commenter noted it was unclear if CMS' proposal intended to implement the full scope of the IRF-PAI version 4.0, or only those Standardized Patient Assessment Data Elements and the two new TOH measures discussed in the proposal. They reference the original change table CMS provided back in 2019. For example, the data elements for IRF-PAI V.4.0 in section O starting on page 26 of the change table are not addressed by CMS's proposed scope of adoption. The commenter asked CMS to clarify what data elements would be adopted to support their proposal.

Response: We believe the commenter is referencing the document titled, "Change Table for Final IRF-PAI Version 4.0 – Effective date: October 1, 2020", that was posted to the CMS QRP website on November 21, 2019.¹⁵⁹ This change table reflects the reporting requirements under the IRF QRP that were finalized in the FY 2020 IRF PPS Final Rule. Our proposal is

¹⁵⁹ File available here: <https://www.cms.gov/files/document/final-irf-pai-version-40-change-table-1.pdf> and on the IRF-PAI and IRF-PAI Manual webpage in the Downloads section at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-PAI-and-IRF-PAI-Manual>.

consistent with the reporting requirements finalized in the FY 2020 IRF PPS Rule; specifically, IRFs would begin using the IRF Patient Assessment Instrument (PAI) V4.0 to report the TOH Information to Provider-PAC and the TOH Information to Patient - PAC measures and certain Standardized Patient Assessment Data Elements. If finalized, we would release an updated draft of the IRF-PAI V.4.0 and accompanying IRF-PAI V.4.0 manual in early 2022.

Comment: A commenter acknowledged that CMS has the authority to issue proposals through a variety of avenues, but requested CMS include proposals impacting IRF payment or the Quality Reporting Program (QRP) in the annual IRF Prospective Payment System (PPS) rulemaking in order to avoid confusion for stakeholders.

Response: We thank the commenter for the suggestion and will take it under consideration. We note, however, that an announcement was posted to the IRF QRP Spotlights and Announcements¹⁶⁰ webpage on June 28, 2021, an announcement was sent from the PAC listserv.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal that IRFs begin collecting the TOH Information to Provider-PAC measure, the TOH Information to the Patient-PAC measure, and on the six categories of Standardized Patient Assessment Data Elements on the IRF-PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

B. Proposed Revised Compliance Date for Certain Long-Term Care Hospital (LTCH) QRP Reporting Requirements

1. Background

In IFC-2 (85 FR 27550), we delayed the compliance date for certain reporting requirements under the LTCH QRP (85 FR 27595 through 27596). Specifically, we delayed the

¹⁶⁰ Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Spotlights-Announcements>. Accessed 10/4/2021.

requirement for LTCHs to begin reporting the TOH Information to Provider-PAC measure and the TOH Information to Patient-PAC measure and the requirement for LTCHs to begin reporting certain Standardized Patient Assessment Data Elements from October 1, 2020, to October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. We also delayed the adoption of the updated version of the LTCH Continuity Assessment and Record of Evaluation (CARE) Data Set (LCDS) V5.0 with which LTCHs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements.

Under IFC-2, LTCHs must use the LCDS V5.0 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. LTCHs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1st of the year that is at least 1 full fiscal year after the end of the COVID-19 PHE. The delay to begin collecting data for these measures was intended to provide relief to LTCHs from the associated burden of implementing an updated instrument during the COVID-19 PHE. We wanted to provide maximum flexibilities for LTCHs to respond to the public health threats posed by the COVID-19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC-2, we believed that the delay in collection of the TOH Information measures, and Standardized Patient Assessment Data Elements would not have a significant impact on the LTCH QRP. However, the COVID-19 PHE showed the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the LTCH QRP. The PHE's disproportionate impact on minority populations demonstrates the importance of analyzing this impact and the needs for these populations in

order to improve quality of care within LTCHs especially during a public health emergency.

2. Current Assessment of LTCHs

To accommodate the COVID-19 PHE, we have provided additional guidance and flexibilities, and as a result LTCHs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID-19 PHE. For example, we held regular “Office Hours” conference calls to provide LTCHs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting and billing. We also supported PAC providers, including LTCHs, by providing flexibilities in the delivery of care in response to the PHE, such as waiving requirement at 42 CFR 482.43(a)(8), 482.61(e), and 485.642(a)(8) to provide detailed information regarding discharge planning. To address workforce concerns related to COVID-19, we waived requirements under 42 CFR 482.22(a)(1) through (4) to allow for physicians whose privileges would expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval. In addition, as of June 9, 2021, 63.8 percent of all the adult population has received at least one vaccination, and COVID-19 cases and deaths have steadily declined over the last 60 days.¹⁶¹ We also believe that much more is known about COVID-19 than at the time we finalized IFC-2.^{162,163,164,165}

Based upon other flexibilities such as the previous examples, the increase in knowledge LTCH providers have about treating patients with COVID-19¹⁶⁶ since finalizing IFC-2, and the

¹⁶¹ CDC COVID Data Tracker. Retrieved from: <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

¹⁶² Here’s Exactly Where We are with Vaccine and Treatments for COVID-19. Healthline. May 11, 2021. Retrieved from: <https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-for-covid-19>.

¹⁶³ COVID research: a year of scientific milestones. Nature. May 5, 2021. Retrieved from: <https://www.nature.com/articles/d41586-020-00502-w>.

¹⁶⁴ Clinical trial of therapeutics for severely ill hospitalized COVID-19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from: <https://www.nih.gov/news-events/news-releases/clinical-trial-therapeutics-severely-ill-hospitalized-covid-19-patients-begins>.

¹⁶⁵ COVID-19 Treatment Guidelines. National Institutes of Health. Updated April 21, 2021. Retrieved from: <https://www.covid19treatmentguidelines.nih.gov/whats-new/>.

¹⁶⁶ Ehsanian R, Workman J, Jones D, et al. Free-standing acute inpatient rehabilitation hospital enhanced practices and policies in response to the COVID-19 outbreak. *Future Sci OA*. 2021 Fe; 7(2): FSO667. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745654/>.

trending data on COVID-19, LTCHs are now in a better position to accommodate reporting of the TOH measures and certain Standardized Patient Assessment Data Elements.¹⁶⁷

After evaluating the impact of the revised compliance date under IFC-2, feasibility around data collection in LTCHs, and support needs of providers during the COVID-19 PHE, we have determined that LTCHs now have the administrative capacity to attend trainings, train their staff, and work with their vendors to incorporate the updated assessment instrument, the LCDS V5.0 into their operations.

We now believe that based upon the advancement of information available about COVID-19 vaccination and treatments described previously, and the importance of the data to the LTCH QRP it would be appropriate to modify the compliance date finalized in IFC-2. This may support future activities under Executive Order 13985, entitled “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” issued January 20, 2021 (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>).

3. Collection of the Transfer of Health Information to Provider-PAC measure, the Transfer of Health Information to Patient-PAC measure, and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2022

We proposed to revise the compliance date from IFC-2 to October 1, 2022. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure, Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the LCDS V5.0. This revised date of October 1, 2022, which is a 2-year delay from this original compliance date finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), balances the support that LTCHs needed during much of the COVID-19 PHE as we provided flexibilities to support LTCHs along with the need to collect this important data.

¹⁶⁷ <https://www.healthaffairs.org/doi/10.1377/hblog20201214.543463/full/>

The need for the Standardized Patient Assessment Data Elements and TOH Information measures have been shown to be even more pressing with issues of inequities the COVID-19 PHE laid bare. This data that includes addressing SDOH provides information expected to improve quality of care for all. Consequently, we proposed to revise the compliance date to reflect this balance and assure that data reporting begins on October 1, 2022.

As stated in the FY 2020 IPPS/LTCH PPS final rule, we will provide the training and education for LTCHs to be prepared for this implementation (84 FR 42540 through 42560). In addition, if we adopt an October 1, 2022, compliance date, we stated that we would release a draft of the updated version of the LCDS, LCDS V5.0, in early 2022.

Based upon our evaluation, we proposed that LTCHs collect the Transfer of Health Information to Provider-PAC measure, the Transfer of Health Information to the Patient-PAC measure, and certain Standardized Patient Assessment Data Elements, beginning on October 1, 2022. We proposed that accordingly, LTCHs begin collecting data on the two TOH measures beginning with discharges on October 1, 2022. We also proposed that LTCHs begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

We invited public comment on these proposals.

Comment: Several commenters raised concerns with revising the compliance date from October 1st of the year that is at least 1 full year after the end of the PHE to October 1, 2022, given the current increase in the number of COVID-19 cases across the nation. Commenters also stated CMS was too optimistic about the COVID-19 data and LTCHs' readiness to train staff on the LCDS V5.0. They point to the CDC's Daily Tracker which shows a 7-day average of new COVID-19 cases having increased by >100,000 since the CY 2022 HH PPS proposed rule (86 FR 35874) was published on July 7, 2021.

Response: As stated in section IX.B. 2 of the CY 2022 HH PPS proposed rule (86 FR 35984 through 35985), we have provided LTCHs a number of flexibilities to accommodate the COVID-19 PHE. In addition to delaying the adoption of the updated version of the LCDSV5.0 with which LTCHs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements (85 FR 27595 through 27596), we also waived the LTCH QRP reporting requirements for Q1 (January 1, 2020 through March 31, 2020) and Q2 (April 1, 2020 through June 30, 2020). Additionally, we waived the requirement at 42 CFR 482.43(a)(8), 482.61(e), and 485.642(a)(8) to provide detailed information regarding discharge planning, and waived the requirements under 42 CFR 482.22(a)(1) through (4) to allow for physicians whose privileges would expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval. Both of these waivers, as well as others, remain in place today. We believe we have provided a number of flexibilities to provide relief to LTCHs throughout the PHE. We have also previously provided LTCHs with the necessary tools they would need to implement the new LTCH V5.0, including release of the item set in 2019 and draft data specifications in early 2020. If this proposal is finalized, we will continue to provide LTCHs with the tools they need well in advance of the implementation of the LTCH V5.0.

Despite the ongoing COVID-19 PHE, we must maintain commitment to the quality of care for all patients, and we continue to believe that the collection of the Standardized Patient Assessment Data Elements and TOH Information measures will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better

measure and analyze disparities across programs and policies^{168,169,170,171,172,173} and improving the quality of care in LTCHs through a reduction in preventable adverse events. 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.^{174,175,176,177,178,179} Poor communication and coordination across health care settings contributes to patient complications, hospital readmissions, emergency department visits and medication

¹⁶⁸ Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf>.

¹⁶⁹ Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at: <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf>.

¹⁷⁰ Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

¹⁷¹ https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf

¹⁷² www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.

¹⁷³ Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID-19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv*. 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

¹⁷⁴ 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.

¹⁷⁵ 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.

¹⁷⁶ 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.

¹⁷⁷ 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.

¹⁷⁸ 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.

¹⁷⁹ Boling, P. A., “Care transitions and home health care,” *Clinical Geriatric Medicine*, 2009, Vol. 25(1), pp. 135-48.

errors.^{180,181,182,183,184,185,186,187,188,189} While we understand that there are concerns related to the timeline proposed, we do not believe that further delaying the data collection is an appropriate response to these concerns. As the healthcare community continues to learn about the enormous impact that social determinants of health (SDOH) and social risk factors (SRFs) have on patient health and health outcomes,¹⁹⁰ it becomes more critical for Medicare to collect this information. The information is extremely important to understanding the impact of the PHE on our healthcare system, and how to improve the inequities the PHE has made so visible, and we believe it will help LTCHs better prepare for the complex and resource-intensive care needs of patients with COVID-19, which will be particularly important during continued surges of this virus or new and emerging viruses. If finalized, this proposal would effectively grant a 2-year delay to the originally planned release of the LCDS V5.0, a delay we granted due to the PHE. We believe that there has been a sufficient timeframe for LTCHs to adjust to the change in care patterns associated with the PHE.

¹⁸⁰ Barnsteiner, J. H., “Medication Reconciliation: Transfer of medication information across settings—keeping it free from error,”

¹⁸¹ 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

¹⁸² 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.

¹⁸³ 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>.

¹⁸⁴ 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.

¹⁸⁵ 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.

¹⁸⁶ 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>.

¹⁸⁷ 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.

¹⁸⁸ 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.

¹⁸⁹ King, B. J., Gilmore- Bykovsky, 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.

¹⁹⁰ Hood CM, Gennuso KP, Swain GR, Catlin BB. County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *Am J Prev Med*. 2016 Feb;50(2):129-35. Available at: <https://pubmed.ncbi.nlm.nih.gov/26526164/>. Accessed 9/1/21.

Comment: Another commenter stated that if the PHE was a valid reason to delay implementation of the TOH measures and certain Standardized Patient Assessment Data Elements a year ago, the recent surge is a valid reason to maintain the delay.

Response: We disagree with the commenter. As described in section XI.A.1 of the CY 2022 HH PPS proposed rule (86 FR 35983 through 35984), at the time we finalized the policy in the IFC-2 (85 FR 27550), we were in the initial months of the COVID-19 PHE and very little was known about the COVID-19 virus. We believed the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements was necessary in order to allow LTCHs to focus on patient care and staff safety during a time when very little was known about COVID-19. However, the COVID-19 PHE has illustrated the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the LTCH QRP. The PHE's disproportionate impact among black, Latino, and American Indian and Alaska Native (AI/AN) persons^{191,192} demonstrates the importance of analyzing this impact in order to improve quality of care within LTCHs especially during a crisis. As stated in section IX.E.7 of the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25616 through 25618) one important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies, and the data collected will support future activities under Executive Order 13985, entitled "Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government," issued January 20, 2021 (<https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>).

¹⁹¹ <https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf>

¹⁹² Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: <https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/>

Currently, there are multiple treatments^{193,194} for COVID-19, and vaccines that are either authorized through FDA's Emergency Use Authorization^{195,196} or have approval from FDA.¹⁹⁷ As of August 13, 2021, 82.2% of the population 65 years of age or older and 64.4% of the population 18 years of age or older have been fully vaccinated.¹⁹⁸

Comment: A commenter stated that the Delta variant of COVID-19, and the potential for other variants, has undermined the knowledge and experience gained by LTCHs earlier in the pandemic. Commenters stated a continued delay would provide LTCHs the necessary capacity to accommodate additional surges.

Response: We understand the conditions under which LTCHs are working to address the number of new COVID-19 cases resulting from the COVID-19 Delta variant. We disagree with the commenter, however, that the knowledge and experience LTCHs have gained since the beginning of the PHE has been undermined by the Delta variant. The Delta variant is a mutation of the original SARS-CoV-2 strain, rather than a novel virus as COVID-19 was when it emerged in January of 2020. While the CDC has described Delta as more transmissible than the Alpha COVID-19 virus,¹⁹⁹ many of the symptoms are similar.²⁰⁰ The methods of reducing transmission of the Delta variant are also similar, that is indoor masking, social distancing, and vaccination.²⁰¹

¹⁹³ National Institutes of Health COVID-19 Treatment Guidelines. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed 9/9/2021.

¹⁹⁴ FDA Approves First Treatment for COVID-19. October 22, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>. Accessed 9/9/2021.

¹⁹⁵ U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download>. Accessed 9/9/2021.

¹⁹⁶ U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download>. Accessed 9/9/2021.

¹⁹⁷ FDA Approves First COVID-19 Vaccine | FDA. Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Accessed 9/28/2021.

¹⁹⁸ COVID-19 Vaccinations in the United States. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total. Accessed 9/9/2021.

¹⁹⁹ Delta Variant: What We Know about the Science. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html> Accessed 9/1/2021.

²⁰⁰ What Are the Symptoms of the COVID-19 Delta Variant? Available at: https://www.emedicinehealth.com/what_are_the_symptoms_of_covid19_delta_variant/article_em.htm. Accessed 9/1/2021.

²⁰¹ 5 Things to Know About the Delta Variant. Available at: <https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid>. Accessed 9/1/2021.

Currently, there are multiple treatments^{202,203} for COVID-19, and vaccines that are either authorized through FDA's Emergency Use Authorization^{204,205} or have approval from FDA.²⁰⁶

Comment: Several commenters stated implementing the LCDS V5.0 would divert critical patient care resources at a time when LTCHs are struggling to keep up with current documentation requirements. They raised concerns that having to train nursing staff to collect and report these data would divert their attention away from direct patient care.

Response: As described in section IX.B.2. of this final rule, we have granted LTCH providers several waivers related to documentation in order to ease burden during the PHE, and many of these are still in effect. We are very mindful of burden that may occur from the collection and reporting of data. Both the TOH Information to the Patient – PAC measure and TOH Information to the Provider – PAC measure are comprised of one item, and further, the activities associated with the measure align with existing requirements related to transferring information at the time of discharge to safeguard patients (84 FR 51882 and § 482.43). Additionally, TEP feedback and pilot testing of the items did not find the burden of reporting to be significant.²⁰⁷

The new Standardized Patient Assessment Data Element items in the LCDS V5.0 are also reflective of patient characteristic that providers are likely already gathering in order to meet hospital conditions of participation, such as patient's preferred language, race, ethnicity, hearing, vision, health literacy, pain, high-risk drug classes and cognitive function.

²⁰² National Institutes of Health COVID-19 Treatment Guidelines. Available at: <https://www.covid19treatmentguidelines.nih.gov/>. Accessed 9/9/2021.

²⁰³ FDA Approves First Treatment for COVID-19. October 22, 2020. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>. Accessed 9/9/2021.

²⁰⁴ U.S. Food and Drug Administration (2021). Janssen Biotech, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/146303/download>. Accessed 9/9/2021.

²⁰⁵ U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID-19 Vaccine EUA Letter of Authorization. Available at <https://www.fda.gov/media/144636/download>. Accessed 9/9/2021.

²⁰⁶ FDA Approves First COVID-19 Vaccine | FDA. Accessed 9/03/21. The Pfizer-BioNTech vaccine also continues to be available under EUA. U.S. Food and Drug Administration (2021). Comirnaty and Pfizer-BioNTech COVID-19 Vaccine. Accessed 9/28/2021.

²⁰⁷ Transfer of Health Information TEP Meeting 4 – June 2018. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf>. Accessed 9/9/2021.

We also understand provider's concerns with developing training materials for the TOH Information to the Patient – PAC measure and TOH Information to the Provider – PAC measure items and the Standardized Patient Assessment Data Elements. We plan to provide multiple training resources and opportunities for LTCHs to take advantage of, reducing the burden to LTCHs in creating their own training resources. These training resources may include online learning modules, tip sheets, questions and answers documents, and/or recorded webinars and videos, and would be available to LTCHs in early 2022, allowing LTCHs several months to ensure their staff take advantage of the learning opportunities. Having the materials online and on-demand would also eliminate the need for large group gatherings, a concern raised by some commenters. The LTCH QRP Helpdesk would also be available for providers to submit their follow up questions by email, further enhancing the educational resources.

Comment: We received comment stating that implementing the LCDS V5.0 would require additional staffing, specifically nursing staff, at a time when there is a pandemic-induced nursing staff shortage, which in some areas is so critical that LTCH beds have been reduced.

Response: We interpret the commenter's concern regarding the nursing shortage with the COVID-19 pandemic. According to the Centers for Disease Control and Prevention's (CDC) COVID Data Tracker Weekly review on October 1, 2021,²⁰⁸ the current 7-day moving average of daily cases has decreased 13.3% compared to the previous 7-day moving average. Additionally, COVID-19 cases have been steadily declining since January 2021. Despite an uptick in weekly reported cases in September, the height of new cases at that time was still 36% less than the numbers reported in January 2021.²⁰⁹ According to the CDC's forecast modeling, new cases are estimated to continue to decline another 30% in the next four weeks. The impacts of the COVID-19 PHE on the healthcare system, including staffing shortages, make it especially

²⁰⁸ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

²⁰⁹ Centers for Disease Control and Prevention. COVID-19 Forecasts: Cases. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/forecasts-cases.html>. Accessed September 27, 2021.

important now to monitor quality of care.²¹⁰ Still, we are mindful of burden that may occur from the collection and reporting of our measures. We emphasize, however, that that TOH Information Provider – PAC and TOH Information Patient – PAC measures consist of one item each, and further, the activities associated with the measures align with the existing requirements related to transferring information at the time of discharge to safeguard patients. Additionally, as stated in the FY 2020 IPPS/LTCH PPS Final Rule (84 FR 42535 through 42588), we convened a Technical Expert Panel (TEP)²¹¹ and conducted a pilot test.²¹² Both the TEP feedback and the pilot participants found the burden of reporting not to be significant.

We have strived to balance the scope and level of detail of the data elements against the potential burden placed on LTCHs. We plan to provide multiple training resources and opportunities for LTCHs to take advantage of, which will reduce the burden to LTCHs. We plan to make these training resources available to LTCHs in early 2022.

Comment: Several commenters pointed out the lack of Information Systems (IT) personnel as a barrier to being able to implement the LCDS V5.0 on October 1, 2022. They state that implementing the LCDS V5.0 would require new flowsheets, interfaces, and reports to inform the new version of the assessment instrument, and they are limited in their resources. They state that IT systems and personnel had to quickly pivot to developing virtual platforms for care during the PHE, and/or develop platforms and reports to implement mandatory and time-sensitive COVID-19-related tracking requirements. A commenter noted that there are also 2020 “maintenance releases” that have been delayed due to the PHE and staffing shortages. As a

²¹⁰ Nursing and Patient Safety. Agency for Healthcare Research and Quality. April 21, 2021. Available at: <https://psnet.ahrq.gov/primer/nursing-and-patient-safety>. Accessed 10/4/2021.

²¹¹ Transfer of Health Information TEP Meeting 4 – June 2018. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-TEP-Meeting-4-June2018.pdf>. Accessed 9/1/2021.

²¹² Transfer of Health Information 2018 Pilot Test Summary Report. Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-Pilot-Test-Summary-Report_Final_Feb2018.pdf. Accessed 9/1/2021.

result, these commenters do not believe they have the operational resources to dedicate to the investment of retooling their electronic health record for the LCDS V5.0.

Response: While we acknowledge there will be some updates required of IT vendors and systems, we believe a significant portion of the work has already been completed. For example, we posted a change table in November 2019 illustrating the changes that would occur to the LCDS with the transition from the LCDS V4.0 to V5.0.²¹³ In March 2020, we posted the LCDS V5.0 Draft Technical Data Submission Specifications.²¹⁴ The LCDS V5.0 was not postponed due to the PHE until June 17, 2020, fewer than 4 months before it was to be implemented October 1, 2020. Therefore, we believe that most LTCHs would have already made the necessary enhancements to their electronic medical records and flowsheets in preparation for the transition. We plan to provide the final draft specifications and release that to providers and vendors in late 2021 or when technically feasible, which would give providers just under 1 year to build their necessary IT programs.

Comment: A commenter stated they believe the benefit to CMS of having this information to study is significantly outweighed by the burden imposed on LTCHs.

Response: We would like to clarify that CMS proposed to begin collecting the TOH Information to the Patient - PAC measure, the TOH Information to the Patient-Provider measure, and the Standardized Patient Assessment Data Elements to support our responsibility to monitor and ensure quality of care for patients. Additionally, this information will provide actionable data on which LTCHs can improve health care outcomes.

Final Decision: After careful consideration of the comments received, we are finalizing our proposal that LTCHs begin collecting the TOH Information to Provider-PAC measure, the

²¹³ File available here: <https://www.cms.gov/files/zip/ltch-care-data-set-v50-effective-october-1-2020-zip.zip> and on the LTCH LCDS and LTCH QRP Manual webpage in the Downloads section at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-CARE-Data-Set-and-LTCH-QRP-Manual>.

²¹⁴ File available here: <https://www.cms.gov/files/zip/ltch-data-specs-v4000-draft-03-05-2020zip.zip> and on the LTCH QRP Technical Information webpage at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information>.

TOH Information to the Patient-PAC measure, and on the six categories of Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

X. COVID-19 Reporting Requirements for Long Term Care Facilities

A. Background

The United States is responding to the COVID-19 Public Health Emergency (PHE) caused by the coronavirus which has been detected in more than 190 countries internationally, and all 50 States and the District of Columbia. In an effort to respond to the COVID-19 PHE and protect the health and safety of LTC facility residents, CMS published three interim final rules with comment period (IFCs) directly affecting LTC facilities. The May 8, 2020 IFC titled, “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (85 FR 27550) revised the infection prevention and control requirements for LTC facilities to more effectively respond to the specific challenges posed by the COVID-19 pandemic. Specifically, this IFC added provisions to require facilities to electronically report information related to confirmed or suspected COVID-19 cases in a standardized format and frequency specified by the Secretary and required facilities to inform residents and their representatives of confirmed or suspected COVID-19 cases in the facility among residents and staff.

The September 2, 2020 IFC, entitled “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (85 FR 54820, 54873) set out provisions regarding testing for COVID-19 in long-term care facilities, including documentation requirements and protocols specifying actions to be taken if a resident or staff member tests positive. The May 13, 2021 IFC, titled "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86 FR 26306) revised the infection control requirements that LTC facilities and intermediate care facilities for individuals with intellectual disabilities (ICFs-IID)

must meet to participate in the Medicare and Medicaid programs. This IFC aimed to reduce the spread of SARS-CoV-2 infections, the virus that causes COVID-19 by requiring education about COVID-19 vaccines for LTC facility residents, ICF-IID clients, and staff serving both populations, and by requiring that such vaccines, when available, be offered to all residents, clients, and staff. It also required LTC facilities to report COVID-19 vaccination status of residents and staff to the Centers for Disease Control and Prevention (CDC). Additional information and data regarding SARS-CoV-2, and populations at greatest risk were presented in these IFCs (85 FR 27550 and 86 FR 26306).

This final rule focuses on the LTC facility COVID-related reporting requirements established in these three IFCs and codifies these requirements in order to extend them beyond the PHE. While COVID-19 cases for both staff and residents had been consistently declining from April to July 2021, there has been a recent increase in confirmed cases for staff and residents of LTC facilities.²¹⁵ In addition, the Delta variant is currently the predominant variant of the virus in the United States. It is more infectious and has led to increased transmissibility when compared to other variants, even in some vaccinated individuals. Specifically, the Delta variant is more than 2x contagious than previous variants. Preliminary data also suggest that the Delta variant may cause more severe illness than previous variants in unvaccinated people. Available data continue to suggest that breakthrough infections are relatively rare, and the majority of new cases are attributable to unvaccinated persons. The greatest risk of transmission is among unvaccinated people who are more likely to become infected, and therefore transmit the virus.²¹⁶ Furthermore, while resident vaccination rates are high in LTC facilities, standing at about 84 percent, it is not reasonable to anticipate complete vaccination coverage, leaving all facilities at risk for a COVID-19 outbreak after the official PHE declaration has ended. It is also important to note that only 64 percent of current nationwide LTC facility staff have been

²¹⁵ 215Data.CMS.gov, *COVID-19 Nursing Home Data*, <https://data.cms.gov/covid-19/covid-19-nursing-home-data>

²¹⁶ Centers for Disease Control and Prevention, *Delta Variant: What We Know About the Science* <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html>.

vaccinated.²¹⁷ The nature of LTC facilities make outbreaks of COVID-19 difficult to control, especially as many staff and potentially residents may be asymptomatic. Asymptomatic people with SARS-CoV-2 may move in and out of the LTC facility and the community, putting residents and staff at risk of infection. The CDC is continuing to assess data on whether fully vaccinated individuals with asymptomatic breakthrough infections can transmit the virus.²¹⁸ Routine testing of LTC residents and staff, along with visitation restrictions, personal protective equipment (PPE) usage, social distancing, and vaccination for residents and staff are the best defense against COVID-19.

The rate of staff vaccination, coupled with the continued threat of numerous variants, including the highly transmissible Delta variant, the congregate living nature of LTC facilities that make them more susceptible to COVID-19 outbreaks, and breakthrough cases, creates an ongoing risk of outbreaks, with significant risks of morbidity and mortality, in this higher risk population. This final rule maintains the current COVID-19 reporting requirements while modifying the reporting frequency of these requirements to no more than weekly, which may be reduced at the discretion of the Secretary, and adds a sunset date of December 31, 2024 for most of the reporting requirements, in order to ensure patient safety and health while informing future pandemic and emergency response.

B. Statutory Authority and Regulatory Background

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, or both, must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate. Long-term care (LTC) facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting Federal participation requirements. LTC facilities include SNFs for Medicare and NFs for Medicaid. The Federal

²¹⁷ Data.CMS.gov, *COVID-19 Nursing Home Data*, <https://data.cms.gov/covid-19/covid-19-nursing-home-data>.

²¹⁸ Centers for Disease Control and Prevention, *Delta Variant: What We Know About the Science* https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html?s_cid=11512:covid%20delta;sem.ga;p:RG:GM;gen:PTN:FY21.

participation requirements for SNFs, NFs, and dually certified facilities, are set forth in sections 1819 and 1919 of the Act and codified in the implementing regulations at 42 CFR part 483, subpart B.

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents. Infection prevention and control is a primary goal of initiatives taking place in LTC facilities during the COVID-19 PHE. Under the explicit instructions of Congress, existing regulations at § 483.80 require facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections.

C. Summary of the Provisions and Responses to Public Comments

In response to the three IFCs that were published on May 8, 2020, September 2, 2020, and May 13, 2021, we received 537 total comments. Commenters included individuals, health care professionals and corporations, national associations and coalitions, patient advocacy organizations, and individual facilities that will be impacted by the rule.

In this final rule, we are finalizing provisions from two of the three IFCs that made amendments to § 483.80. We provide a summary of our proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for LTC facilities. We have organized our proposed provisions and responses to the comments as follows: COVID-19 Reporting and Vaccine Reporting. Comments related to the collection of information requirements and impact analysis sections are addressed in sections XI and XII, “Collection of Information Requirements” and “Regulatory Impact Analysis” of this final rule.

1. Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths Related to COVID-19 (§ 483.80(g)(1) through (3))

In the IFC, “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (85 FR 27550), we finalized a requirement at § 483.80 (g)(1), that LTC facilities electronically report information about COVID-19 in a standardized format specified by the secretary. This report must include suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies in the facility; resident beds and census; access to COVID-9 testing while the resident is in the facility; and staffing shortages.

In addition, §483.80(g)(2) requires that the information specified in §483.80(g)(1) be provided at a frequency specified by the Secretary, but no less than weekly to the CDC’s National Healthcare Safety Network (NHSN). Finally, §483.80(g)(3) requires that residents, their representatives, and their families be informed of the occurrence of either a single or confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must be reported to the residents, their representatives, and their families by 5:00 PM the next calendar day.

In response to the May 8, 2020 IFC, we received 297 public comments. While a significant number of commenters indicated that they supported increased reporting requirements, the majority of the comments expressed concerns about the burden of the reporting requirements.

Comment: A significant number of commenters indicated that the reporting requirements were too burdensome, time consuming, duplicative, and create a heightened sense of alarm.

Response: We understand the burden concerns expressed by commenters. However, due to the unpredictable nature of the virus and the new variants that are arising, we believe that it is vital that this information be collected and recorded. Retaining the data reporting requirements after the end of the PHE is an important element of maintaining effective surveillance of this novel virus. While COVID-19 cases for both staff and residents were consistently declining for several weeks, there has been an increase in confirmed cases for staff and residents of LTC facilities. Specifically, national case rates have continued to climb precipitously, reaching levels not seen since early February 2021. As of October 1, 2021, the current 7-day moving average of daily new cases was 106,395. As of September 25, 2021, the overall rate of COVID-19 hospitalizations per 100,000 was 6.4 hospitalizations.²¹⁹ Collectively, this information highlights the gravity of the delta variant.

The rate of staff vaccinations, coupled with the presence of multiple variants, specifically the highly contagious Delta variant, and breakthrough infections, creates an ongoing risk of outbreaks, with significant risks of morbidity and mortality, in this higher risk population. Timely and actionable surveillance will enable CMS to continue to respond to facilities in need of additional technical support and oversight, should they experience new COVID-19 infections.

In addition, agencies across HHS have released data and guidance that should have addressed and alleviated some of the confusion that commenters are referring to. As such, we will be maintaining the current reporting requirements, which require LTC facilities to report weekly, unless the Secretary specifies a lesser frequency, and the potential to modify the number of data elements reported in the future, contingent upon the state of the pandemic. In an effort to further address concerns regarding burden, we are also finalizing a sunset date of December 31, 2024 for the reporting requirements, with the exception of the staff and resident vaccination reporting requirements in § 483.80(g)(1)(viii). We believe that the need to collect data will likely

²¹⁹ COVID-NET, Laboratory-Confirmed COVID-19-Associated Hospitalizations
https://gis.cdc.gov/grasp/covidnet/covid19_3.html.

extend past the end of the PHE. We therefore are granting ourselves and other government authorities the continued ability to monitor LTC facilities, given that this population has been most vulnerable to the virus. This provision will automatically expire on December 31, 2024 unless it is determined that further regulations must be established.

Comment: Several commenters questioned the need to report COVID related deaths for individuals with multiple comorbidities, as many LTC residents have pre-existing and chronic conditions, and they believe that COVID was not the primary or sole cause of death.

Response: Many individuals that succumb to COVID-19 have multiple co-morbidities, none of which negate a person's COVID-19 infection status. COVID-19 related deaths need to be reported to provide CMS with information that enables us to protect these vulnerable populations and ensure that the appropriate care is being provided. Therefore, we are retaining the requirement that facilities must report nursing home resident and staff infections, potential infections, and deaths related to COVID-19.

In an effort to support surveillance of COVID-19 cases, we are maintaining the requirements to establish explicit reporting requirements for confirmed or suspected cases with the possibility for reduced frequency of reporting and minimizing the number of required data elements in the future at the discretion of the Secretary. Specifically, we are finalizing our requirements by maintaining the provision at § 483.80(g)(1)(i) through (ix), to require facilities to electronically report information about COVID-19 in a standardized format specified by the Secretary. The report includes, but is not limited to, information on: Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID-19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary. In the future, the number of data elements required to be reported may be reduced to allow for greater flexibility

and mitigate burden concerns. This information will be used to monitor trends in infection rates, and inform future public health and emergency preparedness policies.

Comment: A commenter stated that the rationale for additional reporting to Federal authorities is unclear, since LTC facilities must already report to State and local authorities and that a universal reporting system should be used instead.

Response: Federal reporting requirements are used by State and local authorities to inform their operations and pandemic response for their particular population. We understand the burden concerns expressed by commenters and have therefore revised the frequency of reporting information specified in paragraph (g)(1) to weekly, unless the Secretary specifies a lesser frequency, and a reduced number of data elements in the future, at the discretion of the Secretary, when the COVID-19 virus is less prevalent and we may no longer need all of this data as frequently. Due to the variation in mandates across States and localities, we will continue to require surveillance efforts at the Federal level and maintain current reporting requirements.

In addition, at § 483.80(g)(2), we are revising the current requirements to require that LTC facilities provide the information noted previously weekly, unless the Secretary specifies a lesser frequency, to the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) with the possibility for reduced frequency of reporting in the future, contingent on the state of the PHE. Furthermore, we note that the information reported will be shared with us and we will retain and publicly report this information to support protecting the health and safety of residents, in accordance with sections 1819(d)(4)(B) and 1919(d)(4) of the Act, as well as facility personnel, and the general public. These requirements will support our efforts to proactively and transparently inform interested parties and ensure that the most complete information on COVID-19 cases is available. The existing reporting requirements at §483.80(g)(1) and (2) do not relieve LTC facilities of the obligation to continue to comply with § 483.80(a)(2)(ii), which requires facilities to report possible incidents of communicable disease

and infections. This includes complying with State and local reporting requirements for COVID-19.

Comment: Many commenters indicated that the reporting requirements are not stringent or detailed enough, resulting from lack of oversight and the vague definitions/ terminology set out in the IFCs. A significant portion of commenters requested further clarification and more detailed regulations to ensure that programs achieved better quality and lower costs.

Commenters also recommended additional reporting requirements including but not limited to retroactive reporting and the collection of additional demographic information (race, ethnicity, sex, age, disability status, primary language, sexual orientation, gender identity, socio-economic status, and location (urban/rural)). The commenters noted that retroactive reporting dating back to January 1, 2020, is necessary in order to gain a better understanding of the trajectory of SARS-CoV-2 and the rapidly evolving situation. A few commenters also expressed their desire for disability status to be collected as well, as these individuals are often predisposed to disease and are more likely to experience medical complications and succumb to the virus.

The majority of commenters also recommended additional reporting requirements regarding the number of staff and residents who were hospitalized and who recovered from COVID-19. They stated that additional reporting requirements related to testing should include the number of residents and staff who have been tested, the percent of residents and staff who have been tested, the frequency of resident and staff testing, and the number of tests available.

Response: The reporting requirements were written in a manner that would allow for maximum flexibility by covering a broad array of services and entities. While we agree that additional data, including demographic information, could be useful to inform the pandemic response, especially since underserved populations including racial and ethnic minorities have been disproportionately impacted by COVID-19, we also understand that additional requirements could be more burdensome for providers that are caring for residents during the pandemic at this time. However, we are committed to advancing health equity and reducing

disparities for those in underserved populations that have been disproportionately impacted by COVID-19 and we believe that these data reporting requirements are an essential first steps in helping us better understand the impacts of COVID-19 on underserved populations that reside in LTC facilities. Information gained from this reported data will be assessed and used to determine if additional policy changes, especially those affecting underserved populations, should be made in the future. Additionally, the NHSN system already collects this type of information and, therefore, we are not adding additional categories in order to avoid duplicative efforts and further confusion. In an effort to mitigate potential concern about the burdensome nature of the requirements, we will not be adding additional reporting requirements and data elements at this time, but we have modified our regulations to include the flexibility to change the data elements that are required to be reported to NHSN in the future, as appropriate.

Comment: Many commenters noted that the current reporting requirements do not accomplish the goal of ensuring that residents are informed participants in the care that they receive.

Response: We disagree with the commenters. The collection of this data allows for residents and their caregivers to be informed participants in their care, as it allows them to understand the current state of the environment that they reside in. Resident health and safety are of the utmost importance, and therefore, we are continuing all of our current reporting requirements.

Specifically, at § 483.80(g)(3), we are maintaining the provision to require facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility among residents and staff. This reporting requirement supports the overall health and safety of residents by ensuring they are informed participants in the care that they receive as well as providing assurances of the mitigating steps the facility is taking to prevent and control the spread of COVID-19. Facilities must inform residents, their representatives, and families by 5 p.m. the next calendar day following the occurrence of either:

A single confirmed infection of COVID-19; or three or more residents or staff with new-onset of respiratory symptoms that occur within 72 hours of each other. Also, cumulative updates to residents, their representatives, and families must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either: (1) each time a confirmed infection of COVID-19 is identified; or (2) whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other. This information must be reported in accordance with existing privacy regulations and statute and must not include Personally Identifiable Information (PII). Facilities must include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered such as restrictions or limitations to visitation or group activities. For purposes of this reporting requirement and to mitigate the concerns regarding burden that have been expressed in public comments, facilities are not expected to make individual telephone calls. Instead, facilities can utilize communication mechanisms that make this information easily available to all residents, their representatives, and families, such as paper notification, listservs, website postings, or recorded telephone messages.

These reporting requirements, along with public reporting of the data, support our responsibility to protect and ensure the health and safety of residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. In addition, sections 1819(d)(3)(B) and 1919(d)(3) of the Act requires that a facility must establish an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. We believe that the reporting requirements comply with these statutory requirements. We also note that they are necessary for us to monitor whether individual nursing homes are appropriately tracking, responding, and mitigating the spread and impact of COVID-19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area.

We believe that this action strengthens our response to the PHE for the COVID-19 pandemic and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents.

2. COVID-19 Vaccine Reporting for Residents and Staff (§ 483.80(g)(1)(viii))

In the May 2021 IFC, “Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff”, we finalized a requirement, at § 483.80(g)(1)(viii), that LTC facilities report on the COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events. We are also finalizing the requirement at § 483.80(g)(1)(ix) to require the reporting of therapeutics administered to residents for treatment of COVID-19. We received 71 comments in response to this IFC, with no comments discussing the requirement to report information about therapeutics administered to residents for treatment of COVID-19. A significant number of commenters indicated that they supported increased reporting requirements, however, the majority of the comments expressed concerns about the burdensome nature of the requirements.

Comment: Several commenters supported our staff and resident vaccination reporting requirements and cited statistics about the higher rate of contracting COVID-19 and succumbing to the virus compared to the general population. Additionally, they note, continued collection of data and surveillance will allow CDC and other Federal agencies to identify facilities that need additional support. This will also enable current and prospective residents and families to make informed decisions regarding their options for care.

Response: We thank commenters for their support and their ability to recognize the gravity of the situation. Due to the evolving nature of the virus and the continued threat of the delta and other new variants, it is vital that surveillance be maintained. On August 18, CMS

announced the development of an emergency regulation requiring staff vaccinations within the nation's more than 15,000 Medicare and Medicaid-participating nursing homes. Subsequently, on September 9, CMS announced the expansion of the August 18 announcement requiring staff vaccinations in nursing homes to add additional Medicare and Medicaid-certified health care providers and suppliers certified by CMS, including, but not limited to, hospitals, dialysis facilities, ambulatory surgical centers, and home health agencies. We believe maintaining these vaccination reporting requirements aligns with the President's recent announcements²²⁰ regarding staff vaccination.

Comment: Most commenters indicated that this vaccine reporting requirement is challenging to comply with due to staffing shortages, difficulty hiring and retaining a qualified workforce, and paying competitive wages. Many commenters expressed concern about the time it takes to complete the reporting due to short staffing and the requirement to report to multiple entities. Commenters also questioned if this requirement is the best use of resources, and argue that this time would be better utilized providing personal care. A few commenters noted that smaller LTC facilities do not have the same kind of infrastructure and resources that larger agencies and other institutional providers have access to, and that this should be considered when determining compliance and expectations of the rule.

The majority of commenters were concerned that these vaccine reporting requirements were duplicative of other currently existing requirements and systems used for reporting this data. Some of these commenters noted that the requirements are duplicative of requirements to report this data to State and local health departments. Additionally, a few commenters were unclear on where to report vaccination metrics and how to document compliance efforts. A commenter expressed concern that this type of reporting is only beneficial for data analysts, not the residents of the facility.

²²⁰ The White House, *Remarks by President Biden on Fighting the COVID-19 Pandemic*
<https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/>.

Commenters believed that reporting should be more user friendly and less time consuming. Most commenters were in favor of using systems that are already in place and that they use often (Minimum Data Set [MDS], Payroll Based Journal [PBJ]) in order to improve these processes and comply with the requirements. Commenters recommended creating an item for COVID-19 vaccinations in the MDS for residents and pulling data from there. Multiple commenters also proposed adding an item on PBJ data submissions for staff requirements. PBJ and MDS are already required, the commenters stated, and they explained that it would take less time to complete these reporting requirements through these platforms instead of NHSN. Additionally, a small number of commenters shared some privacy concerns and implications of tracking and documenting staff vaccination status through NHSN.

Finally, a commenter indicated that they could use MDS to submit this information as they do for pneumonia and influenza; this would combine processes that are already in place. Another commenter also suggested REDCap as an alternative, as it is used for the Federal Partnership Vaccine Program.

Response: We acknowledge the burdensome nature of some of these requirements and thank the staff for their hard work in complying with these requirements while providing care to their residents. Since this IFC was initially published, CMS and other agencies across HHS have released additional guidance in an effort to address some of these questions and concerns about how to comply to these requirements. Additionally, CMS has standing calls with several key stakeholders in an effort to address some of these questions and concerns. We recognize that some facilities have stronger infrastructures and more resources available to work with. However, while some of this reporting may seem duplicative of other State and local reporting requirements, it has been instrumental in developing a tailored pandemic response and allows authorities to understand where most resources need to be directed.

Consistent vaccination reporting by LTC facilities via the NHSN will help to identify LTC facilities that have potential issues with vaccine confidence or slow uptake among either

residents or staff or both. The NHSN is the nation's most widely used health care-associated infection (HAI) tracking system. It furnishes States, facilities, regions, and the government with data regarding problem areas and measures of progress. CDC and CMS use information from NHSN to support COVID-19 vaccination programs by focusing on groups or locations that would benefit from additional resources and strategies that promote vaccine uptake. CMS surveyors and State agency surveyors will use the vaccination data in conjunction with the reported data that includes COVID-19 cases, resident deaths, staff shortages, PPE supplies and testing. This combination of reported data is used by surveyors to determine individual facilities that need to have focused infection control surveys as well as technical assistance in expanding vaccine delivery and uptake. Facilities having difficulty with vaccine acceptance can be identified through examining trends in NHSN data; and the Quality Improvement Organizations (QIOs), groups of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare, can provide assistance to increase vaccine acceptance. Specifically, QIOs may provide assistance to LTC facilities by targeting small, low performing, and rural nursing homes most in need of assistance, and those that have low COVID-19 vaccination rates; disseminating accurate information related to access to COVID-19 vaccines to facilities; educating residents and staff on the benefits of COVID-19 vaccination; understanding nursing home leadership perspectives and assist them in developing a plan to increase COVID-19 vaccination rates among residents and staff; and assisting providers with reporting vaccinations accurately.

We believe direct submission of data by LTC facilities through NHSN will show actions and trends that can be addressed more efficiently on a national level. All State health departments and many local health departments already have direct access through NHSN to LTC facilities' COVID-19 data and are using the data for their own local response efforts. Thus, reporting in NHSN will, in many cases, serve the needs of State and local health departments.

Therefore, we are modifying the requirements at § 483.80(g)(1)(viii) to require that LTC facilities report to NHSN, on a weekly basis, unless the Secretary specifies a lesser frequency, the COVID-19 vaccination status and related data elements of all residents and staff. The data to be reported each week will be cumulative, that is, data on all residents and staff, including total numbers and those who have received the vaccine, as well as additional data elements. In this way, the vaccination status of every LTC facility will be known on a weekly basis. Data on vaccine uptake will be important to understanding the impact of vaccination on SARS-CoV-2 infections and transmission in nursing homes. This understanding, in turn, will help CDC make changes to guidance to better protect residents and staff in LTC facilities. In addition, LTC facilities must also report any COVID-19 therapeutics administered to residents. CDC has currently defined “therapeutics” for the purposes of the NHSN as a “treatment, therapy, or drug” and stated that monoclonal antibodies are examples of anti-SARS-CoV-2 antibody-based therapeutics used to help the immune system recognize and respond more effectively to the SARS-CoV-2 virus.

Our intent in mandating reporting of COVID-19 vaccines and therapeutics to NHSN is in part to monitor broader community vaccine uptake, but also to allow CDC to identify and alert CMS to facilities that may need additional support in regards to vaccine education and administration. The information reported to CDC in accordance with § 483.80(g) will be shared with CMS and we will retain and publicly report this information to support protecting the health and safety of residents, staff, and the general public, in accordance with sections 1819(d)(3)(B) and 1919(d)(3) of the Act.

Comment: A significant proportion of commenters recommended that CMS expand these vaccination reporting requirements to other facilities where Medicare beneficiaries receive care ([psychiatric] residential treatment facilities, psychiatric hospitals, adult foster care homes, group homes, and assisted living facilities) as these communities are at the highest risk for infection and severe illness. Another commenter stated that this requirement should also be expanded to

include prisons, homeless shelters, forensic hospitals, supervised apartments, and inpatient hospice facilities. Several commenters also emphasized the importance of this due to the emergence of new variants and continued mitigation efforts.

Some commenters highlighted the disproportionate impact that COVID-19 has had on minority groups and individuals with disabilities. Because of this, commenters recommended that CMS arrange and collect vaccination reporting data by race and ethnicity. They stated that the data should be de-aggregated to examine the disparate outcomes for individuals based on sex, age, race, and ethnicity. Another commenter believes that in addition to data on race and ethnicity, data on sexual orientation, gender identity, preferred language, urban/ rural environment, and service setting should be collected. The commenters stated that for people with intellectual and developmental disabilities, as well as other disability groups, the pandemic has revealed the need for public health surveillance systems to include disability status as a basic demographic characteristic.

Response: We agree that additional data collection could be useful in informing emergency preparedness and future pandemic response and we reaffirm our commitment to addressing disparities in healthcare that have disproportionately affected underserved populations. However, in an effort to mitigate some of the burden concerns expressed by commenters, we will not be adding additional data elements or reporting requirements. Instead, we will maintain the current reporting requirements for the reporting of staff and resident vaccinations. The May 2021 IFC sought information regarding the potential application of these requirements in other congregate living settings and suggested ICFs-IID report vaccine administration. However, in light of the commenters overall concerns regarding the burden of these reporting requirements, we do not believe that it is appropriate to mandate these requirements for other congregate living settings at this time. Additionally, CMS does not have the authority to extend these reporting requirements to some of the settings that commenters

discuss, including prisons, assisted living facilities, supervised apartments, or homeless shelters.

We appreciate this feedback and will consider it for future rulemaking.

We believe that all LTC facility residents and the staff who care for them, should be provided with ongoing access to vaccination against COVID-19. The accountable entities responsible for the care of residents and clients of LTC facilities must proactively pursue access to COVID-19 vaccination due to a unique set of challenges that generally prevent these residents and clients from independently accessing the vaccine. These challenges create potential disparities in vaccine access for those residing in LTC facilities. It is CMS's understanding that very few individuals who are residents of LTC facilities are likely able to independently schedule or travel to public offsite vaccination opportunities. People reside in LTC facilities because they need ongoing support for medical, cognitive, behavioral, and/or functional reasons. Because of these issues, they may be less capable of self-care, including arranging for preventive health care. Independent scheduling and traveling off-site may be especially challenging for people with low health literacy, intellectual and developmental disabilities, dementia including Alzheimer's disease, visual or hearing impairments, or severe physical disability. To support national efforts to control the spread of COVID-19, we are finalizing the LTC facility infection control regulations related to reporting COVID-19 data at § 483.80(g)(1)(viii) so that they will continue in effect. We have not finalized a sunset date for these requirements in order to allow for continued monitoring and surveillance of vaccine delivery and uptake.

Comment: Several commenters shared their stance on vaccination and indicated that vaccines should not be required and that this should be a decision between an individual and their provider. A commenter expressed feeling being “discriminated” against because of the commenter's decision to not receive the COVID vaccination.

Response: The IFCs did not finalize a vaccination mandate for LTC staff or residents; therefore, these comments outside the scope of this rule. We are maintaining the requirement at §483.80(g)(1)(viii) for the reporting of staff and resident vaccinations.

Final Decision: After consideration of the public comments we received on the COVID-19 reporting requirements, we are finalizing the requirements at §483.80(g)(1) through (3) with the following modifications: (1) Reporting frequency of the information specified in §483.80(g)(1) is modified to weekly, unless the Secretary specifies a lesser frequency; (2) Reporting data elements are unchanged, but may be reduced, contingent on the state of the pandemic and at the discretion of the Secretary; and (3) with a sunset date of December 31, 2024 for all reporting requirements, with the exclusion of the requirements at § 483.80(g)(1)(viii).

TABLE 37 IFC CROSSWALK OF COVID-19 REPORTING REQUIREMENTS AND PROVISIONS OF THE FINAL RULE

IFC Provisions	Final Requirements	End Date
Provisions Finalized in CMS-5531-IFC (May 8, 2020)		
The facility must—	Until December 31, 2024, with the exception of requirements regarding COVID-19 vaccine status of residents and staff, the facility must do all of the following:	N/A
1. Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to—	1. Electronically report information about COVID-19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following:	N/A
a. Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;	a. Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19.	December 31, 2024
b. Total deaths and COVID-19 deaths among residents and staff;	b. Total deaths and COVID-19 deaths among residents and staff.	December 31, 2024
c. Personal protective equipment and hand hygiene supplies in the facility;	c. Personal protective equipment and hand hygiene supplies in the facility.	December 31, 2024
d. Ventilator capacity and supplies in the facility.	d. Ventilator capacity and supplies in the facility.	December 31, 2024
e. Resident beds and census;	e. Resident beds and census.	December 31, 2024
f. Access to COVID-19 testing while the resident is in the facility;	f. Access to COVID-19 testing while the resident is in the facility.	December 31, 2024
g. Staffing shortages; and	g. Staffing shortages.	December 31, 2024
2. Provide the information specified in item 1. at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.	2. Provide the information specified in item 1. weekly, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.	N/A
3. Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—	3. Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must do all of the following:	N/A
a. Not include personally identifiable information;	a. Not include personally identifiable information.	N/A
b. Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and	b. Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered.	N/A
c. Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.	c. Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.	N/A
Provisions Finalized in CMS-3414-IFC (May 21, 2021)		

1. The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and	1. The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events; and	None
2. Therapeutics administered to residents for treatment of COVID-19.	2. Therapeutics administered to residents for treatment of COVID-19.	December 31, 2024

XI. Collection of Information Requirements and Waiver of Proposed Rulemaking

A. Statutory Requirement for Solicitation of Comments

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 the CY 2022 HH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements.

B. Collection of Information Requirements

1. HH QRP

In section IV.C. of the proposed rule, we proposed 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 quality and reporting. As of March 1, 2021, there are approximately 11,400 HHAs reporting data to CMS under the HH QRP. For purposes of calculating the costs associated with the information collection requirements, we obtained mean hourly wages for these from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). To account for overhead

and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 38.

TABLE 38: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 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	\$38.47	\$38.47	\$76.94
Physical therapists HHAs	29-1123	\$44.08	\$44.08	\$88.16
Speech-Language Pathologists (SLP)	29-1127	\$40.02	\$40.02	\$80.04
Occupational Therapists (OT)	29-1122	\$42.06	\$42.06	\$84.12
Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians	29-2098	\$23.21	\$23.21	\$46.42

In section IV.C.4.a. of the final rule, we are finalizing our proposal to remove the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care measure under removal factor 1, measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. Further, we are finalizing our proposal to remove OASIS item M2016 used to calculate this measure. This item removal results in a decrease in overall burden.

In sections IV.C.4.b. of this final rule, we are finalizing our proposal to adopt the Home Health Within Stay Potentially Preventable Hospitalization measure which is claims-based. We are replacing the Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) measure and the Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173) measure with the Within Stay Potentially Hospitalization measure beginning with the CY 2023 HH QRP under our measure removal factor 6: a measure that is more strongly associated with desired patient outcomes for the particular topic is available. Because the measures are claims-based, their replacement or removal does not impact our collection of information.

Therefore, the result of our final policies is a net reduction of 1 data element at the Discharge from Agency time point and 1 data element at the Transfer of Care time point associated with OASIS item (M2016) collection as a result of the measure removal. We assumed that each data element requires 0.3 minutes of clinician time to complete. Therefore,

we estimated that there would be a reduction in clinician burden per OASIS assessment of 0.3 minutes at Discharge from Agency and 0.3 minutes at Transfer of Care.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OTs) or speech language pathologists (SLT/SP). Data from 2020 show that the OASIS is completed by RNs (approximately 76.5 percent of the time), PTs (approximately 20.78 percent the time) and other therapists including OTs and SLP/STs (approximately 2.72 percent of the time). Based on this analysis, we estimated a weighted estimated clinician average hourly wage of \$79.41, inclusive of fringe benefits using the wage data from Table 38 Individual providers determine the staffing necessary.

Table 39 shows the total number of assessments submitted in CY 2020 and estimated costs at each time point.

TABLE 39: CY 2020 OASIS SUBMISSIONS AND ESTIMATED COSTS, BY TIME POINT

Time Point	CY 2020 Assessments Completed	Estimated Cost (\$)
Transfer of Care	1,788,100	\$4,259,791
Discharge from agency	5,168,903	\$228,832,891
TOTAL	6,957,003	\$233,092,681

* Estimated Burden (\$) at each Time-Point = (# CY 2020 Assessments Completed) x (clinician burden [min]/60) x (\$79.41 [weighted clinician average hourly wage]). Excluding M2016, there are 1.8 minutes to complete 6 transfer of care data elements and 33.45 minutes to complete 123 data elements at discharge.

Based on the data in Tables 38 and 39 for the 11,400 active Medicare-certified HHAs, we estimated the total decrease in costs associated with the changes in the HH QRP at approximately \$242 per HHA annually or \$2,762,277 for all HHAs as derived in the RIA section. This corresponds to an estimated decrease in clinician burden associated with the changes to the HH QRP of approximately 3.1 hours per HHA or approximately 34,785 hours for all HHAs. This decrease in burden will be accounted for in the information collection under OMB control number 0938-1279 (Expiration date: 12/31/2021).

In section IV.C. of this final rule, we are finalizing our proposal to revise the compliance date for certain reporting requirements adopted for the HH QRP. The burden for the proposed

revision to the HH QRP requirements as adopted in the CY 2020 HH PPS final rule (84 FR 60632 through 60642) has been accounted for in OMB control number 0938-1279. Therefore, this proposal would not affect the information collection burden already established.

We did not receive any comments on this proposal and therefore are finalizing this provision without modification.

2. ICRs Regarding Revised Compliance Dates for Certain Reporting Requirements

a. IRF QRP Requirements

In section VIII.A. of the proposed rule, we proposed to revise the compliance date for certain reporting requirements adopted for the IRF QRP. We believe that the burden associated with the IRF QRP proposed provision is the time and effort associated with reporting data. As of April 4, 2021, there are approximately 1,109 IRFs reporting IRF QRP data to CMS. The burden for the proposed revision to the IRF QRP requirements as adopted in the FY 2020 IRF PPS final rule (84 FR 39165 through 39172) has been accounted for in OMB control number 0938-0842 (Expiration date: 12/31/2022). Therefore, this proposed provision would not affect the information collection burden for the IRF QRP.

We did not receive any comments on this proposal and therefore are finalizing this provision without modification.

b. LTCH QRP Requirements

In section VIII.B. of the proposed rule, we proposed a revised compliance date for certain reporting requirements adopted for the LTCH QRP. We believe that the burden associated with the LTCH QRP proposal is the time and effort associated with reporting data. As of April 21, 2021, there are approximately 363 LTCHs reporting LTCH QRP data to CMS. The burden for the proposed revision to the LTCH QRP requirements as adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42602 through 42656) has been accounted for in OMB control number

0938-1163 (Expiration date:12/31/2022). Therefore, this proposal would not affect the information collection burden for the LTCH QRP.

We did not receive any comments on this proposal and therefore are finalizing this provision without modification.

3. ICRs Related to the Changes in the Home Health CoPs

a. ICRs Related to the Virtual Supervision of HHA Aides

In section IV.D. of the final rule, we revised § 484.80(h)(1) to specify that if a patient is receiving skilled care (patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services), the home health aide supervisor (RN or therapist) must complete a supervisory assessment of the aide services being provided, either onsite (that is, an in person visit) or using interactive telecommunications systems no less frequently than every 14 days. The home health aide would not have to be present during the supervisory assessment. The use of interactive telecommunications systems for the aide supervisory assessment must not exceed 2 times per HHA in a 60-day period. We finalized § 484.80(h)(2) to specify that, if a patient is not receiving skilled care, the RN must make an in-person supervisory visit to the location where the patient is receiving care, once every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services met the patient's needs. The home health aide would not need to be present during this visit. We are also finalizing with modification that the RN would make a semi-annual on-site (in-person) visit to the location where a patient is receiving care in order to observe and assess each home health aide while he or she is performing care for each of their assigned patients. This semi-annual supervisory visit of the aide performing care would replace the current every 60-day requirement of direct supervision of the aide performing care. In addition, we are finalizing § 484.80(h)(3), which includes retraining and competency evaluations related to both the skills verified as deficient and any related skills. We believe that this would not add any information collection burden and would enhance the provisions of safe, quality home health services. In accordance with the

implementing regulation of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the proposed revisions to the requirements at 484.80(h) are exempt from the PRA. We believe competency evaluations are a usual and customary business practice and we state as such in the information collection request associated with the Home Health CoPs and approved under OMB control number: 0938-1299 (Expiration date: 06/30/2024). Therefore, we did not propose to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 484.80(h), but we requested public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary, and would be incurred by home health staff even absent this regulatory requirement.

We did not receive comments on this section of the collection of information proposed and therefore are finalizing this provision without modification.

b. ICRs Related to Permitting Occupational Therapist to Complete the Initial and Comprehensive Assessments for Home Health Agencies

In section IV.D. of the final rule, we are implementing Division CC, section 115 of CAA 2021 by finalizing conforming regulations text changes at § 484.55(a)(2) and (b)(3) permitting the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are not initially on the home health plan of care. These changes, which permit occupational therapists to complete these assessments even though the need for occupational therapy would not establish the patient's eligibility for the Medicare home health benefit. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the finalized revisions to the requirements at § 484.55(a)(2) and (b)(3) are exempt from the PRA. We believe patient assessment are a usual and customary business practice and we state such in the information collection request associated with the OASIS data

set, which comprises the core of the patient assessment and is currently approved under OMB control number 0938-1279 (Expiration date: 06/30/2024). Therefore, we did not propose to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 484.55(a)(2) and (b)(3), but we requested public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary and would be incurred by home health staff even absent this regulatory requirement.

We did not receive comments on this section of the collection of information proposed and therefore are finalizing this provision without modification.

4. ICRs Regarding Medicare Provider and Supplier Enrollment Provisions

We did not anticipate any information collection burden associated with our provider and supplier enrollment proposed provisions. Since most of the provisions that we proposed and are finalizing have been in subregulatory guidance for a number of years and we are simply incorporating them into regulation, there would not be any change in burden on the provider community. Those provisions that are not in subregulatory guidance do not implicate information collection requirements.

5. ICRs Regarding Survey and Enforcement Requirements for Hospices

a. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 40 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 40: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wages
Computer and Information Analysts	15-1210	\$48.40	\$48.40	\$96.80
Home Health and Personal Care Aides; and Nursing Assistants, Orderlies, and Psychiatric Aides	31-1100	\$14.10	\$14.10	\$28.20
Medical or Health Services Manager	11-9111	\$55.37	\$55.37	\$110.74
Registered Nurse (RN)	29-1141	\$38.47	\$38.47	\$76.94

We did not receive comments on the ICR proposal for hospice survey and enforcement requirements and therefore are finalizing the application and re-application procedures for national accrediting organizations without modification. CMS has removed the proposed burden estimates for the surveyor qualifications and prohibition of conflicts of interest because no information collection is actually required.

b. Application and Re-application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require AOs with CMS-approved hospice programs to include a statement of deficiencies, (that is, the Form CMS-2567 or a successor form) to document findings of the hospice Medicare CoPs and to submit such in a manner specified by CMS. At the time of the proposed rule, the information collection request for the Form CMS-2567, titled “Statement Of Deficiencies And Plan Of Correction” was active and approved under OMB control number 0938-0391 (Expiration date: 6/30/2021); however, it did not account for any information collection related burden associated with AO use. As discussed in section VII.B.2.b. of the proposed rule, we note that the Form CMS-2567 did not include a place for the name of the AO completing the survey and AOs are not addressed in the instructions. These were minor revisions to the form and we submitted the revised information collection request to OMB for approval.

We discussed in section VII.B.2.b. of the proposed rule, how AOs conduct hospice program surveys and gather deficiency findings into a report that is provided to the surveyed hospice. CMS believes the statutory requirement and subsequent proposed rule for the inclusion of Form CMS-2567 would not add significant burden to AOs as they already develop deficiency finding reports as part of their existing process just in a different format. We noted that AOs

would need to make a one-time update to their existing proprietary electronic documentation systems to include the Form CMS-2567. We estimated that this task would be performed by a computer and information analyst. According to the U.S Bureau of Labor statistics, the mean hourly wages for a computer and information analyst is \$48.40. This wage adjusted for the employer's fringe benefits and overhead would be \$96.80.

We estimated that it would take at least two persons working on a full-time basis for 3 days for the AO staff to revise their system to add the required Form CMS-2567. Therefore, we estimated that the total time required for the two team members to perform this task would be 48 hours. As of March 2021, there are three AOs that accredit Medicare certified hospice programs. The total time burden across these three AOs would be 144 hours.

We estimated that the cost burden related to the work performed by two computer and information analysts would be \$4,646.40 (24 hours X \$193.60 (\$96.80 X 2)). The total cost across the three AOs would be \$13,939.20 (3 AOs X \$4,646.40). The burden associated with this requirement was submitted to OMB for approval under OMB control number 0938-0391. We sought comments that would help us to develop an accurate estimate of the cost and time burden that would result from this collection of information. No comments were received through the proposed rule public comment period.

We sought OMB approval via the required notice and comment periods separate from the proposed rulemaking. The revised information collection request was announced in the **Federal Register** on July 13, 2021 (86 FR 36751) and the public had the opportunity to review and comment. We received one comment on the Form CMS-2567 which was outside the scope of the information collection request. OMB approved the revised Form CMS-2567, titled "Statement Of Deficiencies And Plan Of Correction" under OMB control number 0938-0391 (Expiration date: 02/28/2022) on August 25, 2021.

6. HHVBP Expanded Model

In section III. of the final rule, we proposed policies necessary to implement the expanded Home Health Value-Based Purchasing Model (see final §§484.340 through 484.375), which is aimed at increasing quality and reducing spending through payment adjustments based on quality performance for HHAs nationwide. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the HHVBP expanded model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA does not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

7. COVID-19 Reporting Requirements for Long Term Care Facilities

Section 483.80(g) sets forth the requirements for COVID-19 reporting for LTC facilities. Currently, §483.80(g)(1) states that LTC facilities must electronically report information about COVID-19 in a standardized format specified by the Secretary. Specific pieces of information that must be reported are set forth in that subsection. The required information includes, “(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events”. In this rule, we are revising the requirements, in response to comments that expressed concern about burden, to modify the reporting frequency to weekly, unless the Secretary specifies a lesser frequency, to add the potential for the data elements to be reduced in the future, contingent on the state of the pandemic and at the discretion of the Secretary. In addition, we are providing a sunset, or expiration date, of December 31, 2024, for all of the required information in paragraph (g)(1), except for the information set out at paragraph (g)(1)(viii) that covers that COVID-19 vaccine status of residents and staff.

Since the infection prevention and control program (IPCP) is the responsibility of the infection preventionist (IP), the IP would be responsible for making the necessary changes to the policies and procedures to comply with the requirements in this rule (42 CFR 483.80(b)).

According to the Bureau of Labor Statistics (BLS), a registered nurse in an LTC facility earns a mean hourly wage of \$34.66.²²¹ For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. Hence, the hourly-adjusted wage for an IP in an LTC facility is \$69.

We estimate that it would require 1 hour of the IP's time to update the required policies and procedures to comply with the changes in this rule. For each LTC facility, the burden would be 1 hour at an estimated cost of \$69. According to CMS, there are currently 15,401 LTC facilities. Hence, the total burden for these requirements would be 15,401 hours (1 x 15,401) at an estimated cost of \$1,062,699 (15,401 x \$69).

Comment: Some commenters disagreed with the estimate in the IFC that reporting takes about 30 minutes, and instead they indicated that it would take about 1 to 2 hours to complete. Additionally, many commenters noted that the time by which the weekly reporting would have to be submitted (every Sunday by 11:59 PM) is not realistic. This requirement, they argue, is challenging to meet as there are often less staff working on the weekends, new residents are often admitted on the weekend, and Mondays are often holidays.

Response: After reviewing this comment and other feedback that we have received, we have made modifications to the reporting requirement for LTC facilities regarding COVID-19 in order to address public commenter's concerns regarding burden. The changes in this rule will provide the Secretary with the discretion to reduce the amount of information they must report to the NHSN in the future. Currently they must report no less frequently than weekly. This rule changes that to weekly, unless the Secretary specifies a lesser frequency. In addition, we have inserted a sunset provision for all of the information elements, except for the COVID-19 vaccine status for its residents and staff. The sunset or expiration date is December 31, 2024.

After consideration of the public comments we received, we are finalizing the requirements at

²²¹ BLS. May 2020 National Occupational Employment and Wage Estimates United States. United States Department of Labor. Accessed at https://www.bls.gov/oes/current/oes_nat.htm. Accessed on August 25, 2021.

§483.80(g)(1) through (3) with the following modifications: Reporting frequency is modified to weekly, unless the Secretary specifies a lesser frequency; (2) Reporting data elements are unchanged, but may be reduced, contingent on the state of the pandemic and at the discretion of the Secretary; and (3) with a sunset date of December 31, 2024 for all reporting requirements with the exclusion of § 483.80(g)(1)(viii).

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the collections discussed in this rule, please visit the CMS Web site at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

D. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In section IV.D.2.d. of this final rule, we include a technical change to §484.50(d)(5) that was not proposed. We believe that a notice-and-comment rulemaking procedure is unnecessary for the technical change that added “or allowed practitioner” at § 484.50(d)(5) because we inadvertently omitted the reference at this location during prior rulemaking (85 FR 27550). This change is technical in nature and ensures that all that all providers, physicians and allowed practitioners issuing orders for the patient are informed of a discharge of the patient. This

technical correction aligns with changes made throughout the HHA CoPs in which we amended the home health regulations by adding “or allowed practitioner(s)”. Therefore, we find good cause to waive the notice of proposed rulemaking.

XII. Regulatory Impact Analysis

A. Statement of Need

1. 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 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 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, required the Secretary to implement a 30-day unit of service, for 30-day periods beginning on and after January 1, 2020. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments.

2. HHVBP Model

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through notice and comment rulemaking, the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) the Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits. On January 8, 2021, we announced that the HHVBP Model (the original Model) had been certified for expansion nationwide,²²² as well as our intent to expand the Model through notice and comment rulemaking beginning no sooner than CY 2022. The original Model has resulted in an average 4.6 percent improvement in home health agencies' quality scores as well as average annual savings of \$141 million to Medicare. The CMS Chief Actuary has determined that HHVBP Model would reduce

²²² <https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf>

Medicare expenditures if expanded to all States.

We are finalizing in this rule that all Medicare-certified HHAs in the 50 States, District of Columbia and the territories would be required to participate in the expanded HHVBP Model beginning January 1, 2022 with CY 2022 as a pre-implementation year. As discussed in the preamble, CY 2023 will be the first performance year, beginning January 1, 2023; and CY 2025 will be the first payment year. These HHAs would compete on value based on an array of quality measures that capture the services provided by HHAs. The savings impacts related to the HHVBP Model expansion are estimated at a total projected 5-year gross FFS savings, CYs 2023 through 2027, of \$3,376,000,000. The savings under the original Model are already assumed in the baseline and therefore are not included in the 5-year gross estimated savings under HHVBP Model expansion. As noted in section III.A.3.b. of the final rule, under the expanded duration and scope of this Model, we would continue to examine whether the adjustments to the Medicare payment amounts that would otherwise be made to competing HHAs would result in statistically significant improvements in the quality of care being delivered to Medicare beneficiaries, as well as reductions in Medicare spending.

3. HH QRP

Section 1895(b)(3)(B)(v) of the Act authorizes the HH QRP which requires HHAs to submit data in accordance with the requirements of the 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 an HHA for that calendar year by 2 percentage points.

Finalizing the removal of the Drug Education on All Medications Provided to Patient/Caregiver measure supports the CMS Meaningful measures framework by reducing where possible the burden on providers and clinicians. The addition of the Potentially Preventable Hospitalization measure, which is claims-based, to the HH QRP effective January 1, 2022 as a replacement of the Acute Care Hospitalization During the First 60 Days of Home

Health (NQF # 0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) beginning with the CY 2023 HH QRP addresses attribution issues identified and would capture observation stay which are currently not addressed with the existing measures. The public reporting of the Application of Percent of Residents Experiencing One or More Major Falls with Injury (NQF #0674) and The Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Function Assessment and a Care Plan That Addresses Function (NQF #2631) supports the requirements that the Secretary provide public reporting of PAC provider performance, including HHAs, on quality measures under section 1899B(c)(1) of the Act. Given the recent Executive order on “Advancing Racial Equity and Support for Underserved Communities throughout the Federal Government,”²²³ we proposed an earlier effective date for the adoption of the assessment instruments whereby HHAs would begin reporting on January 1, 2023 on items related to Social Determinants of Health.

a. Virtual Supervision of HHA Aides

In accordance with sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. In this rule, we are finalizing our proposed changes to make permanent selected regulatory blanket waivers related to home health aide supervision that we extended to Medicare participating home health agencies during the COVID-19 PHE.

b. Permitting Occupational Therapists to Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

Division CC, section 115 of CAA 2021 requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with

²²³ Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government | The White House

either physical therapy or speech therapy, and skilled nursing services are not initially on the plan of care. These conforming changes are being finalized in this regulation.

5. Medicare Coverage of 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. This payment system requires a single payment to 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. 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 percentage increase in the CPI-U for all urban consumers for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment. The unit of single payment 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, and the single payment amount cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Finally, Division N, section 101 of CAA 2021 amended section 1848(t)(1) of the Act and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payments only for CY 2021.

6. Medicare Provider and Supplier Enrollment Provisions

Our provisions concerning Medicare provider and supplier enrollment are needed to: (1) incorporate various subregulatory policies into 42 CFR part 424, subpart P, and (2) clarify several policy issues. We believe these provisions will increase transparency by allowing the provider community to furnish public comments on them while eliminating uncertainty regarding the scope and applicability of the provisions in question.

7. Survey and Enforcement Requirements for Hospice Providers

In accordance with section 407 of the CAA 2021, we are making conforming regulations which establish new hospice program survey and enforcement requirements. We believe these provisions not only meet the statutory requirements but will increase public transparency by encouraging a consistent survey and enforcement process and providing the public with information necessary to make an informed decision regarding where they seek high quality, safe care hospice program organizations for themselves or loved ones.

8. COVID-19 Reporting Requirements for Long Term Care Facilities

The COVID-19 PHE has precipitated the greatest health crises since the 1918 Influenza pandemic. Of the approximately 666,440 Americans estimated to have died from COVID-19 through September 2021,²²⁴ over one-third are estimated to have died during or after a nursing home stay.²²⁵ The development and large-scale utilization of vaccines to prevent COVID-19 cases have the potential to end future COVID-19 related nursing home deaths. In addition, continued reporting of COVID-19 data in LTC facilities, beyond the COVID-19 PHE, will have

²²⁴ https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.

²²⁵ <https://www.kff.org/coronavirus-covid-19/issue-brief/state-covid-19-data-and-policy-actions/>.

a significant positive impact by maintaining effective surveillance of this novel virus. This final rule finalizes the important reporting requirements that were issued in previous IFCs so that CMS can continue to respond to facilities in need of additional technical support and oversight, should they experience new COVID-19 infections.

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 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), and the Congressional Review Act (5 U.S.C. 801(a)(1)(B)(i)).

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.

Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is “economically significant” as measured by the \$100 million

threshold, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared, to the best of our ability, a final Regulatory Impact Analysis that presents the costs and benefits of the rulemaking.

C. Detailed Economic Analysis

1. Impacts for the HH PPS

This final rule updates Medicare payments under the HH PPS for CY 2022. The net transfer impact related to the changes in payments under the HH PPS for CY 2022 is estimated to be \$570 million (3.2 percent). The \$570 million increase in estimated payments for CY 2022 reflects the effects of the CY 2022 home health payment update percentage of 2.6 percent (\$465 million increase), an estimated 0.7 percent increase that reflects the effects of an updated FDL (\$125 million increase) and an estimated 0.1 percent decrease in payments due to the changes in the rural add-on percentages for CY 2022 (\$20 million decrease). We note that we inadvertently did not account for the impact of the proposed changes to the FDL in the CY 2022 HH PPS proposed rule (86 FR 35873). However, in this final rule we have included the payment effects of the new lower FDL in Table 41.

We use the latest data and analysis available. However, 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 home health benefit, based primarily on Medicare claims data for periods that began in CY 2020 and ended on or before December 31, 2020. 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 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 41 represents how HHA revenues are likely to be affected by the finalized policy changes for CY 2022. For this analysis, we used an analytic file with linked CY 2020 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2020. The first column of Table 41 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 recalibration of the case-Mix weights offset by the case-mix weights budget neutrality factor.

The fourth column shows the payment effects of updating to the CY 2022 wage index. The fifth column shows the payment effects of the CY 2022 rural add-on payment provision in statute. The sixth column shows the payment effects of the final CY 2022 home health payment update percentage. The seventh column shows the payment effects of the new lower FDL and the last column shows the combined effects of all the finalized provisions.

Overall, it is projected that aggregate payments in CY 2022 would increase by 3.2 percent which reflects the 2.6 payment update percentage increase, the 0.7 percent increase from lowering the FDL and the 0.1 percent decrease from the effects of the rural add-on policy. As illustrated in Table 41, 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 2022 wage index, the percentage of total HH PPS payments that were subject to the LUPA or paid as outlier payments, and the degree of Medicare utilization.

TABLE 41: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2022

	Number of Agencies	CY 2022 Case-mix Weights	CY 2022 Updated Wage Index	CY 2022 Rural Add-On	CY 2022 HH Payment Update Percentage	Fixed-Dollar Loss (FDL) Update	Total
All Agencies	9,490	0.0%	0.0%	-0.1%	2.6%	0.7%	3.2%
Facility Type and Control							
Free-Standing/Other Vol/NP	947	0.4%	-0.3%	-0.1%	2.6%	0.8%	3.4%
Free-Standing/Other Proprietary	7,680	-0.2%	0.0%	-0.1%	2.6%	0.6%	2.9%
Free-Standing/Other Government	180	0.7%	0.1%	-0.4%	2.6%	0.7%	3.7%
Facility-Based Vol/NP	483	0.5%	-0.1%	-0.2%	2.6%	1.0%	3.8%
Facility-Based Proprietary	48	0.3%	0.0%	-0.2%	2.6%	0.6%	3.3%
Facility-Based Government	152	0.4%	0.3%	-0.3%	2.6%	0.8%	3.8%
Subtotal: Freestanding	8,807	0.0%	0.0%	-0.1%	2.6%	0.6%	3.1%
Subtotal: Facility-based	683	0.5%	0.0%	-0.2%	2.6%	0.9%	3.8%
Subtotal: Vol/NP	1,430	0.4%	-0.3%	-0.1%	2.6%	0.8%	3.4%
Subtotal: Proprietary	7,728	-0.2%	0.0%	-0.1%	2.6%	0.6%	2.9%
Subtotal: Government	332	0.5%	0.2%	-0.3%	2.6%	0.8%	3.8%
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	224	0.3%	0.0%	-0.7%	2.6%	0.7%	2.9%
Free-Standing/Other Proprietary	808	-0.2%	0.1%	-0.3%	2.6%	0.4%	2.6%
Free-Standing/Other Government	122	0.8%	0.1%	-0.8%	2.6%	0.8%	3.5%
Facility-Based Vol/NP	213	0.6%	0.0%	-0.7%	2.6%	0.9%	3.4%
Facility-Based Proprietary	19	0.3%	-0.3%	-0.6%	2.6%	0.6%	2.6%
Facility-Based Government	113	0.4%	0.4%	-0.7%	2.6%	1.0%	3.7%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	723	0.4%	-0.3%	-0.1%	2.6%	0.8%	3.4%
Free-Standing/Other Proprietary	6,872	-0.1%	0.0%	0.0%	2.6%	0.6%	3.1%
Free-Standing/Other Government	58	0.6%	0.0%	-0.1%	2.6%	0.6%	3.7%
Facility-Based Vol/NP	270	0.5%	-0.1%	-0.1%	2.6%	1.0%	3.9%
Facility-Based Proprietary	29	0.3%	0.2%	-0.1%	2.6%	0.7%	3.7%
Facility-Based Government	39	0.4%	0.3%	0.0%	2.6%	0.7%	4.0%
Facility Location: Urban or Rural							
Rural	1,499	0.0%	0.1%	-0.4%	2.6%	0.5%	2.8%
Urban	7,991	0.0%	0.0%	0.0%	2.6%	0.7%	3.3%
Facility Location: Region of the Country (Census Region)							
New England	327	0.2%	-0.7%	-0.1%	2.6%	0.8%	2.8%
Mid Atlantic	433	0.7%	-0.6%	-0.1%	2.6%	0.7%	3.3%
East North Central	1,603	0.0%	-0.3%	-0.2%	2.6%	0.6%	2.7%
West North Central	622	0.3%	0.1%	-0.3%	2.6%	0.9%	3.6%
South Atlantic	1,552	0.2%	0.5%	-0.1%	2.6%	0.6%	3.8%
East South Central	370	-0.1%	-0.4%	-0.1%	2.6%	0.4%	2.4%
West South Central	2,224	-0.3%	-0.3%	0.0%	2.6%	0.6%	2.6%
Mountain	682	-0.1%	0.1%	-0.1%	2.6%	0.8%	3.3%
Pacific	1,634	-0.5%	0.4%	0.0%	2.6%	0.7%	3.2%
Outlying	43	0.8%	-1.4%	-0.4%	2.6%	0.6%	2.2%
Facility Size (Number of 30-day Periods)							
< 100 periods	1,984	0.3%	-0.1%	-0.1%	2.6%	0.9%	3.6%
100 to 249	1,508	0.0%	-0.1%	-0.1%	2.6%	0.8%	3.2%
250 to 499	1,709	-0.2%	0.0%	-0.1%	2.6%	0.7%	3.0%
500 to 999	1,928	-0.2%	0.0%	-0.1%	2.6%	0.7%	3.0%
1,000 or More	2,361	0.1%	0.0%	-0.1%	2.6%	0.6%	3.2%

Source: CY 2020 Medicare claims data for periods with matched OASIS records (only) starting and ending in CY2020 (as of July 12, 2021).

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
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

2. Impacts for the Expanded HHVBP Model

Based on finalized policies discussed in section III.A. of this final rule, Tables 43 and 44 display our analysis of the distribution of possible payment adjustments using 2019 data as the performance year, while Table 42 provides information on the estimated impact of this finalized expansion. We note that this impact analysis is based on the aggregate value of savings associated with all Medicare-certified HHAs in each State, territory, and the District of Columbia.

Table 43 shows the value-based incentive payment adjustments for the estimated 7,500-plus HHAs that would qualify to compete in the HHVBP Model expansion based on the CY 2019 data stratified by size, as defined in section III.F. of the final rule. For example, Table 43 shows California has 69 HHAs that do not provide services to at least 60 unique beneficiaries in the prior calendar year, and therefore, would be considered to be in the smaller-volume cohort under the Model expansion. Using 2019 performance year data and the finalized payment adjustment of 5-percent, based on 8 outcome measures, the smaller-volume HHAs in California would have a mean payment adjustment of positive 0.042 percent. Only 10-percent of home health agencies would be subject to downward payment adjustments of more than minus 3.139 percent (-3.139 percent). The next columns provide the distribution of scores by percentile. We see that the value-based incentive percentage payments for smaller-volume home health agencies in California range from -3.139 percent at the 10th percentile to +3.899 percent at the 90th percentile, while the value-based incentive payment at the 50th percentile is -0.607 percent. The smaller-volume HHA cohort table identifies that some locations do not have any qualifying HHAs in the smaller-volume cohort, including Connecticut, the District of Columbia, and Delaware.

It was brought to our attention after the close of the comment period for the proposed rule that the larger-volume cohort section of Table 43: HHA Cohort Payment Adjustment Distributions as presented in the proposed rule (86 FR 35994 and 35995) inadvertently ended with the entry for the state of Montana (MT). In this final rule, we are presenting Table 43 from the proposed rule in its entirety, along with the other impact tables included in the proposed rule.

Table 43 provides the payment adjustment distribution based on proportion of dual eligible beneficiaries, average case mix (using HCC scores), proportion that reside in rural areas, as well as HHA organizational status. To define cutoffs for the “percentage of dual eligible beneficiaries,” low, medium, or high percentage dual-eligible are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of percent dual eligible beneficiaries, respectively, across HHAs in CY 2019. To define case mix cutoffs, low, medium, or high acuity are also based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2019. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries’ core-based statistical area (CBSA) urban versus rural designation. We would note that, based on 2019 data, a higher proportion of dually-eligible beneficiaries served is associated with better performance.

TABLE 42. ESTIMATED GROSS FFS SAVINGS UNDER EXPANDED HHVBP MODEL CYs 2023-2027

CY 2023	CY 2024	CY 2025	CY 2026	CY 2027
\$373,000,000	\$715,000,000	\$713,000,000	\$761,000,000	\$814,000,000

**TABLE 43: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS
(Based on a maximum 5 percent payment adjustment)**

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)
AL	1	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601
AR	2	0.794	(2.454)	(2.454)	(2.454)	(2.454)	0.794	4.041	4.041	4.041	4.041
AZ	2	0.710	(2.446)	(2.446)	(2.446)	(2.446)	0.710	3.866	3.866	3.866	3.866
CA	69	0.042	(3.139)	(2.503)	(1.748)	(1.495)	(0.607)	0.878	1.586	2.605	3.899

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
CO	4	0.127	(2.367)	(2.367)	0.445	0.445	0.572	0.698	0.698	1.733	1.733
CT	0										
DC	0										
DE	0										
FL	51	0.756	(3.080)	(1.928)	(1.016)	(0.014)	0.612	1.482	3.336	3.935	5.000
GA	0										
GU	0										
HI	0										
IA	7	(0.840)	(2.816)	(1.831)	(1.641)	(1.641)	(1.422)	(1.096)	(1.096)	(0.082)	3.009
ID	1	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)
IL	61	0.652	(3.275)	(2.451)	(1.614)	(0.772)	1.170	1.856	2.794	3.627	5.000
IN	11	0.596	(2.821)	(1.241)	(0.390)	0.683	0.729	1.028	1.367	2.944	3.059
KS	4	0.321	(3.256)	(3.256)	(1.255)	(1.255)	0.031	1.317	1.317	4.476	4.476
KY	0										
LA	0										
MA	5	(0.709)	(4.469)	(4.107)	(3.744)	(2.321)	(0.898)	0.489	1.876	2.784	3.692
MD	2	0.345	(2.576)	(2.576)	(2.576)	(2.576)	0.345	3.265	3.265	3.265	3.265
ME	1	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)
MI	52	0.896	(2.662)	(2.081)	(0.494)	0.397	1.011	1.790	2.787	3.255	4.814
MN	7	(2.227)	(4.577)	(4.453)	(3.677)	(3.677)	(3.244)	(0.514)	(0.514)	(0.480)	1.359
MO	7	(1.996)	(4.370)	(3.431)	(3.223)	(3.223)	(2.419)	(2.106)	(2.106)	0.176	1.399
MP	0										
MS	0										
MT	2	2.049	(0.847)	(0.847)	(0.847)	(0.847)	2.049	4.944	4.944	4.944	4.944
NC	4	(0.681)	(2.371)	(2.371)	(1.204)	(1.204)	(0.473)	0.259	0.259	0.592	0.592
ND	0										
NE	8	(0.751)	(4.403)	(3.062)	(2.029)	(0.282)	(0.165)	(0.047)	0.750	1.211	1.851
NH	1	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)
NJ	0										
NM	3	0.394	(1.562)	(1.562)	(1.562)	(0.746)	(0.746)	(0.746)	3.490	3.490	3.490
NV	8	(0.691)	(3.671)	(3.033)	(1.997)	(1.029)	(0.905)	(0.780)	(0.181)	0.164	5.000
NY	0										
OH	8	(2.409)	(4.307)	(4.178)	(3.890)	(3.739)	(3.618)	(3.497)	(1.041)	(0.905)	2.286
OK	8	(2.008)	(4.351)	(3.004)	(2.942)	(2.347)	(2.068)	(1.788)	(1.747)	0.042	0.076
OR	1	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)
PA	9	(1.965)	(4.263)	(4.023)	(3.537)	(3.056)	(2.969)	(1.039)	(0.725)	0.543	1.385
PR	0										
RI	0										
SC	0										
SD	4	(1.081)	(3.754)	(3.754)	(2.073)	(2.073)	(1.170)	(0.267)	(0.267)	1.770	1.770
TN	1	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)
TX	85	(0.727)	(4.121)	(3.224)	(2.548)	(1.714)	(0.565)	0.303	0.875	1.215	2.576
UT	6	0.244	(1.724)	(1.517)	(1.517)	(0.461)	(0.115)	0.231	1.618	1.618	3.319
VA	5	0.794	(4.066)	(1.925)	0.216	0.860	1.504	1.864	2.223	3.158	4.093
VI	0										
VT	0										
WA	0										
WI	0										
WV	0										
WY	2	(1.247)	(2.474)	(2.474)	(2.474)	(2.474)	(1.247)	(0.020)	(0.020)	(0.020)	(0.020)
All	443	(0.079)	(3.677)	(2.703)	(1.967)	(1.141)	(0.267)	0.635	1.413	2.621	3.975

Larger-volume Cohort

State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	12	(0.627)	(3.202)	(2.588)	(2.199)	(1.448)	(1.007)	(0.774)	1.275	1.423	1.897
AL	114	1.632	(1.583)	(0.520)	0.510	1.110	1.856	2.392	3.058	3.833	4.653
AR	90	1.114	(1.830)	(1.158)	(0.185)	0.854	1.403	2.060	2.643	3.090	4.097
AZ	106	0.441	(2.830)	(2.073)	(1.522)	(0.188)	0.547	1.077	1.774	2.880	4.504
CA	991	0.799	(2.856)	(1.930)	(1.130)	(0.306)	0.381	1.528	2.710	4.200	5.000
CO	104	0.059	(3.260)	(2.293)	(1.588)	(0.912)	(0.219)	0.392	1.246	1.946	4.482
CT	74	(0.829)	(3.321)	(2.908)	(2.511)	(1.846)	(1.481)	(0.390)	0.059	1.206	2.448
DC	7	(0.428)	(3.672)	(2.455)	(1.306)	(1.306)	(0.938)	0.289	0.289	0.767	4.319
DE	12	0.141	(2.604)	(1.897)	(1.874)	(1.282)	(0.076)	0.965	1.626	2.274	2.798
FL	676	0.933	(2.436)	(1.416)	(0.655)	0.139	0.760	1.471	2.448	3.530	5.000
GA	99	(0.021)	(2.516)	(1.652)	(1.037)	(0.654)	(0.186)	0.435	0.966	1.653	2.274
GU	3	(1.612)	(1.897)	(1.897)	(1.897)	(1.703)	(1.703)	(1.703)	(1.236)	(1.236)	(1.236)
HI	14	0.760	(2.334)	(2.053)	(0.805)	0.284	1.318	1.711	2.149	2.998	4.064
IA	94	0.344	(2.920)	(2.173)	(1.254)	(0.604)	0.638	1.208	1.865	2.880	3.762
ID	42	0.245	(2.673)	(2.309)	(0.645)	(0.236)	0.028	0.865	1.383	2.297	3.059
IL	398	0.407	(2.854)	(2.065)	(1.441)	(0.656)	(0.008)	0.823	1.873	3.137	5.000
IN	138	(0.149)	(3.068)	(2.166)	(1.455)	(0.890)	(0.452)	0.226	0.991	1.629	3.179
KS	84	0.252	(3.170)	(1.706)	(1.103)	(0.348)	0.131	0.675	1.328	2.425	3.665
KY	90	0.990	(2.331)	(0.892)	(0.404)	0.332	0.781	1.381	2.258	3.365	4.290
LA	167	1.333	(1.902)	(0.762)	0.078	0.597	1.367	2.234	2.865	3.746	4.840
MA	127	(0.162)	(2.991)	(2.207)	(1.508)	(0.943)	(0.091)	0.356	0.752	1.582	2.980
MD	49	0.823	(1.649)	(1.207)	(0.831)	(0.260)	0.298	1.769	2.378	2.867	4.019
ME	19	1.081	(1.718)	(0.501)	0.039	0.505	0.704	0.917	2.069	2.862	4.562
MI	322	0.802	(2.660)	(1.818)	(1.197)	(0.270)	0.657	1.634	2.672	3.671	5.000
MN	97	(0.799)	(3.469)	(2.791)	(2.154)	(1.559)	(1.130)	(0.629)	(0.127)	1.111	2.747
MO	122	0.512	(2.814)	(2.014)	(1.458)	(0.482)	0.222	1.345	2.042	3.280	4.334
MP	1	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)
MS	45	1.325	(1.351)	(0.689)	(0.102)	0.776	1.448	2.121	2.718	3.370	4.414
MT	22	(0.839)	(3.220)	(2.745)	(1.807)	(1.760)	(1.373)	(0.874)	(0.009)	0.957	1.328
NC	152	0.616	(2.257)	(1.285)	(0.666)	(0.012)	0.448	1.006	1.614	2.613	3.762
ND	12	2.004	0.142	0.465	1.497	1.589	2.186	2.644	3.232	3.503	4.315
NE	40	0.279	(3.014)	(2.221)	(1.674)	(0.356)	0.114	0.780	1.370	2.965	4.103
NH	20	(0.376)	(3.127)	(2.041)	(1.361)	(0.813)	(0.189)	(0.036)	0.814	1.494	2.083
NJ	42	(0.730)	(2.343)	(1.931)	(1.734)	(1.582)	(1.311)	(0.870)	(0.178)	0.656	1.208
NM	58	(0.460)	(3.833)	(2.687)	(1.863)	(1.169)	(0.568)	0.110	0.623	1.249	3.225
NV	96	(0.189)	(3.176)	(2.313)	(1.590)	(1.193)	(0.486)	0.155	0.815	1.849	3.523
NY	104	(0.462)	(2.848)	(2.342)	(1.803)	(1.221)	(0.854)	(0.111)	0.481	1.287	2.364
OH	286	(0.139)	(3.402)	(2.490)	(1.704)	(1.166)	(0.423)	0.303	1.166	2.347	3.416
OK	183	0.335	(2.631)	(1.817)	(1.009)	(0.395)	0.237	0.889	1.567	2.451	3.611
OR	43	(0.310)	(3.107)	(1.910)	(1.480)	(0.975)	(0.349)	(0.075)	0.702	1.413	2.627
PA	228	0.280	(2.600)	(1.832)	(1.167)	(0.706)	0.010	0.712	1.460	2.573	3.769
PR	31	(0.018)	(3.553)	(2.449)	(1.745)	(1.616)	(0.124)	0.358	1.822	3.215	3.871
RI	18	0.504	(2.851)	(1.925)	(0.527)	(0.256)	0.663	1.176	1.496	1.658	4.907
SC	63	0.572	(1.607)	(0.821)	(0.586)	(0.066)	0.608	1.248	1.692	2.047	2.317
SD	19	0.574	(2.095)	(1.940)	(1.215)	0.354	0.796	1.388	1.543	2.167	4.535
TN	112	1.031	(2.095)	(0.708)	(0.149)	0.553	0.900	1.633	2.061	2.929	3.796
TX	978	0.154	(3.261)	(2.350)	(1.577)	(0.914)	(0.090)	0.826	1.758	2.732	4.087
UT	68	0.892	(2.072)	(1.279)	(0.552)	0.067	0.392	0.989	1.910	3.410	4.416
VA	186	(0.030)	(3.072)	(2.361)	(1.144)	(0.606)	0.029	0.517	0.968	1.630	3.062
VI	1	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)	(1.511)
VT	10	(1.145)	(3.557)	(2.771)	(2.155)	(1.759)	(1.555)	(1.435)	(1.006)	0.310	2.546
WA	56	(0.248)	(2.946)	(1.795)	(1.467)	(1.001)	(0.352)	0.096	0.937	1.367	2.383
WI	73	0.204	(2.398)	(1.908)	(1.361)	(0.520)	0.353	0.754	1.281	2.179	3.032
WV	50	1.274	(1.393)	(0.795)	0.261	0.711	1.090	1.718	2.131	3.175	4.930
WY	16	(0.500)	(3.502)	(2.228)	(1.931)	(0.548)	(0.506)	(0.225)	0.690	0.777	2.007

Larger-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
All	7,064	0.429	(2.812)	(1.919)	(1.219)	(0.502)	0.244	0.969	1.787	2.857	4.414

TABLE 44: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS
(Based on a maximum 5 percent payment adjustment)

Percentage of Dually-eligible Beneficiaries	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
Low % dually-eligible	2,061	0.464	(2.592)	(1.656)	(0.970)	(0.313)	0.295	0.991	1.658	2.618	3.889
Medium % dually-eligible	4,118	0.153	(2.962)	(2.134)	(1.447)	(0.774)	(0.051)	0.662	1.446	2.425	3.832
High % dually-eligible	1,316	1.066	(3.145)	(1.943)	(1.043)	0.200	1.059	2.226	3.327	4.710	5.000
Acuity (HCC)	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
Low acuity	1,479	1.283	(2.545)	(1.426)	(0.457)	0.435	1.275	2.276	3.265	4.451	5.000
Middle acuity	4,290	0.320	(2.756)	(1.905)	(1.247)	(0.560)	0.187	0.851	1.604	2.601	3.913
High acuity	1,726	(0.162)	(3.283)	(2.446)	(1.753)	(1.143)	(0.460)	0.255	1.081	2.104	3.545
% Rural Beneficiaries	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
All non-rural	3,849	0.483	(2.969)	(2.046)	(1.318)	(0.552)	0.266	1.099	2.020	3.249	5.000
Up to 50% rural	2,265	0.024	(2.873)	(2.089)	(1.438)	(0.822)	(0.140)	0.469	1.200	2.108	3.323
Over 50% rural	1,368	0.783	(2.408)	(1.539)	(0.672)	0.066	0.819	1.390	2.214	3.121	4.414
Organizational Type	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
Religious affiliation	289	0.085	(2.658)	(1.807)	(1.294)	(0.794)	(0.252)	0.465	1.123	2.062	3.232
Private not-for-profit	579	(0.010)	(2.961)	(2.053)	(1.432)	(0.891)	(0.262)	0.422	1.098	2.055	3.562
Other not-for-profit	478	0.230	(2.618)	(1.812)	(1.144)	(0.470)	0.160	0.752	1.314	2.296	3.280
Private for-profit	5,869	0.459	(2.913)	(1.997)	(1.271)	(0.500)	0.278	1.044	1.918	3.039	4.677
State	186	0.548	(3.244)	(1.790)	(0.699)	(0.225)	0.441	1.317	2.151	3.047	4.263
Gov't & voluntary	10	1.059	(0.356)	(0.171)	0.073	0.322	0.879	1.395	1.565	1.618	3.134
Local	96	0.583	(2.604)	(1.584)	(0.797)	(0.102)	0.507	1.361	1.834	2.749	3.799

Note: The total number of HHAs differ by category due to missing HHAs in some data sources.

3. Impacts for the HH QRP for CY 2022

Estimated impacts for the HH QRP for CY 2022 are based on analysis discussed in section XI.B. of this final rule. Finalizing the HH QRP requirements reduces burden to the active collection under OMB control number #0938-1279 (CMS-10545; expiration 12/31/21).

Failure to submit HH QRP 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 an HHA for that calendar year by 2 percentage points. For the CY 2021, representing HH QRP data collected from July 1, 2019 to June 30, 2020, by HHAs, 527 of the 11,196 active Medicare-certified HHAs, or approximately 4.7 percent, did not receive the full annual percentage increase (the methodology accommodated the COVID-19 PHE exception). These 527 HHAs represented \$253 million in home health claims payment dollars during the reporting period out of a total \$16.7B for all HHAs.

As discussed in section IV.C. of this final rule, we are finalizing the removal of one OASIS-based measure beginning with the CY 2023 HH QRP. The assessment-based measure we are removing is: (1) Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care. We also are replacing the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization measure beginning with the CY 2023 HH QRP under our measure removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available. Because these three measures are claims-based, there would be no impact to our collection of information.

Section XI.B. of this final rule provides a detailed description of the net decrease in burden associated with these proposed changes. The associated burden is for CY 2023 because HHAs would submit HH QRP data beginning CY 2023. The cost impact related to OASIS item collection as a result of the changes to the HH QRP is estimated to be a net decrease of \$2,762,277 in annualized cost to HHAs, discounted at 7 percent relative to year 2020, over a perpetual time horizon beginning in CY 2023.

We described the estimated burden and cost reductions for these measures in section XI.B. of this final rule.

In summary, the HH QRP measure removals results in a burden reduction of \$242 per HHA annually, or \$2,762,277 for all HHAs annually. We have described the burden costs savings in Table 45:

TABLE 45: BURDEN SAVINGS CALCULATIONS

Time Point	Costs with 2020 data	Removal of M2016	Estimate Cost
Transfer of Care	\$4,969,755.73	\$4,259,790.63	\$709,965
Discharge from agency	\$230,885,202.34	\$228,832,890.59	\$2,052,312
			2,762,277
TOTAL			\$242 per HHA (2,762,277/11,400)

We did not receive comments on the outlined burden estimates for the HH QRP proposals.

4. Changes to the Home Health CoPs

a. Virtual Supervision of HHA Aides

In section IV.D. we are finalizing the 14-day aide supervisory visit at § 484.80(h)(1) with modification. We will permit the one virtual supervisory visit per patient per 60-day episode. This visit must only be permitted only in rare instances for circumstances outside the HHA’s control and must include notations in the medical record detailing the circumstances. We are finalizing the supervisory visit requirements for non-skilled patients with modification. We are modifying the proposed semi-annual onsite visit to require that this visit be conducted on “each” patient the aide is providing services to rather than “a” patient. Lastly, we are finalizing the assessment of deficient skills as proposed. We believe the burden associated with addressing skills related to those identified as deficient skills is minimal. Moreover, supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and State and Federal compliance purposes constitutes a usual and customary business practice. Therefore, the regulatory impact is negligible.

b. Permitting Occupational Therapists to Conduct the Initial Assessment Visit and Complete the

Comprehensive Assessment for Home Health Agencies Under the Medicare Program

In accordance with Division CC, section 115 of CAA 2021, we finalizing conforming regulations text changes to permit the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are also not ordered. We do not expect any increase in burden for any of these modifications. In fact, for home health agencies, this may facilitate efficiencies by expanding the type of therapy discipline able to complete the initial and comprehensive assessments, in some circumstances, for Medicare patients. We do not expect the changes for these provisions would cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

5. Impact of the CY 2022 Payment for Home Infusion Therapy Services

We are finalizing two provisions in this final rule related to payments for home infusion therapy services in CY 2022: the proposal to maintain the CY 2021 percentages for the initial subsequent policy and the proposal to wage adjust home infusion therapy service payments using the CY 2022 GAFs. The provision to maintain the percentages for the initial subsequent policy as well as the provision to use the CY 2022 GAFs to wage adjust home infusion therapy service payments are both implemented in a budget neutral manner, therefore, there is no estimated impact on payments to HIT suppliers due to these policies. As noted previously, Division N, section 101 of CAA 2021 amended added section 1848(t)(1) of the Act, which applied and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payment amounts only for CY 2021.²²⁶ For CY 2022, we will remove the 3.75 percent increase from the PFS amounts used to establish the CY 2021 home infusion therapy payment rates and use the unadjusted CY 2021 rates for the CY 2022 home infusion therapy services payment amounts.

²²⁶ Medicare Learning Network Connects “Special Edition: Physician Fee Schedule Update” (January 7, 2021). <https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf>.

The unadjusted CY 2021 rates will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the 5.4 percentage increase in the CPI-U for the 12-month period ending in June of 2021 reduced by the productivity adjustment of 0.3 percentage point, which results in a 5.1 percent increase (\$300,000) to HIT suppliers for CY 2022.

6. Medicare Provider and Supplier Enrollment Provisions

a. General Impact

Similar to our position regarding information collection requirements, and except as discussed in section XI.C.6.b. of this final rule, we did not anticipate any costs, savings, or transfers associated with our proposed provider and supplier enrollment provisions. Most of these provisions have been in sub-regulatory guidance for a number of years, and we are merely incorporating them into regulation; those provisions that are not in subregulatory guidance do not involve any costs, savings, or transfers.

b. Deactivation of Billing Privileges – Payment Prohibition

As explained in section VI.B. of the proposed rule, we proposed in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). Existing sub-regulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation of the provider's or supplier's billing privileges. Our proposal would reverse this policy for the reasons stated in section VI.B. of the proposed rule.

Although the figure varies widely by individual provider or supplier, internal CMS data suggests that the average provider/supplier impacted by the aforementioned proposal receives roughly \$50,000 in Medicare payments each year. (We used a similar \$50,000 annual payment estimate for our provider enrollment provisions in a CMS final rule published in the **Federal Register** on November 15, 2019 titled, “CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies” (84 FR 62568).) As with annual payment amounts, the number of deactivations vary per year. Nonetheless, and

again based on internal CMS data, we estimate 13,000 deactivations annually. This results in an approximate burden of \$54,145,000 per year (13,000 x 50,000 x 0.0833). (The 0.0833 figure represents 30 days, or 1/12 of a year.) The following table reflects the estimated transfers associated with our proposed addition of new § 424.540(e) concerning payments for services and items furnished by deactivated providers and suppliers:

PROHIBITION OF PAYMENT FOR SERVICES OR ITEMS FURNISHED BY DEACTIVATED PROVIDERS AND SUPPLIERS FROM CY 2021 TO 2022	
Providers/Suppliers to Federal Government	\$54.1 million

We did not receive comments on this estimate and are therefore finalizing it as proposed and without modification.

7. Survey and Enforcement Requirements for Hospice Providers

Estimated impacts for the Survey and Certification Requirements for Hospice Program Providers are based on analysis discussed in section VII. of the proposed rule.

a. Application and Re-application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require AOs with CMS-approved hospice programs to include a statement of deficiencies, (that is, the Form CMS-2567 or a successor form) to document survey findings of the hospice Medicare CoPs and to submit such in a manner specified by CMS. This implements new section 1822(a)(2)(A)(ii) of the Act. We anticipate effects on AO administrative expenses but are not able to provide an accurate estimate of how much cost and time will result from including the Form CMS-2567 into their proprietary IT systems and subsequently submitting the information to CMS. Currently, there are three AOs with CMS-approved hospice programs affected by this proposal. We sought comments that would help us to develop an accurate estimate of the cost and time burden that would result from this collection of information.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

b. Release and Use of Accreditation Surveys (§ 488.7)

CAA 2021 adds section 1822(a)(2)(B) of the Act which requires that CMS publish hospice survey information from the Form CMS-2567 in a way that is readily understandable and useable by the public in a meaningful way. We anticipate the need for CMS to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices' performance. CMS recognizes that the implications of releasing national survey data will require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

c. Hospice Hotline (§ 488.1110)

Section 1864(a) of the Act was amended by inserting “hospice programs” after information on the home health toll-free hotline. The infrastructure for a State or local agency toll-free hotline is already in place for HHAs to collect and maintain complaint information related to HHAs. The requirement allows the existing hotline to collect complaint information on hospices. We do not expect the changes for this provision will cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

We proposed at § 488.1115, to require AO hospice program surveyors to complete the CMS hospice basic training currently available online. We have removed the proposed burden estimates for the surveyor qualifications because we do not expect any increase in burden for this provision. In fact, for AOs with hospice programs, this may facilitate efficiencies by removing the need for AOs to develop and maintain their own training courses based on the CMS

regulations and process. Therefore, the regulatory impact (including benefits of such provisions) is negligible. Additionally, we did not receive comments on the estimated impact.

We also proposed to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with new section 1822(a)(4)(B) of the Act. We do not expect these changes would cause any appreciable amount of expense or anticipated saving because the provisions codify longstanding policies and basic principles to ensure there is no conflict of interest between organizations and surveyors.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

e. Survey Teams (§ 488.1120)

We proposed at § 488.1120 that when the survey team comprises more than one surveyor, the additional slots would be filled by multidisciplinary professionals such as physicians, nurses, medical social workers, pastoral or other counselors—bereavement, nutritional, and spiritual. At this time, we do not have specific information related to current survey team compositions but we do know there are approximately 977 hospice surveys per year, with at least one member of the survey team being a registered nurse. The proposed inclusion of multidisciplinary survey team members could potentially increase the overall cost of surveys if SA and AOs were not already using a mixed team.

The 2020 Bureau of Labor Statistics estimates RN adjusted hourly wages at \$76.94 (including fringe benefits and overhead). Other potential disciplines fall below and above the RN adjusted hourly wage, for example: social workers-\$50.12 per hour, pharmacists-\$120.64 per hour, and psychologists-\$108.36 per hour. A survey team of all nurses (assuming a two-person team) costs \$153.88 ($\76.94×2) per hour. However, CMS believes the most common multidisciplinary team for hospice program surveys may include a nurse and a social worker. Using this assumption, we calculate it will cost \$127.06 ($\$76.94 + \50.12) per hour for this multidisciplinary 2-person survey team composition. Therefore, a two-person multidisciplinary

team at \$127.06 per hour, assuming a 5-day survey (8 hours per day X 5 days = 40 hours), would cost \$5,082.40 per survey, times 960 surveys per year, or \$4,879,104 per year. We sought comments on the current professional makeup of the AO and SA survey teams, and providers' estimates of the time needed to effectuate multidisciplinary teams where they do not currently exist.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

f. Consistency of Survey Results (§ 488.1125)

Actions to improve consistency of survey results are discussed elsewhere in terms of implementing the use of the Form CMS-2567 across surveying entities and utilizing a common training platform. We do not anticipate additional costs or burdens to surveying entities. Some cost will be incurred by CMS to develop the system (technical and personnel) to analyze and apply correction where needed.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification.

g. Enforcement Remedies (§§ 488.1200 through § 488.1265)

We proposed enforcement remedies for hospices consistent with the established alternative sanctions for HHAs. In CY 2019, out of 11,738 deemed and non-deemed HHAs enrolled in the Medicare program, 749 HHA providers had the potential to be sanctioned based on repeat deficiencies during two consecutive standard or complaint surveys. This was approximately 15 percent of the HHAs, which is less than 37.5 percent of the total HHAs surveyed. Of all the alternative sanctions available for implementation, very few HHA enforcement actions were imposed. In CY 2019, less than 10 percent of all HHAs with surveys identifying an immediate jeopardy level deficiency citation received an alternative sanction.

The probability of impact for alternative enforcement remedies imposed against hospices is based on CY 2019 data for 5,065 deemed and non-deemed hospices enrolled in the Medicare program. These data were examined using the survey data for the CY 2019 in the CMS QCOR system. Of the total number of CMS-certified hospices, 4,399 received an unannounced standard and/or complaint survey and 236 were cited for noncompliance with one or more condition-level deficiencies. Therefore, approximately 5 percent of the total hospices surveyed had the potential to receive an enforcement remedy based on noncompliance with one or more CoPs.

The enforcement remedy provisions in this proposed rule mirror the alternative sanctions used in HHAs that have already been incorporated into CMS policy. Therefore, in terms of the administrative expenses to design and manage these types of remedies, the infrastructure is already in place. In terms of training for Federal and State surveyors, it is common for surveyors that survey HHAs to be cross-trained to survey hospices. Since the enforcement remedies for hospice are similar to those for HHAs, we expect that there will be a minimal burden on seasoned surveyors to become familiar with these provisions. Additionally, the data analysis described previously for hospices in CY 2019 reflects the probability of a low impact for civil monetary penalties to be imposed on hospice providers.

We did not receive comments on this estimated impact and therefore are finalizing this section without modification. However, we have removed the SFP regulatory impact analysis because we are not finalizing the SFP in this rule.

8. Certain Compliance Date Changes for the IRF QRP and LTCH QRP

a. Impacts for the Inpatient Rehabilitation Facility Quality Reporting Program for FY 2023

This final rule does not impose any new information collection requirements under the IRF QRP. However, this final rule does reference associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of this information collection, which have already received OMB approval.

In accordance with section 1886(j)(7)(A) of the Act, the Secretary must reduce by 2 percentage points the annual market basket increase factor otherwise applicable to an IRF for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. As stated in section VIII.A. of the proposed rule, for purposes of calculating the FY 2023 Annual Increase Factor (AIF), we proposed that IRFs would begin collecting data on the TOH Information to Provider-PAC and the TOH Information to Patient-PAC measures beginning with admissions and discharges on October 1, 2022. We also proposed that IRFs would begin collecting data on certain Standardized Patient Assessment Data Elements, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022. If finalized as proposed, IRFs would use the IRF-PAI V4.0 to submit IRF QRP data.

We are finalizing the proposed IRF QRP requirements, which do not add additional burden or cost to the active collection under OMB control number 0938-0842 (expiration 12/31/2022).

b. Impacts for the Long-Term Care Hospital Quality Reporting Program for FY 2023

This proposed provision does not impose any new information collection requirements under the LTCH QRP. However, this proposed provision does reference associated information collections that are not discussed in the regulation text of the proposed or this final rule. The following is a discussion of this information collection discussed in section XI. of the proposed rule, which have already received OMB approval.

In accordance with section 1886(m)(5) of the Act, the Secretary must reduce by 2 percentage points the annual market basket payment update otherwise applicable to a LTCH for a fiscal year if the LTCH does not comply with the requirements of the LTCH QRP for that fiscal year. As stated in section VIII.B. of the proposed rule for purposes of calculating the FY 2023 Annual Payment Update (APU), we proposed that LTCHs would begin collecting data on the TOH Information to Provider-PAC and the TOH Information to Patient-PAC measures beginning with admissions and discharges on October 1, 2022. We also proposed that LTCHs

would begin to collect data on certain Standardized Patient Assessment Data Elements, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022. If finalized as proposed, LTCHs would use the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) V5.0 to submit LTCH QRP data.

The proposed LTCH QRP requirements would add no additional burden or cost to the active collection under OMB control number 0938-1163 (expiration 12/31/2022).

9. COVID-19 Reporting Requirements for Long Term Care Facilities

a. Anticipated Cost

Section 483.80(g) sets forth the requirements for COVID-19 reporting for LTC facilities. Currently, §483.80(g)(1) states that LTC facilities must electronically report information about COVID-19 in a standardized format specified by the Secretary. Specific pieces of information that must be reported are set forth in that subsection. One of the information requirements is “the COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events”.

This final rule requires LTC facilities to continue to report certain information required by CDC’s NHSN. However, this change will provide flexibility if there are future changes to the information NHSN requires to be reported. In addition, we are revising paragraph (g)(1) to include a sunset, or expiration date, of December 31, 2024, for all of the required information in paragraph (g)(1), except for the information set out at (g)(1)(viii) that covers that COVID-19 vaccine status of residents and staff. In §483.80(g)(2), we are removing the “less” after “no” and inserting “more” so that the required frequency of reporting is no more than weekly instead of no less than weekly.

For the estimated costs contained in the analysis below, we used data from the United States Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions

used in this analysis.²²⁷ For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in .50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in the chart below.

TABLE 46 - SUMMARY TABLE FOR LTC FACILITY POSITIONS

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage (\$/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) (\$/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	LTC Medical Director	\$85.70	\$171
29-1141	Registered Nurses (Nursing Facilities/ Skilled Nursing Facilities)	LTC Infection Preventionist (IP);	\$34.66	\$69
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	LTC Director of Nursing (DON); LTC Administrator	\$48.15	\$96

As determined in the COI section, the burden for ICR requirements for this rule would be 15,401 hours (1 x 15,401) at an estimated cost of \$1,062,669 (15,401 x \$69). In addition to the ICR requirements, there would be addition requirements for the IP to report on these changes in policies and procedures to the medical director, director of nursing (DON), and an administrator. We believe this would require an addition 10 minutes or 0.1666 hours for the IP, medical director, DON, and administrator. According to Table 1 above, the medical director earns an adjusted hourly wage of \$171. Thus, the burden for the medical director would be 0.1666 hours at an estimated cost of \$28.50 (0.1666 x \$171). The adjusted hourly wage for both the DON and administrator is \$96. Thus, the burden for each of them would be 0.1666 hours at an estimated cost of \$16 (0.1666 x \$96) and for both it would be 0.3332 hours at an estimated cost of \$32.

²²⁷ BLS. May 2020 National Occupational Employment and Wage Estimates United States. United States Department of Labor. Accessed at https://www.bls.gov/oes/current/oes_nat.htm. Accessed on August 25, 2021.

The adjust hourly wage for the IP is \$69. The burden for the IP would be 0.1666 hours at an estimated cost of \$11.50 (0.1666 x \$69). Thus, the burden for each LTC facility would be 0.67 hour or about 40 minutes (0.1666 x 4) at an estimated cost of \$ 72 (\$28.50 + \$16 + \$16 + \$11.50). For all 15,401 LTC facilities the total burden would be 10,319 hours (0.67 x 15,401) at an estimated cost of \$1,108,872 (15,401 x \$72).

Thus, the total burden for the requirements in this rule is 25,720 hours (15,401 + 10,319) at an estimated cost of \$2,171,541 (\$1,062,669 + \$1,108,872).

b. Anticipated Benefits

These changes will provide LTC facilities will more flexibility and eliminate unnecessary burden on these facilities by revising the requirements for the reporting frequency to no more than weekly, with the possibility of reduced reporting at the discretion of the Secretary and the data reporting elements may be changed in the future. The reporting requirements, with the exception of the requirements at § 483.80 (g)(1)(viii), will end on December 31, 2024. We did not receive comments on this proposal and therefore are finalizing this provision without modification.

D. Limitations of Our Analysis

Our estimates of the effects of this final rule are subject to significant uncertainty. It is difficult to estimate the burden and savings from the proposed changes that are being finalized in this rule because they depend on several factors previously described. We appreciate that our assumptions are simplified and that actual results could be considerably higher or lower.

Although there is uncertainty concerning the magnitude of all of our estimates, we do not have the data to provide specific estimates for each proposal, as to the range of possibilities, or to estimate all categories of possible benefits. We sought comments on all aspects of this analysis.

E. 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 final rule would be similar to the number of reviewers on this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed 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 also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. While we solicited comments on the approach in estimating the number of entities which would review the proposed rule and the assumption of how much of the rule reviewers would read, we did not receive any comments.

Therefore, 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 \$114.24 per hour, including overhead and fringe benefits ([https:// www.bls.gov/oes/current/oes_nat.htm](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 5.73 hours for the staff to review half of this final rule, which consists of approximately 171,832 words. For each HHA that reviews the rule, the estimated cost is \$654.34 (5.73 hours × \$114.24). Therefore, we estimate that the total cost of reviewing this final rule is \$135,447.61 (\$654.34 × 207 reviewers). For purposes of this estimate, the number of reviewers of this year's rule is equivalent to the number of comments received for the CY 2022 HH PPS proposed rule.

F. Alternatives Considered

1. HH PPS

For the CY 2022 HH PPS final rule, we considered alternatives to the provisions articulated in section II. of this final rule. We considered using CY 2019 data for ratesetting. However, our analysis showed there were only small differences in the payment rates and

impacts in the aggregate when using CY 2019 data compared to CY 2020 data. These differences in payment rates reflect small differences in the wage index budget neutrality factors calculated using CY 2020 data compared to using CY 2019 claims data. We note, we would not have recalibrated the case-mix weights using CY 2019 data because CY 2019 data would use simulated 30-day periods from 60-episodes as CY 2020 is the first year of actual PDGM data. Therefore, no case-mix weight budget neutrality factor using CY 2019 utilization data would be applied. We believe it is best to continue with our established policy of using the most recent, complete data at the time of rulemaking for CY 2022 rate setting, which would be CY 2020 claims data. Additionally, we considered alternatives to our case-mix recalibration proposal. These alternatives included an option to do a full recalibration of the case-mix weights, including the functional impairment levels, comorbidity subgroups as proposed, but also updating the LUPA thresholds, as well as an option to not recalibrate the case-mix weights, functional impairment levels, comorbidity subgroups and LUPA thresholds. However, we believe that recalibrating the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the LUPA thresholds for CY 2022 would more accurately adjust home health payments because the data would reflect 30-day periods under the new PDGM system based on actual data rather than data that simulated 30-day episodes under the old system. The recalibrated case-mix weights would also more accurately reflect the types of patients currently receiving home health services while mitigating instability by maintaining the LUPA thresholds. As stated previously, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (as is used to generate the case-mix weight) that would control for the impacts of the PHE. We note that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Also, our analysis shows that there is more variation in the case-mix weights with the full recalibration (including updates to the LUPA thresholds) than the recalibration with the case-mix weights

maintained. Maintaining the LUPA thresholds creates more stability in the weights. The recalibrated case-mix weights using the current LUPA thresholds are more similar to the CY 2020 weights than the recalibrated case-mix weights with the updated LUPA thresholds. For these reasons, we believe it is best to maintain the LUPA thresholds for CY 2022 instead of the alternative full recalibration including updates to the LUPA thresholds.

2. HHVBP

We considered alternatives to the proposed policies in sections III.A. and III.B. of the proposed rule. Specifically, we considered not expanding the HHVBP Model at this point in time, and waiting until we have final evaluation results from the original HHVBP Model before pursuing a national expansion. However, we considered that we have evaluation results from multiple years of the original HHVBP Model, showing significant reductions in spending and improvements in quality. We believe this evidence is sufficient for a national expansion of the Model, and note that we will continue to review evaluation results as they come in for the later years of the original HHVBP Model.

For the expanded HHVBP Model, we also considered utilizing the same State- and volume-based cohorts as the original HHVBP Model in lieu of the national volume-based cohorts we proposed. However, this approach could require grouping together of certain States, territories, and the District of Columbia that have an insufficient number of HHAs at the end of the performance year, based solely on their lower HHA counts. This would also preclude providing benchmarks and achievement thresholds prospectively. An analysis of the State-level impacts of using the revised cohorts, including our proposed option, nationwide with volume-based cohorts, and our alternative, State-level without volume-based cohorts, demonstrates minimal impacts at the State-level. We refer readers to Table 43 of this final rule for an analysis of the shifts of expenditures, as represented by the average payment adjustments for small- and large-volume HHAs in each of the States, territories, and the District of Columbia, simulated with the proposed national size-based cohorts using 2019 data and a maximum adjustment of ± 5

percent. When the small- and large-volume HHAs in each of the States, territories, and the District of Columbia are combined, the average payment adjustment for the majority of States, territories, and the District of Columbia is within ± 1 percent, with none exceeding ± 2 percent. Relative to the State- and volume-based cohorts, the national volume-based cohorts resulted in the largest increases in overall payment amounts to Alabama (+1.8 percent), Mississippi (+1.8 percent), and TN (+1.4 percent). The largest decreases in overall payment amounts are from Minnesota (-1.7 percent), Connecticut (-1.6 percent), and the Marianas Islands (-1.6 percent). We do not see any obvious correlation of the impacts within States that are currently in the original Model versus those that will be new to the expanded Model.

3. Deactivation Payment Prohibition

As discussed in section VI.B. of the proposed rule, we proposed in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). Current subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation of the provider's or supplier's billing privileges. We considered the alternative of retaining this 30-day retroactive period. After careful consideration, however, we concluded that prohibiting such retroactive payments would be the best approach from a program integrity perspective. As we stated in section VI.B. of the proposed and final rules, we do not believe a provider or supplier should be effectively rewarded for its non-adherence to enrollment requirements by receiving retroactive payment for services or items furnished while out of compliance. Moreover, the prospect of a payment prohibition could well spur providers and suppliers to avoid such non-compliance.

4. COVID-19 Reporting in Long-Term Care Facilities

We considered retaining all of the requirements in §483.80(g). However, we anticipate that NHSN will change the information items that are required in the future. The change made to this section will enable LTC facilities to continue to report the information required by the

NHSN without requiring the facilities to report information that the NHSN no longer requires. We also considered not setting a sunset or expiration date for all of the requirements for the information elements in paragraph (g)(1). However, we do not believe that all of this information will be needed in the future. The information on the vaccine status for the residents and staff is necessary so that health authorities can assess the needs in this area though. Thus, we have added the sunset date of December 31, 2024 for all of the information elements, except for paragraph (g)(1)(viii) which covers the vaccinations. Hence, this reduces the burden for the LTC facilities while maintaining the requirement to report information so that health authorities can assess the COVID-19 vaccination environment in LTC facilities. There has also been some confusion created by the language in (g)(2), which indicated that the frequency of the reporting was to be “no less than weekly”. We considered retaining the language in (g)(2); however, we believe that the confusion was adding undue burden to some LTC facilities. Thus, we have changed the language to read, “no more than weekly” to address any confusion. LTC facilities should report as NHSN requires.

G. Accounting Statement and Tables

1. HH PPS

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 46, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2022 HH PPS provisions of this rule.

TABLE 46: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2021 TO 2022

Category	Transfers
Annualized Monetized Transfers	\$570 million
From Whom to Whom?	Federal Government to HHAs

2. HHVBP Model Expansion

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 47, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule as they relate to hospitals and SNFs. Table 47 provides our best estimate of the decrease in Medicare payments under the expanded HHVBP Model.

TABLE 47: ACCOUNTING STATEMENT: EXPANDED HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS FOR CYs 2023 – 2027

Category	Transfers	Discount Rate	Period Covered
Annualized Monetized Transfers	-\$662.4 Million	7%	CYs 2023-2027
Annualized Monetized Transfers	-\$669.7 Million	3%	CYs 2023-2027
From Whom to Whom?	Federal Government to Hospitals and SNFs		

3. HHQRP

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 48, we have prepared an accounting statement showing the classification of the expenditures associated with this final rule as they relate to HHAs. Table 48 provides our best estimate of the decrease in Medicare payments.

TABLE 48: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2021 TO CY 2022

Category	Costs
Annualized Net Monetary Burden for HHAs' Submission of the OASIS	\$-2,762,277

H. Regulatory Flexibility Act (RFA)

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. In addition, HHAs and home infusion therapy suppliers are small entities, as that is the term used in the RFA. Individuals and States are not included in the definition of a small entity.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business

economy. We utilized the NAICS U.S. industry title “Home Health Care Services” and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of \$16.5 million²²⁸ and approximately 96 percent of HHAs and home infusion therapy suppliers are considered small entities. Table 49 shows the number of firms, revenue, and estimated impact per home health care service category.

TABLE 49: NUMBER OF FIRMS, REVENUE, AND ESTIMATED IMPACT OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS Code	NAICS Description	Enterprise Size	Number of Firms	Receipts (\$1,000)	Estimated Impact (\$1,000) per Enterprise Size
621610	Home Health Care Services	<100	5,861	210,697	\$35.95
621610	Home Health Care Services	100-499	5,687	1,504,668	\$264.58
621610	Home Health Care Services	500-999	3,342	2,430,807	\$727.35
621610	Home Health Care Services	1,000-2,499	4,434	7,040,174	\$1,587.77
621610	Home Health Care Services	2,500-4,999	1,951	6,657,387	\$3,412.29
621610	Home Health Care Services	5,000-7,499	672	3,912,082	\$5,821.55
621610	Home Health Care Services	7,500-9,999	356	2,910,943	\$8,176.81
621610	Home Health Care Services	10,000-14,999	346	3,767,710	\$10,889.34
621610	Home Health Care Services	15,000-19,999	191	2,750,180	\$14,398.85
621610	Home Health Care Services	≥20,000	961	51,776,636	\$53,877.87
621610	Home Health Care Services	Total	23,801	82,961,284	\$3,485.62

Source: Data obtained from United States Census Bureau table “us_6digitnaics_reptsizesize_2017” (SOURCE: 2017 County Business Patterns and Economic Census) Release Date: 5/28/2021: <https://www2.census.gov/programs-surveys/susb/tables/2017/>
Notes: Estimated impact is calculated as Receipts (\$1,000)/Enterprise Size.

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 not result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. We note also, and as discussed in section XI.C.6. of this final rule, our provision to prohibit payments for services and items furnished by deactivated providers and suppliers will affect only a very limited number of

²²⁸ https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%202019%2C%202019_Rev.pdf

Medicare providers and suppliers. Therefore, the Secretary has determined that this HH PPS final rule would not have significant economic impact on a substantial number of small entities.

Guidance issued by the Department of Health and Human Services interpreting the Regulatory Flexibility Act considers the 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. Among the over 7,500 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this rule would be larger than 3 percent, in magnitude, for about 28 percent of competing HHAs (estimated by applying a 5-percent maximum payment adjustment under the expanded Model to CY 2019 data). As a result, more than the RFA threshold of 5-percent of HHA providers nationally would be significantly impacted. We refer readers to Tables 43 and 44 of this final rule for our analysis of payment adjustment distributions by State, HHA characteristics, HHA size and percentiles.

Thus, the Secretary has certified that this final rule would have a significant economic impact on a substantial number of small entities. Though the RFA requires consideration of alternatives to avoid economic impacts on small entities, the intent of the rule, itself, is to encourage quality improvement by HHAs through the use of economic incentives. As a result, alternatives to mitigate the payment reductions would be contrary to the intent of the rule, which is to test the effect on quality and costs of care of applying payment adjustments based on HHAs’ performance on quality measures.

In addition, section 1102(b) of the Act requires us to prepare an 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 604 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 certified that this final rule will not have a significant economic impact on the operations of small rural hospitals.

I. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA 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 2021, that threshold is approximately \$158 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 \$158 million or more.

J. Federalism

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 final rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on State or local governments.

K. Conclusion

In conclusion, we estimate that the provisions in this final rule will result in an estimated net increase in home health payments 3.2 percent for CY 2022 (\$570 million). The \$570 million increase in estimated payments for CY 2022 reflects the effects of the CY 2022 home health payment update percentage of 2.6 percent (\$465 million increase), a 0.7 percent increase in payments due to the new lower FDL ratio, which will increase outlier payments in order to target to pay no more than 2.5 percent of total payments as outlier payments (\$125 million increase) and an estimated 0.1 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2022 (\$20 million decrease).

L. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2021.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical centers, Health facilities, Health professions, Medicare, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as 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--

a. By revising the paragraph (b) heading;

b. In paragraph (c)(1)(i)(C) by removing the phrase "physician's orders" and adding in its place the phrase "physician's or allowed practitioner's orders";

c. In paragraphs (c)(1)(i)(D), (c)(2)(i), and (c)(3) by removing the term "physician" and adding in its place the phrase "physician or allowed practitioner"; and

d. In paragraph (d) by removing the phrase "based on a physician's oral orders" and adding in its place the phrase "based on a physician's or allowed practitioner's oral orders".

The revision reads as follows:

§ 409.43 Plan of care requirements.

* * * * *

(b) *Physician's or allowed practitioner's orders.* * * *

* * * * *

PART 424-CONDITIONS FOR MEDICARE PAYMENT

3. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

4. Section 424.520 is amended by revising paragraph (d) to read as follows:

§ 424.520 Effective date of Medicare billing privileges.

* * * * *

(d) *Additional provider and supplier types.* (1) The effective date of billing privileges for the provider and supplier types identified in paragraph (d)(2) of this section is the later of--

(i) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(ii) The date that the provider or supplier first began furnishing services at a new practice location.

(2) The provider and supplier types to which paragraph (d)(1) of this section applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

5. Section 424.521 is amended by revising the section heading and paragraph (a) to read as follows:

§ 424.521 Request for payment by certain provider and supplier types.

(a) *Request for payment by certain provider and supplier types.* (1) The providers and suppliers identified in paragraph (a)(2) of this section may retrospectively bill for services when the provider or supplier has met all program requirements (including State licensure requirements), and services were provided at the enrolled practice location for up to--

(i) Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or

(ii) Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(2) The provider and supplier types to which paragraph (a)(1) of this section applies are as follows:

- (i) Physicians.
- (ii) Non-physician practitioners.
- (iii) Physician organizations.
- (iv) Non-physician practitioner organizations.
- (v) Ambulance suppliers.
- (vi) Opioid treatment programs.
- (vii) Part B hospital departments.
- (viii) Clinical Laboratory Improvement Amendment labs.
- (ix) Intensive cardiac rehabilitation facilities.
- (x) Mammography centers.
- (xi) Mass immunizers/pharmacies.
- (xii) Radiation therapy centers.
- (xiii) Home infusion therapy suppliers.
- (xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

* * * * *

6. Section 424.522 is added to read as follows:

§ 424.522 Additional effective dates.

(a) *Reassignments.* A reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS-855R is submitted if all applicable requirements during that period were otherwise met.

(b) *Form CMS-855O enrollment.* The effective date of a Form CMS-855O enrollment is the date on which the Medicare contractor received the Form CMS-855O application if all other requirements are met.

7. Section 424.525 is amended—

a. By revising the section heading and paragraph (a)(1);

b. In paragraphs (a)(2) and (3) and (b) by removing the phrase "prospective provider" and adding the word "provider" in its place; and

c. By adding paragraph (e).

The revision and addition read as follows:

§ 424.525 Rejection of a provider's or supplier's application for Medicare enrollment.

(a) * * *

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information. This includes the following situations:

(i) The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.

(v) The application is signed by a person unauthorized to do so under this subpart.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or e-mail when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS-855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS-855 application.

* * * * *

(e) *Applicability.* Except as otherwise specified in the applicable reason for rejection under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions, including, but not limited to, the following:

(1) Form CMS-855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.

(3) Form CMS-20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (e)(1) through (3) of this section.

8 Section 424.526 is added to read as follows:

§ 424.526 Return of a provider's or supplier's enrollment application.

(a) *Reasons for return.* CMS may return a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier sent its paper Form CMS-855, Form CMS-588, or Form CMS-20134 application to the incorrect Medicare contractor for processing.

(2) The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. (This paragraph (a)(2) does not apply to providers and suppliers submitting a Form CMS-855A application, ambulatory surgical centers, or portable x-ray suppliers.)

(3) The seller or buyer in a change of ownership submitted its Form CMS-855A or Form CMS-855B application more than 90 days prior to the anticipated date of the sale.

(4) The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from a provider or supplier submitting a Form CMS-855A application, an ambulatory surgical center, or a portable x-ray supplier.

(5) The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider or supplier submitted an initial enrollment application prior to the expiration of their existing re-enrollment bar under § 424.535 or reapplication bar under § 424.530(f).

(7) The application is not needed for (or is inapplicable to) the transaction in question.

(8) The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.

(9) A Medicare Diabetes Prevention Program supplier submitted an application with a coach start date more than 30 days in the future.

(10) The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.

(11) The provider or supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider or supplier submits a paper Form CMS-855 or Form CMS-20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider or supplier submits a Form CMS-855A or Form CMS-855B initial application followed by a Form CMS-855A or Form CMS-855B change of ownership application. If the Medicare contractor--

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS-855A or Form CMS-855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS-855A or Form CMS-855B application.

(b) *Appeals.* A provider or supplier is not afforded appeal rights if their application is returned under this section.

(c) *Applicability.* Except as otherwise specified in the applicable return reason under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions including, but not limited to, the following:

(1) Form CMS-855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS-588 submissions.

(3) Form CMS-20134 submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (c)(1) through (3) of this section.

9. Section 424.540 is amended—

- a. By revising paragraph (a)(2);
- b. By adding paragraphs (a)(4) through (8);
- c. By revising paragraphs (b)(1) and (c); and
- d. By adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 424.540 Deactivation of Medicare billing privileges.

(a) * * *

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title.

* * * * *

(4) The provider or supplier is not in compliance with all enrollment requirements in this title.

(5) The provider's or supplier's practice location is non-operational or otherwise invalid.

(6) The provider or supplier is deceased.

(7) The provider or supplier is voluntarily withdrawing from Medicare.

(8) The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

(b) * * *

(1) In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

* * * * *

(c) *Effect of deactivation.* The deactivation of Medicare billing privileges does not have any effect on a provider's or supplier's participation agreement or any conditions of participation.

(d) *Effective dates.* (1)(i) Except as provided in paragraph (d)(1)(ii) of this section, the effective date of a deactivation is the date on which the deactivation is imposed under this section.

(ii) A retroactive deactivation effective date (based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)) may be imposed in the following instances:

(A) For the deactivation reasons in paragraphs (a)(2) through (4) of this section, the effective date is the date on which the provider or supplier became non-compliant.

(B) For the deactivation reason in paragraph (a)(5) of this section, the effective date is the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

(C) For the deactivation reason in paragraph (a)(6) of this section, the effective date is the date of death of the provider or supplier.

(D) For the deactivation reason in paragraph (a)(7) of this section, the effective date is the date on which the provider or supplier voluntarily withdrew from Medicare.

(E) For the deactivation reason in paragraph (a)(8) of this section, the effective date is the date of the sale.

(2) The effective date of a reactivation of billing privileges under this section is the date on which the Medicare contractor received the provider's or supplier's reactivation submission that was processed to approval by the Medicare contractor.

(e) *Payment prohibition.* A provider or supplier may not receive payment for services or items furnished while deactivated under this section.

10. Section 424.550 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(2)(i) The HHA submitted two consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. For purposes of the exception in this paragraph (b)(2)(i), low utilization or no utilization cost reports do not qualify as full cost reports.

* * * * *

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

11. The authority for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r.

12. Section 483.80 is amended by revising paragraph (g) to read as follows:

§ 483.80 Infection control.

* * * * *

(g) *COVID-19 reporting.* Until December 31, 2024, with the exception of the requirements in paragraph (g)(1)(viii) of this section, the facility must do all of the following:

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include the following:

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19.

(ii) Total deaths and COVID-19 deaths among residents and staff.

(iii) Personal protective equipment and hand hygiene supplies in the facility.

(iv) Ventilator capacity and supplies in the facility.

(v) Resident beds and census.

(vi) Access to COVID-19 testing while the resident is in the facility.

(vii) Staffing shortages.

(viii) The COVID-19 vaccine status of residents and staff, including total numbers of residents and staff, numbers of residents and staff vaccinated, numbers of each dose of COVID-19 vaccine received, and COVID-19 vaccination adverse events.

(ix) Therapeutics administered to residents for treatment of COVID-19.

(2) Provide the information specified in paragraph (g)(1) of this section weekly, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must do all of the following:

(i) Not include personally identifiable information.

(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered.

(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

* * * * *

PART 484—HOME HEALTH SERVICES

13. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§484.50 [Amended]

14. Section 484.50 is amended in paragraph (d)(5)(i) by removing the phrase "representative (if any), the physician(s) issuing orders" and adding in its place the phrase "the representative (if any), the physician(s) or allowed practitioner(s) issuing orders".

15. Section 484.55 is amended by revising paragraphs (a)(2) and (b)(3) to read as follows:

§484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(a) * * *

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

(b) * * *

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, a physical therapist, speech-language pathologist, or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. For Medicare patients, the occupational therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

* * * * *

16. Section 484.80 is amended by:

- a. Revising paragraph (h)(1)(i);
- b. Redesignating paragraphs (h)(1)(ii) and (iii) as paragraphs (h)(1)(iii) and (iv), respectively;
- c. Adding a new paragraph (h)(1)(ii); and
- d. Revising paragraphs (h)(2) and (3).

The revisions and addition read as follows:

§484.80 Condition of participation: Home health aide services.

* * * * *

(h) * * *

(1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services—

(A) A registered nurse or other appropriate skilled professional who is familiar with the patient, the patient’s plan of care, and the written patient care instructions described in paragraph (g) of this section, must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days; and

(B) The home health aide does not need to be present during the supervisory assessment described in paragraph (h)(1)(i)(A) of this section.

(ii) The supervisory assessment must be completed onsite (that is, an in person visit), or on the rare occasion by using two-way audio-video telecommunications technology that allows for real-time interaction between the registered nurse (or other appropriate skilled professional) and the patient, not to exceed 1 virtual supervisory assessment per patient in a 60-day episode.

* * * * *

(2)(i) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech language pathology services—

(A) The registered nurse must make an onsite, in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs; and

(B) The home health aide does not need to be present during this visit.

(ii) Semi-annually the registered nurse must make an on-site visit to the location where each patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation for the deficient and all related skills.

* * * * *

17. The heading for subpart F is revised to read as follows:

Subpart F—Home Health Value-Based Purchasing (HHVBP) Models

18. Add an undesignated center heading before § 484.300 to read as follows:

*HHVBP Model Components for Competing Home Health Agencies Within State Boundaries for
the Original HHVBP Model*

* * * * *

19. Section 484.305 is amended by revising the definition of "Applicable percent" to read as follows:

§484.305 Definitions.

* * * * *

Applicable percent means a maximum upward or downward adjustment for a given performance year, not to exceed the following:

- (1) For CY 2018, 3-percent.
- (2) For CY 2019, 5-percent.

(3) For CY 2020, 6-percent.

(4) For CY 2021, 7-percent.

* * * * *

§ 484.315 [Amended]

20. Section 484.315 is amended by removing paragraph (d).

21. Add an undesignated center heading and §§ 484.340 through 484.375 to read as follows:

*HHVBP Model Components for Competing Home Health Agencies (HHAs) for HHVBP Model
Expansion--Effective January 1, 2022*

Sec.

484.340 Basis and scope of this subpart.

484.345 Definitions.

484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.

484.360 Calculation of the Total Performance Score.

484.365 Payments for home health services under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

*HHVBP Model Components for Competing Home Health Agencies (HHAs) for HHVBP Model
Expansion--Effective January 1, 2022*

§ 484.340 Basis and scope of this subpart.

This subpart is established under sections 1102, 1115A, and 1871 of the Act (42 U.S.C. 1315a), which authorizes the Secretary to issue regulations to operate the Medicare program and test innovative payment and service delivery models to reduce program expenditures while

preserving or enhancing the quality of care furnished to individuals under Titles XVIII and XIX of the Act.

§ 484.345 Definitions.

As used in this subpart—

Achievement threshold means the median (50th percentile) of home health agency performance on a measure during a baseline year, calculated separately for the larger- and smaller-volume cohorts.

Applicable measure means a measure (OASIS- and claims-based measures) or a measure component (HHCAHPS survey measure) for which a competing HHA has provided a minimum of one of the following:

- (1) Twenty home health episodes of care per year for each of the OASIS-based measures.
- (2) Twenty home health episodes of care per year for each of the claims-based measures.
- (3) Forty completed surveys for each component included in the HHCAHPS survey measure.

Applicable percent means a maximum upward or downward adjustment for a given payment year based on the applicable performance year, not to exceed 5 percent.

Baseline year means the year against which measure performance in a performance year will be compared.

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts.

Competing home health agency or agencies (HHA or HHAs) means an agency or agencies that meet the following:

- (1) Has or have a current Medicare certification; and
- (2) Is or are being paid by CMS for home health care services.

Home health prospective payment system (HH PPS) refers to the basis of payment for HHAs as set forth in §§484.200 through 484.245.

Improvement threshold means an individual competing HHA's performance level on a measure during the baseline year.

Larger-volume cohort means the group of competing HHAs that are participating in the HHCAPHS survey in accordance with § 484.245.

Linear exchange function is the means to translate a competing HHA's Total Performance Score into a value-based payment adjustment percentage.

Nationwide means the 50 States and the U.S. territories, including the District of Columbia.

Payment adjustment means the amount by which a competing HHA's final claim payment amount under the HH PPS is changed in accordance with the methodology described in § 484.370.

Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

Performance year means the calendar year during which data are collected for the purpose of calculating a competing HHA's performance on measures.

Pre-Implementation year means CY 2022.

Smaller-volume cohort means the group of competing HHAs that are exempt from participation in the HHCAPHS survey in accordance with §484.245.

Total Performance Score (TPS) means the numeric score ranging from 0 to 100 awarded to each competing HHA based on its performance under the expanded HHVBP Model.

§ 484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General rule.* The expanded HHVBP Model applies to all Medicare-certified HHAs nationwide.

(b) *New HHAs.* For an HHA that is certified by Medicare on or after January 1, 2019, the baseline year is the first full calendar year of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year is calendar year (CY) 2021, and the first performance year is the first full calendar year (beginning with CY 2023) following the baseline year.

§ 484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

(1) *Data submission.* Except as provided in paragraph (d) of this section, for the pre-implementation year and each performance year, an HHA must submit all of the following to CMS in the form and manner, and at a time, specified by CMS:

(i) Data on measures specified under the expanded HHVBP model.

(ii) HHCAHPS survey data. For purposes of HHCAHPS Survey data submission, the following additional requirements apply:

(A) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf.

(B) *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.

(C) *Definition of survey of individuals.* For the HHCAHPS survey, 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.

(D) *Administration of the HHCAHPS survey.* No organization, firm, or business that owns, operates, or provides staffing for an 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 are not approved by CMS as HHCAHPS survey vendors.

(E) *Compliance by HHCAHPS survey vendors.* Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors' company locations.

(F) *Patient count exemption.* An HHA that has less than 60 eligible unique HHCAHPS survey patients must annually submit to CMS its total HHCAHPS survey patient count to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

(2) [Reserved]

(b) Competing home health agencies are required to collect and report such information as the Secretary determines is necessary for purposes of monitoring and evaluating the expanded HHVBP Model under section 1115A(b)(4) of the Act (42 U.S.C. 1315a).

(c) For each performance year of the expanded HHVBP Model, CMS publicly reports applicable measure benchmarks and achievement thresholds for each cohort as well as all of the following for each competing HHA that qualified for a payment adjustment for the applicable performance year on a CMS website:

- (1) The Total Performance Score.
- (2) The percentile ranking of the Total Performance Score.
- (3) The payment adjustment percentage.
- (4) Applicable measure results and improvement thresholds.

(d) CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. CMS may grant an exception as follows:

(1) A competing HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on the CMS website.

(2) CMS may grant an exception to one or more HHAs that have not requested an exception if CMS determines either of the following:

(i) That a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data.

(ii) That an extraordinary circumstance has affected an entire region or locale.

§ 484.360 Calculation of the Total Performance Score.

A competing HHA's Total Performance Score for a performance year is calculated as follows:

(a) CMS awards points to the competing home health agency for performance on each of the applicable measures.

(1) CMS awards greater than or equal to 0 points and less than 10 points for achievement to each competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's achievement threshold but is less than the applicable cohort's benchmark for that measure.

(2) CMS awards greater than 0 but less than 9 points for improvement to each competing home health agency whose performance on a measure during the applicable performance year exceeds the improvement threshold but is less than the applicable cohort's benchmark for that measure.

(3) CMS awards 10 points to a competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's benchmark for that measure.

(b) For all performance years, CMS calculates the weighted sum of points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and HHCAHPS Survey-based) weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS survey

measure category when all three measure categories are reported, to calculate a value worth 100 percent of the Total Performance Score.

(1) Where a single measure category is not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all of the measures in the category, the remaining measure categories are reweighted such that the proportional contribution of each remaining measure category is consistent with the weights assigned when all three measure categories are available. Where two measure categories are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all measures in those measure categories, the remaining measure category is weighted at 100 percent of the Total Performance Score.

(2) When one or more, but not all, of the measures in a measure category are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for at least one measure in the category, the remaining measures in the category are reweighted such that the proportional contribution of each remaining measure is consistent with the weights assigned when all measures within the category are available.

(c) The sum of the weight-adjusted points awarded to a competing HHA for each applicable measure is the competing HHA's Total Performance Score for the calendar year. A competing HHA must have a minimum of five applicable measures to receive a Total Performance Score.

§ 484.365 Payments for home health services under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

CMS determines a payment adjustment up to the applicable percent, upward or downward, under the expanded HHVBP Model for each competing HHA based on the agency's Total Performance Score using a linear exchange function that includes all other HHAs in its cohort that received a Total Performance Score for the applicable performance year. Payment adjustments made under the expanded HHVBP Model are calculated as a percentage of

otherwise-applicable payments for home health services provided under section 1895 of the Act (42 U.S.C. 1395fff).

§ 484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General.* Competing home health agencies are ranked within the larger-volume and smaller-volume cohorts nationwide based on the performance standards in this part that apply to the expanded HHVBP Model for the baseline year, and CMS makes value-based payment adjustments to the competing HHAs as specified in this section.

(b) *Calculation of the value-based payment adjustment amount.* The value-based payment adjustment amount is calculated by multiplying the home health prospective payment final claim payment amount as calculated in accordance with §484.205 by the payment adjustment percentage.

(c) *Calculation of the payment adjustment percentage.* The payment adjustment percentage is calculated as the product of all of the following:

- (1) The applicable percent as defined in §484.345.
- (2) The competing HHA's Total Performance Score divided by 100.
- (3) The linear exchange function slope.

§ 484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation—(1) Matters for recalculation.* Subject to the limitations on judicial and administrative review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

- (i) Interim performance scores.
- (ii) Annual total performance scores.
- (iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the CMS website, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for recalculation additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS issues a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration—(1) Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the HHA's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a) of this section.

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the CMS website within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. The documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* CMS reconsideration officials issue a written final determination.

PART 488--SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

22. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

23. Section 488.2 is amended by adding provision “1822” in numerical order to read as follows:

§ 488.2 Statutory basis.

* * * * *

1822 – Hospice Program survey and enforcement procedures.

* * * * *

24. Section 488.5 is amended by adding paragraph (a)(4)(x) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(4) * * *

(x) For accrediting organizations applying for approval or re-approval of CMS-approved hospice programs, a statement acknowledging that the accrediting organization (AO) will include a statement of deficiencies (that is, the Form CMS-2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

* * * * *

25. Section 488.7 is amended by revising paragraph (b) and adding paragraph (c) to read as follows.

§ 488.7 Release and use of accreditation surveys.

* * * * *

(b) With the exception of home health agency and hospice program surveys, general disclosure of an accrediting organization’s survey information is prohibited under section 1865(b) of the Act. CMS may publicly disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

(c) CMS posts inspection reports from a State or local survey agency or accrediting organization conducted on or after October 1, 2022, for hospice programs, including copies of a hospice program’s survey deficiencies, and enforcement actions (for example, involuntary terminations) taken as a result of such surveys, on its public website in a manner that is

prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.

26. Section 488.28 is amended by revising the section heading to read as follows:

§ 488.28 Providers or suppliers, other than SNFs, NFs, HHAs, and Hospice programs with deficiencies.

* * * * *

27. Add subparts M and N to read as follows:

Subpart M – Survey and Certification of Hospice Programs

Sec.

- 488.1100 Basis and scope.
- 488.1105 Definitions.
- 488.1110 Hospice program: surveys and hotline.
- 488.1115 Surveyor qualifications and prohibition of conflicts of interest.
- 488.1120 Survey teams.
- 488.1125 Consistency of survey results.

Subpart N – Enforcement Remedies for Hospice Programs with Deficiencies

Sec.

- 488.1200 Statutory basis.
- 488.1205 Definitions.
- 488.1210 General provisions.
- 488.1215 Factors to be considered in selecting remedies.
- 488.1220 Available remedies.
- 488.1225 Action when deficiencies pose immediate jeopardy.
- 488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.
- 488.1235 Temporary management.
- 488.1240 Suspension of payment for all new patient admissions.
- 488.1245 Civil money penalties.
- 488.1250 Directed plan of correction.
- 488.1255 Directed in-service training.
- 488.1260 Continuation of payments to a hospice program with deficiencies.
- 488.1265 Termination of provider agreement.

Subpart M – Survey and Certification of Hospice Programs

§ 488.1100 Basis and scope.

Sections 1812, 1814, 1822, 1861, 1864, and 1865 of the Act establish requirements for Hospice programs and to authorize surveys to determine whether they meet the Medicare conditions of participation.

§ 488.1105 Definitions.

As used in this subpart—

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received or other indicators of specific concern.

Complaint survey means a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.

Condition-level deficiency means noncompliance as described in § 488.24.

Deficiency is a violation of the Act and regulations contained in part 418, subparts C and D, of this chapter, is determined as part of a survey, and can be either standard or condition-level.

Noncompliance means any deficiency found at the condition-level or standard-level.

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for hospice programs.

Standard survey means a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards or conditions of participation or both to determine the quality of care and services furnished by a hospice program.

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State.

§ 488.1110 Hospice program: surveys and hotline.

(a) *Basic period.* Each hospice program as defined in section 1861(dd) of the Act is subject to a standard survey by an appropriate State or local survey agency, or an approved

accreditation agency, as determined by the Secretary, not less frequently than once every 36 months. Additionally, a survey may be conducted as frequently as necessary to –

(1) Assure the delivery of quality hospice program services by determining whether a hospice program complies with the Act and conditions of participation; and

(2) Confirm that the hospice program has corrected deficiencies that were previously cited.

(b) *Complaints.* A standard survey, or abbreviated standard survey-

(1) Must be conducted of a hospice program when complaints against the hospice program are reported to CMS, the State, or local agency.

(2) The State, or local agency is responsible for maintaining a toll-free hotline to collect, maintain, and continually update information on Medicare-participating hospice programs including significant deficiencies found regarding patient care, corrective actions, and remedy activity during its most recent survey, and to receive complaints and answer questions about hospice programs. The State or local agency is also responsible for maintaining a unit for investigating such complaints.

§ 488.1115 Surveyor qualifications and prohibition of conflicts of interest.

(a) *Minimum qualifications.* Surveyors must meet minimum qualifications prescribed by CMS. Before any accrediting organization, State or Federal surveyor may serve on a hospice survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic Hospice Surveyor Training Course, and additional training as specified by CMS.

(b) *Disqualifications.* Surveyor(s) must disclose actual or perceived conflicts of interest prior to participating in a hospice program survey and be provided the opportunity to recuse themselves as necessary. Any of the following circumstances disqualifies a surveyor from surveying a particular hospice program:

(1) The surveyor currently serves, or, within the previous 2 years has served, with the hospice program to be surveyed as one of the following:

(i) A direct employee.

(ii) An employment agency staff at the hospice program.

(iii) An officer, consultant, or agent for the hospice program to be surveyed concerning compliance with conditions of participation specified in or in accordance with sections 1861(dd) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the hospice program to be surveyed.

(3) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who has a financial interest or an ownership interest with the hospice program to be surveyed.

(4) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who is a patient of the hospice program to be surveyed.

§ 488.1120 Survey teams.

Standard surveys conducted by more than one surveyor must be conducted by a multidisciplinary team of professionals typically involved in hospice care and identified as professionals providing hospice core services at §418.64 of this chapter. The multidisciplinary team must include a registered nurse. Surveys conducted by a single surveyor, must be conducted by a registered nurse.

§ 488.1125 Consistency of survey results.

A survey agency or accrediting organization must provide a corrective action plan to CMS for any disparity rates that are greater than the threshold established by CMS.

Subpart N – Enforcement Remedies for Hospice Programs with Deficiencies

§ 488.1200 Statutory basis.

Section 1822 of the Act authorizes the Secretary to take actions to remove and correct

deficiencies in a hospice program through an enforcement remedy or termination or both. This section specifies that these remedies are in addition to any others available under State or Federal law, and, except for the final determination of civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.1205 Definitions.

As used in this subpart—

Directed plan of correction means CMS or the temporary manager (with CMS/survey agency (SA) approval) may direct the hospice program to take specific corrective action to achieve specific outcomes within specific timeframes.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient(s).

New admission means an individual who becomes a patient or is readmitted to the hospice program on or after the effective date of a suspension of payment remedy.

Per instance means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy.

Plan of correction means a plan developed by the hospice program and approved by CMS that is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a condition-level deficiency that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated.

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The hospice program's governing

body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the hospice program to correct deficiencies identified in the hospice program's operation.

§ 488.1210 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of a hospice program.

(b) *Basis for imposition of remedies.* When CMS chooses to apply one or more remedies specified in § 488.1220, the remedies are applied on the basis of noncompliance with one or more conditions of participation and may be based on failure to correct previous deficiency findings as evidenced by repeat condition-level deficiencies.

(c) *Number of remedies.* CMS may impose one or more remedies specified in § 488.1220 for each condition-level deficiency constituting noncompliance.

(d) *Plan of correction requirement.* Regardless of which remedy is applied, a non-compliant hospice program must submit a plan of correction for approval by CMS or the State Survey Agency.

(e) *Notification requirements—(1) Notice of intent.* CMS provides written notification to the hospice program of the intent to impose the remedy, the statutory basis for the remedy, the nature of the noncompliance, the proposed effective date of the sanction, and the appeal rights. For civil money penalties, the notice of intent would also include the amount being imposed.

(2) *Final notice.* With respect to civil money penalties, CMS provides a written final notice to the hospice program, as set forth in § 488.1245(e), once the administrative determination is final.

(3) *Date of enforcement action.* The notice periods specified in §§ 488.1225(b) and 488.1230(b) begin the day after the hospice receives the notice of intent.

(f) *Appeals.* (1) The hospice program may request a hearing on a determination of noncompliance leading to the imposition of a remedy, including termination of the provider agreement, under the provisions of part 498 of this chapter.

(2) A pending hearing does not delay the effective date of a remedy, including termination, against a hospice program. Remedies continue to be in effect regardless of the timing of any appeals proceedings.

§ 488.1215 Factors to be considered in selecting remedies.

CMS bases its choice of remedy or remedies on consideration of one or more factors that include, but are not limited to, the following:

(a) The extent to which the deficiencies pose immediate jeopardy to patient health and safety.

(b) The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

(c) The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.

(d) The extent to which the deficiencies are directly related to a failure to provide quality patient care.

(e) The extent to which the hospice program is part of a larger organization with performance problems.

(f) An indication of any system-wide failure to provide quality care.

§ 488.1220 Available remedies.

The following enforcement remedies are available instead of, or in addition to, termination of the hospice program's provider agreement under § 489.53 of this chapter, for a period not to exceed 6 months:

(a) Civil money penalties.

- (b) Suspension of payment for all new patient admissions.
- (c) Temporary management of the hospice program.
- (d) Directed plan of correction.
- (e) Directed in-service training.

§ 488.1225 Action when deficiencies pose immediate jeopardy.

(a) *Immediate jeopardy.* If there is immediate jeopardy to the hospice program's patient health or safety, the following rules apply:

(1) CMS immediately terminates the hospice program provider agreement in accordance with § 489.53 of this chapter.

(2) CMS terminates the hospice program provider agreement no later than 23 calendar days from the last day of the survey, if the immediate jeopardy has not been removed by the hospice program.

(3) In addition to a termination, CMS may impose one or more enforcement remedies, as appropriate.

(b) *2-calendar day notice.* Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is immediate jeopardy, notice must be given at least 2 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) *Transfer of care.* A hospice program, if its provider agreement is terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination.

§ 488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.

(a) *Noncompliance with conditions of participation.* If the hospice program is no longer in compliance with the conditions of participation, either because the condition-level deficiency or deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose

immediate jeopardy, or the hospice program has repeat condition-level deficiencies based on the hospice program's failure to correct and sustain compliance, CMS does either of the following.

(1) Terminates the hospice program's provider agreement.

(2) Imposes one or more enforcement remedies set forth in § 488.1220(a) through (e) in lieu of termination, for a period not to exceed 6 months.

(b) *15-calendar day notice.* Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) *Not meeting criteria for continuation of payment.* If a hospice program does not meet the criteria for continuation of payment under § 488.1260(a), CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(d) *Termination timeframe when there is no immediate jeopardy.* CMS terminates a hospice program within 6 months of the last day of the survey, if the hospice program is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met.

(e) *Transfer of care.* A hospice program, if its provider agreement terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination. The State must assist the hospice program in the safe and orderly transfer of care and services for the patients to another local hospice program.

§ 488.1235 Temporary management.

(a) *Application.* CMS may impose temporary management of a hospice program if it determines that a hospice program has a condition-level deficiency and CMS determines that management limitations or the deficiencies are likely to impair the hospice program's ability to correct the noncompliance and return the hospice program to compliance with all of the

conditions of participation within the timeframe required.

(b) *Procedures*—(1) *Notice of intent*. Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e) that a temporary manager is being appointed.

(2) *Termination*. If the hospice program fails to relinquish authority and control to the temporary manager, CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(c) *Duration and effect of remedy*. Temporary management continues until one of the following occur:

(1) CMS determines that the hospice program has achieved substantial compliance and has the management capability to ensure continued compliance with all the conditions of participation.

(2) CMS terminates the provider agreement.

(3) The hospice program resumes management control without CMS approval. In this case, CMS initiates termination of the provider agreement and may impose additional remedies.

(4) Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

(d) *Payment of salary*. (1) The temporary manager's salary must meet the following:

(i) Is paid directly by the hospice program while the temporary manager is assigned to that hospice program.

(ii) Must be at least equivalent to the sum of the following:

(A) The prevailing salary paid by providers for positions of this type in what the State considers to be the hospice program's geographic area (prevailing salary based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates).

(B) Any additional costs that would have reasonably been incurred by the hospice

program if such person had been in an employment relationship.

(C) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(2) A hospice program's failure to pay the salary and other costs of the temporary manager described in paragraph (d)(1) of this section is considered a failure to relinquish authority and control to temporary management.

§ 488.1240 Suspension of payment for all new patient admissions.

(a) *Application.* (1) CMS may suspend payment for all new admissions to a hospice program on or after the date on which the Secretary determines that remedies should be imposed.

(2) CMS considers the remedy in paragraph (a)(1) of this section for any deficiency related to poor patient care outcomes, regardless of whether the deficiency poses immediate jeopardy.

(b) *Procedures—(1) Notice of intent.* (i) Before suspending payments for all new admissions, CMS provides the hospice program notice of the suspension of payment in accordance with § 488.1210(e).

(ii) The hospice program may not charge a newly admitted hospice patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the hospice program can show that, before initiating care, it gave the patient or his or her representative oral and written notice of the suspension of Medicare payment in a language and manner that the beneficiary or representative can understand.

(2) *Restriction.* (i) The suspension of payment for all new admissions remedy may be imposed anytime a hospice program is found to be out of substantial compliance with the conditions of participation.

(ii) The suspension of payment for all new admissions remains in place until CMS determines that the hospice program has achieved substantial compliance with the conditions of participation or is terminated, as determined by CMS.

(3) *Resumption of payments.* Payments for all new admissions to the hospice program resume prospectively on the date that CMS determines that the hospice program has achieved substantial compliance with the conditions of participation.

(c) *Duration and effect of remedy.* The remedy in paragraph (a) of this section ends when any of the following occur—

(1) CMS determines that the hospice program has achieved substantial compliance with all of the conditions of participation.

(2) When the hospice program is terminated or CMS determines that the hospice program is not in compliance with the conditions of participation at a maximum of 6 months from the date of the survey identifying the noncompliance.

§ 488.1245 Civil money penalties.

(a) *Application.* (1) CMS may impose a civil money penalty against a hospice program for either the number of days the hospice program is not in compliance with one or more conditions of participation or for each instance that a hospice program is not in compliance, regardless of whether the hospice program's deficiencies pose immediate jeopardy.

(2) CMS may impose a civil money penalty for the number of days of immediate jeopardy.

(3) A per-day and a per-instance civil money penalty (CMP) may not be imposed simultaneously for the same deficiency in conjunction with a survey.

(4) CMS may impose a civil money penalty for the number of days of noncompliance since the last standard survey, including the number of days of immediate jeopardy.

(b) *Amount of penalty—(1) Factors considered.* CMS takes into account the following factors in determining the amount of the penalty:

(i) The factors set out at § 488.1215.

(ii) The size of a hospice program and its resources.

(iii) Evidence that the hospice program has a built-in, self-regulating quality assessment

and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

(2) *Adjustments to penalties.* Based on revisit survey findings, adjustments to penalties may be made after a review of the provider's attempted correction of deficiencies.

(i) CMS may increase a CMP in increments based on a hospice program's inability or failure to correct deficiencies, the presence of a system-wide failure in the provision of quality care, or a determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

(ii) CMS may also decrease a CMP in increments to the extent that it finds, in accordance with a revisit, that substantial and sustainable improvements have been implemented even though the hospice program is not yet in compliance with the conditions of participation.

(iii) No penalty assessment exceeds \$10,000, as adjusted annually under 45 CFR part 102, for each day a hospice program is not in substantial compliance with one or more conditions of participation.

(3) *Upper range of penalty.* Penalties in the upper range of \$8,500 to \$10,000 per day, as adjusted annually under 45 CFR part 102, are imposed for a condition-level deficiency that is immediate jeopardy. The penalty in this range continues until substantial compliance can be determined based on a revisit survey.

(i) \$10,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm.

(ii) \$9,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm.

(iii) \$8,500, as adjusted annually under 45 CFR part 102, per day for a deficiency based on an isolated incident in violation of established hospice policy.

(4) *Middle range of penalty.* Penalties in the range of \$1,500 up to \$8,500, as adjusted annually under 45 CFR part 102, per day of noncompliance are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy but is directly related to poor quality patient care outcomes.

(5) *Lower range of penalty.* Penalties in this range of \$500 to \$4,000, as adjusted annually under 45 CFR part 102, are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy and that are related predominately to structure or process-oriented conditions rather than directly related to patient care outcomes.

(6) *Per instance penalty.* Penalty imposed per instance of noncompliance may be assessed for one or more singular events of condition-level deficiency that are identified and where the noncompliance was corrected during the onsite survey. When penalties are imposed for per instance of noncompliance, or more than one per instance of noncompliance, the penalties will be in the range of \$1,000 to \$10,000 per instance, not to exceed \$10,000 each day of noncompliance, as adjusted annually under 45 CFR part 102.

(7) *Decreased penalty amounts.* If the immediate jeopardy situation is removed, but a condition-level deficiency exists, CMS shifts the penalty amount imposed per day from the upper range to the middle or lower range. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

(8) *Increased penalty amounts.* (i) In accordance with paragraph (b)(2) of this section, CMS increases the per day penalty amount for any condition-level deficiency or deficiencies which, after imposition of a lower-level penalty amount, become sufficiently serious to pose potential harm or immediate jeopardy.

(ii) CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower-level penalty amount was previously imposed.

(iii) CMS may impose a more severe amount of penalties for repeated noncompliance

with the same condition-level deficiency or uncorrected deficiencies from a prior survey.

(c) *Procedures*—(1) *Notice of intent*. CMS provides the hospice program with written notice of the intent to impose a civil money penalty in accordance with § 488.1210(e).

(2) *Appeals*—(i) *Appeals procedures*. A hospice program may request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The request must meet the requirements in § 498.40 of this chapter.

(ii) *Waiver of a hearing*. A hospice program may waive the right to a hearing, in writing, within 60 calendar days from the date of the notice imposing the civil money penalty. If a hospice program timely waives its right to a hearing, CMS reduces the penalty amount by 35 percent, and the amount is due within 15 calendar days of the hospice program agreeing in writing to waive the hearing. If the hospice program does not waive its right to a hearing in accordance to the procedures specified in this section, the civil money penalty is not reduced by 35 percent.

(d) *Accrual and duration of penalty*—(1) *Accrual of per day penalty*. (i) The per day civil money penalty may start accruing as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance, as determined by CMS.

(ii) A civil money penalty for each per instance of noncompliance is imposed in a specific amount for that particular deficiency, with a maximum of \$10,000 per day per hospice program.

(2) *Duration of per day penalty when there is immediate jeopardy*. (i) In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy is not removed.

(ii) A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the hospice program achieves substantial compliance, whichever occurs first.

(3) *Duration of penalty when there is no immediate jeopardy*. (i) In the case of

noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice of intent specified in paragraph (c)(1) of this section and an additional period of no longer than 6 months following the last day of the survey.

(ii) If the hospice program has not achieved compliance with the conditions of participation within 6 months following the last day of the survey, CMS terminates the provider agreement. The accrual of civil money penalty stops on the day the hospice program agreement is terminated or the hospice program achieves substantial compliance, whichever is earlier.

(e) *Computation and notice of total penalty amount.* (1) When a civil money penalty is imposed on a per day basis and the hospice program achieves compliance with the conditions of participation as determined by a revisit survey, once the administrative determination is final, CMS sends a final notice to the hospice program containing of the following information:

- (i) The amount of penalty assessed per day.
- (ii) The total number of days of noncompliance.
- (iii) The total amount due.
- (iv) The due date of the penalty.
- (v) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(2) When a civil money penalty is imposed per instance of noncompliance, once the administrative determination is final, CMS sends a final notice to the hospice program containing all of the following information:

- (i) The amount of the penalty that was assessed.
- (ii) The total amount due.
- (iii) The due date of the penalty.
- (iv) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(3) In the case of a hospice program for which the provider agreement has been involuntarily terminated, CMS sends the final notice after one of the following actions has occurred:

(i) The administrative determination is final.

(ii) The hospice program has waived its right to a hearing in accordance with paragraph (c)(2)(ii) of this section.

(iii) Time for requesting a hearing has expired and the hospice program has not requested a hearing.

(f) *Due date for payment of penalty.* A penalty is due and payable 15 calendar days from notice of the final administrative decision.

(1) Payments are due for all civil money penalties within 15 calendar days of any of the following:

(i) After a final administrative decision when the hospice program achieves substantial compliance before the final decision or the effective date of termination occurs before the final decision.

(ii) After the time to appeal has expired and the hospice program does not appeal or fails to timely appeal the initial determination.

(iii) After CMS receives a written request from the hospice program requesting to waive its right to appeal the determinations that led to the imposition of a remedy.

(iv) After the effective date of termination.

(2) A request for hearing does not delay the imposition of any penalty; it only potentially delays the collection of the final penalty amount.

(3) If a hospice program waives its right to a hearing according to paragraph (c)(2)(ii) of this section, CMS applies a 35 percent reduction to the CMP amount for any of the following:

(i) The hospice program achieved compliance with the conditions of participation before CMS received the written waiver of hearing.

(ii) The effective date of termination occurs before CMS received the written waiver of hearing.

(4) The period of noncompliance may not extend beyond 6 months from the last day of the survey.

(5) The amount of the penalty, when determined, may be deducted (offset) from any sum then or later owing by CMS or State Medicaid to the hospice program.

(6) Interest is assessed and accrues on the unpaid balance of a penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(g) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, may not do any of the following:

(1) Set a penalty of zero or reduce a penalty to zero.

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty.

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

§ 488.1250 Directed plan of correction.

(a) *Application.* CMS may impose a directed plan of correction when a hospice program--

(1) Has one or more condition-level deficiencies that warrant directing the hospice program to take specific actions; or

(2) Fails to submit an acceptable plan of correction.

(b) *Procedures.* (1) Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) CMS or the temporary manager (with CMS approval) may direct the hospice program to take corrective action to achieve specific outcomes within specific timeframes.

(c) *Duration and effect of remedy.* If the hospice program fails to achieve compliance

with the conditions of participation within the timeframes specified in the directed plan of correction, which may not to exceed 6 months, CMS does one of the following:

- (1) May impose one or more other remedies set forth in § 488.1220.
- (2) Terminates the provider agreement.

§ 488.1255 Directed in-service training.

(a) *Application.* CMS may require the staff of a hospice program to attend in-service training program(s) if CMS determines all of the following:

- (1) The hospice program has condition-level deficiencies.
- (2) Education is likely to correct the deficiencies.
- (3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare hospice providers, or as deemed acceptable by CMS or the State (by review of a copy of curriculum vitas or resumes and references to determine the educator's qualifications).

(b) *Procedures—(1) Notice of intent.* Before imposing the remedy in paragraph (a) of this section, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) *Action following training.* After the hospice program staff has received in-service training, if the hospice program has not achieved substantial compliance, CMS may impose one or more other remedies specified in § 488.1220.

(3) *Payment.* The hospice program pays for the directed in-service training for its staff.

§ 488.1260 Continuation of payments to a hospice program with deficiencies.

(a) *Continued payments.* CMS may continue payments to a hospice program with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) *Criteria.* CMS may continue payments to a hospice program not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) An enforcement remedy, or remedies, has been imposed on the hospice program and termination has not been imposed.

(ii) The hospice program has submitted a plan of correction approved by CMS.

(iii) The hospice program agrees to repay the Federal Government payments received under this paragraph (a) if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) *Termination.* CMS may terminate the hospice program's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments for new admissions.* If termination is imposed, either on its own or in addition to an enforcement remedy or remedies, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the hospice program will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) *Failure to achieve compliance with the conditions of participation.* If the hospice program does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS terminates the provider agreement of the hospice program in accordance with § 488.1265.

§ 488.1265 Termination of provider agreement.

(a) *Effect of termination by CMS.* Termination of the provider agreement ends—

(1) Payment to the hospice program; and

(2) Any enforcement remedy.

(b) *Basis for termination.* CMS terminates a hospice program's provider agreement under any one of the following conditions:

(1) The hospice program is not in compliance with the conditions of participation.

(2) The hospice program fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The hospice program fails to relinquish control to the temporary manager, if that

remedy is imposed by CMS.

(4) The hospice program fails to meet the eligibility criteria for continuation of payment as set forth in § 488.1260(a)(1).

(c) *Notice.* CMS notifies the hospice program and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) *Procedures for termination.* CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter.

(e) *Payment post termination.* Payment is available for up to 30 calendar days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination as set forth in § 489.55 of this chapter.

(f) *Appeal.* A hospice program may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

PART 489--PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

28. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

29. Section 489.28 is amended by revising paragraphs (d) and (e) to read as follows:

§ 489.28 Special capitalization requirements for HHAs.

* * * * *

(d) *Required proof of availability of initial reserve operating funds.* The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, will include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution (if the financial institution offers such attestations) that the funds are in the account(s) and that the funds are immediately available to the HHA. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are

readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds. As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS later may require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds is non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

(e) *Borrowed funds.* If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution (if the financial institution offers such attestations) that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

* * * * *

§ 489.53 [Amended]

30. Section 489.53 is amended in paragraph (a)(17) by removing the phrase "an HHA," and adding in its place the phrase "an HHA or hospice program,".

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

31. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

32. Section 498.1 is amended by adding paragraph (l) to read as follows:

§ 498.1 Statutory basis.

* * * * *

(l) Section 1822 of the Act provides that for hospice programs that are no longer in compliance with the conditions of participation, the Secretary may develop remedies to be imposed instead of, or in addition to, termination of the hospice program's Medicare provider agreement.

33. Section 498.3 is amended—

- a. By revising paragraph (b)(13);
- b. In paragraph (b)(14) introductory text by removing the phrase "NF, or HHA but only" and adding in its place the phrase "NF, HHA, or hospice program, but only";
- c. By revising paragraph (b)(14)(i); and
- d. In paragraph (d)(10) introductory text by removing the phrase "NF, or HHA—" and adding in its place the phrase "NF, HHA, or hospice program—".

The revisions read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(13) Except as provided at paragraph (d)(12) of this section for SNFs, NFs, HHAs, and hospice programs, the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406, § 488.820, or § 488.1170 of this chapter, but not the determination as to which sanction or remedy was imposed. The scope of review on the imposition of a civil money penalty is specified in § 488.438(e), § 488.845(h), or § 488.1195(h) of this chapter.

(14) * * *

(i) The range of civil money penalty amounts that CMS could collect (for SNFs or NFs, the scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter and for HHAs and hospice programs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in §§ 488.845(h) and 488.1195(h) of this chapter); or

* * * * *

§ 498.60 [Amended]

34. Section 498.60 is amended--

a. In paragraph (c)(1) by removing the reference "§§ 488.438(e) and 488.845(h)" and adding in its place the reference "§§ 488.438(e), 488.845(h), and 488.1195(g)".

b. In paragraph (c)(2) by removing the phrase "or HHA" and adding in its place the phrase "HHA, or hospice program".

Dated: October 29, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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