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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 414, 422, 423, 424, 484, and 498

[CMS-1844-F]

RIN 0938-AV80

Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies

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

ACTION: Final rule.

SUMMARY: This final rule sets forth routine updates to the Medicare home health payment rates in accordance with existing statutory and regulatory requirements. In addition, this final rule discusses the behavior adjustments and finalizes a temporary behavior adjustment. It also finalizes the recalibrated case-mix weights and updated functional impairment levels; comorbidity subgroups; and low-utilization payment adjustment (LUPA) thresholds for CY 2027. Additionally, this final rule discusses and responds to comments on the provision of home health palliative care services and includes a summary of comments received on the request for information (RFI) on a home health specific wage index included in the proposed rule.

This rule also finalizes changes to the Home Health Quality Reporting Program (HH QRP) and summarizes potential initiatives to improve alignment between the HH QRP and expanded Home Health Value-Based Purchasing (HHVBP) Model.

Lastly, the rule clarifies the application of the DMEPOS face-to-face encounter requirements for the replacement of DMEPOS items; makes changes to the provider and supplier

enrollment requirements; makes changes to implement a DME benefit expansion for infusion pumps and drugs; and discusses collection of information requirement changes regarding the DMEPOS Competitive Bidding Program (CBP) country of origin.

DATES: With the exception of the HH PPS and HH QRP provisions specified in sections II. and III. of this final rule and the regulatory changes at 42 CFR 484.245, these regulations are effective on [insert 60 days after date of filing for public inspection at the **Federal Register**]. The HH PPS and HH QRP provisions specified in sections II. and III. of this final rule and the regulatory changes at 42 CFR 484.245 are effective January 1, 2027.

FOR FURTHER INFORMATION CONTACT:

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

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

For more information about the expanded Home Health Value-Based Purchasing (HHVBP) Model, please visit the Expanded HHVBP Model webpage at https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model or send your inquiry via email to HHVBPquestions@cms.hhs.gov.

Nancy Allert (410) 786-4317, Jennifer Phillips (410) 786-1023, Olufemi Shodeke (410) 786-1649, Misty Whitaker (410) 786-4975, for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Encounter Requirements for Identical Replacement Items.

Frank Whelan (410) 786-1302, for Medicare provider and supplier enrollment and DMEPOS accreditation.

For more information about the DME Benefit Expansion for Infusion Pumps and Drugs, send your inquiry via email to DMEPOS@cms.hhs.gov.

Austin Gutowski, (410) 786-1643, for DME Competitive Bidding Program--Country of Origin and Technical Corrections.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose and Legal Authority

1. Home Health Prospective Payment System (HH PPS)

As required under section 1895(b) of the Social Security Act (the Act), this final rule updates the CY 2027 Medicare payment rates for home health agencies (HHAs). In this final rule, we include an analysis of home health utilization, as well as analysis of the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments as a result of the change in the unit of payment to 30 days and the implementation of the Patient Driven Groupings Model (PDGM) case-mix adjustment methodology. This final rule also discusses the permanent adjustments applied in previous years and finalizes a temporary adjustment to the CY 2027 home health base payment rate. In addition, this rule recalibrates the PDGM case-mix weights and updates the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups under sections 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2027. This final rule updates the CY 2027 fixed-dollar loss (FDL) ratio for outlier payments (so that outlier payments as a percentage of estimated total payments are projected not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act).

Additionally, this rule responds to comments received on the discussion of the provision of palliative care services under the Medicare home health benefit and summarizes public comments received on the request for information (RFI) regarding the construction of a home health specific wage index.

2. Home Health (HH) Quality Reporting Program (QRP)

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are finalizing updated quality reporting policies. First, we summarize potential initiatives to improve alignment between the HH QRP and expanded HHVBP Model. We also finalize revisions to the

HH QRP data submission deadlines beginning with the CY 2027 HH QRP. We also revise the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We also finalize revisions to the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We finalize some revisions to regulatory text in support of rule proposals and to improve digital transfer of information during the reconsiderations process. Finally, we summarize the public comments received in response to a Request for Information (RFI) on future measure concepts for the HH QRP.

3. Expanded Home Health Value-Based Purchasing (HHVBP) Model

We did not propose any expanded HHVBP Model-specific policy changes in the CY 2027 HH PPS proposed rule. However, we have included a brief summary of the Model with context relevant to a potential alignment between the HH QRP and the expanded HHVBP Model.

4. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Encounter Requirements for Identical Replacement Items

We are finalizing clarifications regarding the application of the DMEPOS face-to-face encounter requirements, as outlined in 42 CFR 410.38, and the related documentation necessary to support the replacement of DMEPOS items. We do not believe it necessary to require an additional in-depth beneficiary examination to "gather[] subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered" for replacement items. Such information should be recorded when the beneficiary is initially assessed and receives the item, and the practitioner should only write replacement orders for beneficiaries with an ongoing medical need for the item(s). Therefore, we are finalizing our proposal that an additional face-to-face encounter within the 6 months preceding an order/prescription for replacement of a DMEPOS item will not be required per 42 CFR 410.38. We clarify that for purposes of 42 CFR 410.38(d)(2), a "replacement" refers to the provision of

an item that replaces an item falling under the same Healthcare Common Procedure Coding System (HCPCS) code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition.

5. Provider Enrollment and DMEPOS Accreditation

Consistent with section 1866(j) of the Act, we are finalizing a number of Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) adding grounds for denying or revoking a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe will assist in protecting the Trust Funds and Medicare beneficiaries.

We also are finalizing several minor changes to our DMEPOS accreditation provisions in § 424.58, such as a timeframe by which an accrediting organization must report suspected fraud, waste, and abuse to CMS. We believe these changes will help improve the DMEPOS accreditation program's efficiency.

6. Durable Medical Equipment (DME) Benefit Expansion for Infusion Pumps and Drugs

We are finalizing changes to the Medicare Part B definition of DME at 42 CFR 414.202 to implement amendments made to the definition of DME at section 1861(n) of the Act by section 6222(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026), expanding the scope of the benefit for DME to include certain external infusion pumps and associated home infusion drugs or other associated supplies. The legal authority for this final rule is provided by section 1861(n) of the Act, as amended by section 6222(a) of the CAA, 2026, and section 1871 of the Act.

7. DMEPOS Competitive Bidding Program--Country of Origin

We discuss requesting to revise the DMEPOS Competitive Bidding Program (CBP) information collection under Office of Management and Budget (OMB) Control Number

0938-1408 (CMS-10744) to require DMEPOS CBP contract suppliers to report the country of origin for the lead items furnished during the contract's period of performance. This information will allow beneficiaries and interested parties to learn where the DMEPOS item originated, if interested.

8. DMEPOS Competitive Bidding Program—Technical Corrections

We discuss technical corrections that need to be made to § 414.414(d) based on a regulations text error in the CY 2026 HH PPS final rule.

B. Summary of the Provisions of the Final Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this final rule, we discuss the permanent behavior adjustment and finalize a temporary adjustment to the base payment rate under the HH PPS.

In section II.C. of this final rule, we finalize the recalibrated CY 2027 PDGM case-mix weights and updated low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups.

In section II.D. of this final rule, we finalize updates to the home health wage index. We also finalize updates to the CY 2027 national, standardized 30-day period payment rates and the CY 2027 national per-visit payment amounts by the home health payment update percentage. Additionally, this rule finalizes the CY 2027 fixed dollar loss (FDL) ratio to ensure that aggregate outlier payments are projected not to exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.E. of this final rule, we discuss and respond to comments on the provision of palliative care services under the Medicare home health benefit.

In section II.F. of this final rule, we summarize comments received on the request for information (RFI) on the construction of a home health specific wage index.

2. Home Health Quality Reporting Program (HH QRP)

In section III.D. of this final rule, we summarize potential initiatives to improve alignment between the HH QRP and expanded HHVBP Model.

In section III.E. of this final rule, we are finalizing as proposed to revise the HH QRP data submission deadlines beginning with the CY 2027 HH QRP.

We also are finalizing our proposed revisions to the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). Additionally, we are finalizing as proposed some revisions to regulatory text in support of rule proposals or to improve digital transfer of information during the reconsiderations process.

In section III.F. of this final rule, we discuss the public comments received in response to our request for information (RFI) on future measure concepts for the HH QRP.

3. Expanded Home Health Value Based Purchasing (HHVBP) Model

In section IV. of this final rule, we summarize the expanded HHVBP Model with context relevant to a potential alignment between the HH QRP and expanded HHVBP Model. We did not propose any expanded HHVBP Model-specific changes in the CY 2027 HH PPS proposed rule.

4. DMEPOS Encounter Requirements for Identical Replacement Items

In section V.B. of this final rule, we are finalizing a clarification that while an order would continue to be required for replacement of DMEPOS items, a new face-to-face encounter would not need to occur to support payment for these DMEPOS items.

5. Provider Enrollment and DMEPOS Accreditation

In section V.C. of this final rule, we discuss a number of finalized Medicare provider enrollment provisions designed to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited to, the following:

- Adding grounds for denying or revoking a provider's or supplier's Medicare enrollment.

- Expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations.

- CMS can currently impose a reapplication bar of up to 10 years if the provider or supplier is denied enrollment for submitting false or misleading information on or with their enrollment application. (This means they cannot reapply to Medicare for up to 10 years.) We are expanding this to permit a reapplication bar regardless of the denial reason.

We believe these revisions will help keep unqualified providers and suppliers out of the Medicare program, which, in turn will prevent improper Medicare payments to such parties.

We also are finalizing several minor changes to our DMEPOS accreditation provisions in § 424.58, such as a timeframe by which an accrediting organization must report suspected fraud, waste, or abuse to CMS. We believe these changes will help improve the DMEPOS accreditation program's efficiency.

6. DME Benefit Expansion for Infusion Pumps and Drugs

In section V.D. of this final rule, we finalize a modification to the definition of "durable medical equipment" at 42 CFR 414.202 to implement section 6222(a) of the CAA, 2026 by providing that certain external infusion pumps, associated home infusion drugs, or other associated supplies are treated as meeting the "appropriate for use in the home" requirement when specified statutory criteria are satisfied.

7. DMEPOS Competitive Bidding Program--Country of Origin

In sections V.E. and VI.B.5. of this final rule, we plan to request a revision to the collection currently approved under OMB Control Number 0938-1408 (CMS-10744) to collect from DMEPOS CBP contract suppliers the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance.

As done historically with the product information reported on Form C by a DMEPOS CBP contract supplier, the reported country of origin information would be populated in the Medicare Supplier Directory for the contract supplier during the contract period of performance.

8. DMEPOS Competitive Bidding Program—Technical Corrections

In section V.F. of this final rule, we discuss the technical corrections to the provisions at §414.414(d) regarding the covered document review date that were finalized in the CY 2026 HH PPS final rule.

C. Summary of the Regulatory Impact Analysis

TABLE 1: SUMMARY OF ECONOMIC COSTS AND TRANSFERS, BY FINAL PROVISION

Provision Description	Costs and Cost Savings	Transfers	Other Notes
CY 2027 HH PPS Payment Rate Update		The overall economic impact related to the finalized changes in payments under the HH PPS for CY 2027 is estimated to be $415 million (2.4 percent). The $415 million increase in estimated payments for CY 2027 reflects the effects of the CY 2027 final home health payment update percentage of 2.1. percent ($365 million increase), and an estimated 0.3 percent increase that reflects the effects of an updated FDL ($50 million increase).	To ensure that home health payments are consistent with statutory payment authority for CY 2027.
HH QRP	There are no anticipated changes to burden related to the HH QRP proposals.		
Expanded HHVBP Model		The overall economic impact of the expanded HHVBP Model for CYs 2023 through 2027 is an estimated $3.376 billion in total savings to fee-for-service (FFS) Medicare from a reduction in unnecessary hospitalizations and skilled nursing facility (SNF) usage as a result of greater quality improvements in the home health industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to HHAs competing in the expanded HHVBP Model.	
DMEPOS Encounter Requirements for Identical Replacement Items			The fiscal impact of this proposed clarification cannot be estimated as it only identifies whether a face-to-face encounter is required for payment for replacement of DMEPOS items.
Provider Enrollment and DMEPOS Accreditation	We project an annual cost of approximately $1.4 million to conduct the State surveys or accreditations for reactivating hospices. We project a total cost of $46.8 million over the first three years of this rule (or $15.6 million per year) for providers and suppliers to comply with the signage requirement in § 424.510(f).	We estimate an annual transfer from Medicare providers and suppliers to the federal government of approximately $82 million. This will stem from our expansion of the grounds for which we can retroactively revoke providers and suppliers.	
DME Benefit Expansion for Infusion Pumps and Drugs		The expansion is estimated to result in net savings to Medicare of approximately $800,000 per year.	Beneficiaries may be able to choose to receive additional drugs via home infusion that are currently only available in an outpatient healthcare setting.
DMEPOS Competitive Bidding Program--Country of Origin	We anticipate a minimal financial impact for DMEPOS contract suppliers as we believe they will be familiar with the DMEPOS they provide and should be able to identify the country of origin based on the markings on the product or by obtaining documentation from the manufacturer. The estimated burden estimates for DMEPOS contract suppliers are included in the COI section.		

Provision Description	Costs and Cost Savings	Transfers	Other Notes
DMEPOS Competitive Bidding Program—Technical Corrections	There are no costs or savings associated with these technical corrections.		

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)(A) of the Act requires that, in defining a prospective payment amount, the Secretary shall 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), we issued a final rule which appeared in the July 3, 2000, **Federal Register** (65 FR 41128) to implement the HH PPS legislation.

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 home health payment update percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. Pursuant to section 1895(b)(3)(B)(v)(I) of the Act, 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 issued 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 annually to 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.

Division FF, section 4136 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328) amended section 1834(s)(3)(A) of the Act to require that, beginning with 2024, the separate payment for furnishing negative pressure wound therapy (NPWT) be for just the device and not for nursing and therapy services. Payments for nursing and therapy services are to be included as part of payments under the HH PPS. The separate payment for 2024 was required to be equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (as of January 1, 2022) for the applicable disposable device updated by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U). The separate payment for 2025 and each subsequent year is to be the payment amount for the previous year updated by the percentage increase in the CPI-U (United States city average) for the 12-month period ending in June of the previous year reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act for such year. The CAA, 2023 also added section 1834(s)(4) of the Act to require that beginning with 2024, as part of submitting claims for the separate payment, the Secretary shall accept, and process claims

submitted using the type of bill that is most commonly used by HHAs to bill services under a home health plan of care.

2. Current System for Payment of Home Health Services

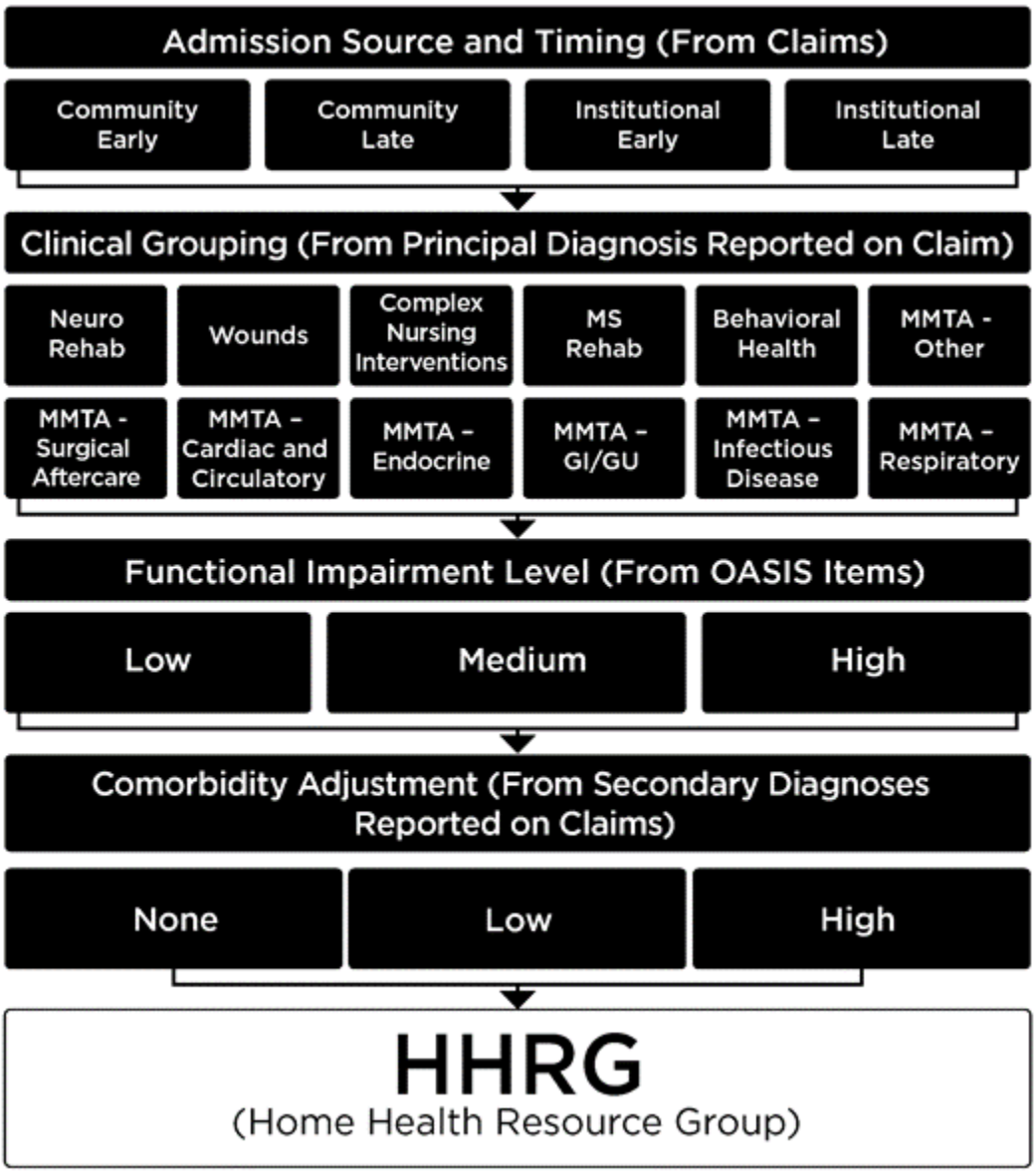
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The 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 also part of the national, standardized 30-day period rate. Durable medical equipment (DME) provided as a home health service, as defined in section 1861(m)(5) 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. Additionally, the 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and disposable negative pressure wound therapy (dNPWT) devices, but such drugs and devices must be billed by the HHA while a patient is under a home health plan of care, as the law requires separate consolidated billing of certain osteoporosis drugs and dNPWT devices.

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, including the removal of therapy thresholds, 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 if 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 SE20005 available at https://www.cms.gov/regulations-and-guidanceguidancetransmittals2020-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) 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. 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 through 70305) for further information.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



Notes: MMTA (Medication Management, Teaching and Assessment), MS (Musculoskeletal), GI (Gastrointestinal tract), GU (Genitourinary system)

B. CY 2027 Payment Adjustments Under the HH PPS

1. Behavior Adjustments Under the HH PPS

a. Background

As discussed in section II.A.1. of this final rule, starting in CY 2020, the Secretary was required by section 1895(b)(2)(B) of the Act to change the unit of payment under the HH PPS from a 60-day episode of care to a 30-day period of care. CMS was also required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-

day unit of payment and the case-mix adjustment factors that eliminated the use of therapy thresholds. In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior change assumptions which were also described in the CY 2022 and 2023 HH PPS rules (86 FR 35890, 87 FR 37614, and 87 FR 66795 through 66796). In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we included these behavior change assumptions in the calculation of the 30-day budget neutral payment amount for CY 2020, finalizing a negative 4.36 percent behavior change assumption adjustment ("assumed behaviors"). We did not propose any changes for CYs 2021 and 2022 related to the behavior change assumptions finalized in the CY 2019 HH PPS final rule with comment period, or to the negative 4.36 percent behavior change assumption adjustment, finalized in the CY 2020 HH PPS final rule with comment period.

In the CY 2023 HH PPS final rule (87 FR 66796), we stated that we had concluded, based on our annual monitoring at that time, that the three expected behavior changes did in fact occur as a result of the implementation of the PDGM and that other behaviors, such as changes in the provision of therapy and changes in functional impairment levels, had also occurred. We also reminded readers that in the CY 2020 HH PPS final rule with comment period (84 FR 60513), we stated that we interpret actual behavior changes to encompass behavior changes that were previously outlined as assumed by CMS, and other behavior changes not identified at the time we established the budget-neutral 30-day payment rate for CY 2020. In the CY 2023 HH PPS final rule (87 FR 66796), we provided supporting evidence that indicated the number of therapy visits declined in CYs 2020 and 2021, as well as a slight decline in therapy visits beginning in CY 2019 after the finalization of the removal of therapy thresholds, but prior to implementation of the PDGM. In section II.B.1. of the CY 2025 HH PPS proposed rule (89 FR 55318), our analysis continued to show the actual 30-day periods are similar overall to the simulated 30-day periods as well as a continued decline in therapy visits, indicating that HHAs changed their behavior to reduce therapy visits. Although the analysis demonstrates evidence of

individual behavior changes (for example, in the volume of visits for LUPAs, therapy sessions, etc.), we use the entirety of the behaviors to calculate estimated aggregate expenditures. The law instructs us to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been made under the prior system.

Section 4142(a) of the CAA, 2023 required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020 through 2026. This subsection of the CAA, 2023 also required CMS to provide datasets underlying the simulated 60-day episodes and discuss and provide time for stakeholders to provide input on and ask questions about the payment rate development for CY 2023. CMS complied with these requirements by posting online both the supplemental limited data set (LDS) and descriptive files and the description of actual behavior changes that affected CY 2023 payment rate development. Additionally, on March 29, 2023, CMS conducted a webinar entitled "Medicare Home Health Prospective Payment System (HH PPS) Calendar Year (CY) 2023 Behavior Change Recap, 60-Day Episode Construction Overview, and Payment Rate Development." The webinar was open to the public and discussed the actual behavior changes that occurred upon implementation of the PDGM; our approach used to construct simulated 60-day episodes using 30-day periods; payment rate development for CY 2023; and information on the supplemental data files containing information on the simulated 60-day episodes and actual 30-day periods used in calculating the permanent adjustment to the payment rate. Materials from the webinar, including the presentation and the CY 2023 descriptive statistics from the supplemental LDS files containing information on the number of simulated 60-day episodes and actual 30-day periods in CY 2021 that were used to construct the permanent adjustment to the payment rate, as well as information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments, can be found on the Home Health Patient-Driven Groupings Model web page at *https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-patient-driven-groupings-model*.

b. Method to Annually Determine the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Expenditures

In the CY 2023 HH PPS final rule (87 FR 66804), we finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures. In the CY 2024 HH PPS final rule (88 FR 77687 through 77688), we provided an overview of the methodology with detailed instructions for each step of the calculation.

Under the prior 153-group system (and the first 3 years for assessments associated with the PDGM completed prior to CY 2023), HHAs submitted the Outcome and Assessment Information Set (OASIS) instrument version D. However, OMB approved an updated version of the OASIS instrument, OASIS-E, under OMB control number 0938-1279,[1]on November 30, 2022, effective January 1, 2023. Therefore, in the CY 2025 HH PPS final rule (89 FR 88364), we finalized two additional methodological assumptions related to mapping and imputation of OASIS-D responses from OASIS-E. We refer readers to the CY 2024 and CY 2025 HH PPS final rules for further information about the methodology.

c. Calculating Permanent and Temporary Payment Adjustments

To adjust the base payment rate based on increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes for 2020 through 2026, we calculate one or more permanent prospective adjustments by calculating the percent change between the actual 30-day base payment rate and the recalculated 30-day base payment rate. This percent change is converted into an adjustment factor and applied in the annual rate update process.

To account for increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes from 2020 through 2026, we calculate one or more temporary prospective adjustments by calculating the dollar

[1] The current expiration date for this information collection request is December 31, 2027.

amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for each of those years once data is available (87 FR 66804). In other words, when determining the dollar amount of aggregate expenditures in prior years that we must offset in future years, we use the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. In accordance with section 1895(b)(3)(D)(iii) of the Act, each temporary adjustment is applied prospectively but, as its name suggests, only with respect to the year for which such temporary increase or decrease is made.

Therefore, after we determine the dollar amount we plan to reconcile in a given year, we calculate a temporary adjustment factor to be applied to the base payment rate for that year. The temporary adjustment factor is based on an estimated number of 30-day periods in the next year using historical data trends, and as applicable, controls for any permanent adjustment factor, case-mix weight recalibration neutrality factor, wage index budget neutrality factor, and the home health payment update. The temporary adjustment factor is applied last since the adjustment applies only to the respective year. That is, the temporary adjustment is not permanently fixed into future base payment rates. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims, the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims, and the CY 2026 HH PPS final rule (90 FR 55365 through 55367) for analysis of CY 2024 claims.

d. CY 2025 Final Claims Results

We stated in the CY 2026 HH PPS final rule (90 FR 55365) that we were exercising our authority expressly delegated under the statute to apply permanent adjustments “at a time and in a manner appropriate” not to apply any permanent adjustment for CY 2026 based on CY 2023 or 2024 data, as these years may contain data with behaviors attributable to factors beyond the implementation of the PDGM and a 30-day unit of payment. However, we also noted we will

continue to annually analyze the data through CY 2026 claims, as required by law, to determine if any additional permanent adjustments would need to be made based on the impact of assumed versus actual behavior change on estimated aggregate expenditures resulting from the implementation of the PDGM and the 30-day unit of payment. While the law requires us to continue to evaluate the need for any additional permanent adjustments in future rulemaking, we reiterate that any additional permanent adjustment(s) would need to be related to actual behavior change resulting only from the implementation of the PDGM and the change in the unit of payment as required by law. Therefore, we will continue to compare estimated aggregate expenditures under the PDGM and the 153-group payment system, using the most recent complete home health claims data available at the time of rulemaking, as required by section 1895(b)(3)(D)(i) of the Act. The CY 2027 HH PPS final rule uses the complete CY 2025 data to determine any permanent and temporary adjustments needed to the CY 2027 payment rate. However, while the claims data and the permanent and temporary adjustments results are considered complete for CY 2027, any adjustments to future payment rates may be subject to additional considerations such as permanent adjustments taken in previous years.

The claims data used in rulemaking is released in the HH PPS LDS file twice each year, one with the proposed and one with the final rule. Accordingly, the HH PPS LDS file released with this final rule includes two files: the actual CY 2025 30-day periods and the CY 2025 simulated 60-day episodes.

We remind readers that a data use agreement (DUA) is required to purchase the CY 2027 final HH PPS LDS file using the CMS-R-0235A form under OMB control number 0938-0734. Access would be granted for both the 30-day periods and the simulated 60-day episodes under one DUA. Visit the HH PPS LDS web page for more information.[2] In addition, the final CY 2027 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH

[2] *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.*

PPS Regulations and Notices web page,[3] does not require a DUA and is available at no cost to interested parties. The spreadsheet contains information on the number of simulated 60-day episodes and actual 30-day periods in CY 2025 that were used to determine the adjustments. The spreadsheet also provides information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments.

e. Applying the Methodology to CY 2025 Data to Determine the CY 2027 Permanent and Temporary Adjustments

To comply with Section 1895(b)(3)(D)(ii) of the Act, we are required to annually analyze data from CY 2020 through CY 2026 and show the calculations to illustrate how the aggregate expenditures differ from actual and assumed behavior changes. We also continue to analyze differences in aggregate expenditures and calculate what the budget neutral rate would be to understand how the budget neutral rate differs from the actual finalized payment rate for CY 2025. We then determine whether the difference between the budget neutral rate and actual finalized payment rate can be directly attributed to behavior from PDGM implementation as discussed in CY 2026 HH PPS final rule.

Using the methodology finalized in the CY 2023 HH PPS final rule to apply for all the years in which an adjustment is appropriate, we continue to use actual CY 2025 30-day periods to determine what the final permanent and temporary payment adjustments should be to offset for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes. We provide tables 2 and 3 to illustrate the same information displayed in prior rules to show the permanent adjustment that would need to be applied if the comparison of the aggregate expenditures was a result of behavior change due to the implementation of the PDGM. However, similar to what was finalized in the CY 2026 HH PPS final rule (90 FR 55364 through 55365), we believe any

[3] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.

behavior changes reflected in the final CY 2025 claims for this CY 2027 final rule are not directly attributable to the PDGM but other confounding factors related to policy changes that began in CY 2023 (that is, continued recalibration of case-mix weights, a change to the OASIS-E, and previous reductions to the home health payment rate). The permanent adjustment calculated will be illustrative as part of our analysis of CY 2025 claims; however, we did not propose to apply a permanent adjustment to the CY 2027 payment rate, as discussed previously. We provide table 4 as another illustrative example showing a calculated permanent adjustment, using CY 2025 aggregate expenditures if we were to determine that the behavior changes that occurred could be directly attributed to the implementation of the PDGM.

Using the final CY 2025 dataset, we began with 8,382,176 30-day periods of care and dropped 491,954 30-day periods of care that had a claim occurrence code 50 date after October 31, 2025. We also excluded 847,742 30-day periods of care that had a claim occurrence code 50 date before January 1, 2025, to ensure the 30-day period will not be part of a simulated 60-day episode that began in CY 2024. Applying the additional exclusions and assumptions as described in the finalized methodology (87 FR 66804), an additional 61,147 30-day periods were excluded. Additionally, we excluded 319,999 simulated 60-day episodes of care where no OASIS information was available in the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC), a recent start of care/resumption of care (SOC/ROC) OASIS was not available, a wage index was not available, or the episode could not be grouped to a Health Insurance Prospective Payment System (HIPPS) code due to a missing primary diagnosis or other reason.

Using the final dataset for CY 2025 (6,661,334 actual 30-day periods which made up the 3,917,201 simulated 60-day episodes) we determined the estimated aggregate expenditures using the finalized CY 2025 HH PPS payment rate were lower than the actual estimated aggregate expenditures under the PDGM HH PPS. As shown in table 2, aggregate expenditures under the PDGM were higher than if the 153-group payment system were still in place in CY 2025 and

therefore, we determined the CY 2025 30-day base payment rate should have been $1,959.08 based on actual behavior changes.

We determined that for CYs 2020 through CY 2022 a total of −9.480 percent permanent adjustment was needed (after accounting for the −3.925 percent applied to the CY 2023 payment rate, the −2.890 percent applied to the CY 2024 payment rate, and the −1.975 percent applied to the CY 2025 payment rate). The CY 2026 permanent adjustment was calculated using the permanent adjustments already applied to CYs 2023, 2024, and 2025 finalized payment rates and to reach the payment rate reduction needed for CYs 2020 through 2022.

In order to determine behavior changes only applicable to CY 2025, we simulated what the CY 2025 base payment rate would have been if the −1.023 percent adjustment that we determined using CY 2024 claims had been implemented and to compare PDGM claims with 153-group priced claims using 60-day simulated episodes.

To do so, we started with the budget neutral CY 2024 base payment of $1,914.73 generated by CY 2024 simulated 60-day episodes (as published in the CY 2026 HH PPS final rule (90 FR 55366)) and applied the CY 2025 case-mix weights recalibration neutrality factor (1.0039), the CY 2025 wage index budget neutrality factor (0.9988), the CY 2024 labor-related share budget neutrality factor (1.0), and the CY 2025 home health payment update factor (1.027). We determined the CY 2025 base payment rate for assumed behavior would have been $1,971.73.

For the CY 2025 annual permanent adjustment, we calculated the percent change between the two payment rates for only CY 2025. For the CY 2025 annual temporary adjustment we calculated the difference in aggregate expenditures in dollars for all CY 2025 PDGM 30-day claims using the two payment rates. This difference is shown as the retrospective dollar amount we would need to offset payment using one or more temporary adjustments in future years. Our results for the CY 2025 annual (single year) permanent and temporary adjustment calculations using CY 2025 final claims data are shown in table 2.

TABLE 2: ILLUSTRATIVE CY 2025 PERMANENT AND TEMPORARY ADJUSTMENT CALCULATIONS WHEN COMPARING PDGM CLAIMS USING SIMULATED 60-DAY EPISODES

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	CY 2025 Only Adjustment
Base Payment Rate	$1,971.73*	$1,959.08	**Permanent** -0.642%
Aggregate Expenditures	$ 16,957,268,010.43**	$ 16,237,591,241.69	**Temporary** -$ 719,676,768.74

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

*The $1,971.73 (shown in table 2) is equal to the recalculated budget neutral 30-day base payment rate of $1,914.73 for CY 2024 multiplied by the CY 2025 recalibration factor (1.0039), CY 2025 wage index budget neutrality factor (0.9988), CY 2025 labor-related share budget neutrality factor (1.0), and the CY 2025 home health payment update factor (1.027).

** The estimated aggregate expenditures for assumed behavior ($16.6 billion), uses the actual CY 2025 payment rate of $2,057.35 as finalized in the CY 2025 HH PPS final rule (89 FR 88424).

Table 2 illustrates that a permanent prospective adjustment of −0.642 percent to the CY 2027 30-day payment rate (assuming all adjustments from prior years were applied) for CY 2025 would be required to offset for such increases in estimated aggregate expenditures. Again, table 2 is illustrative because we are continuing to limit the calculation of the permanent adjustments to only include data from CYs 2020 through 2022 as finalized in the CY 2026 HH PPS final rule (90 FR 55365 through 55367) and the calculated permanent adjustment does not include implemented permanent adjustments from prior years. We reiterate that any additional permanent adjustment(s) must be determined to be related to actual behavior change resulting only from the implementation of the PDGM and the change in the unit of payment as required by law.

f. CY 2027 Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we describe how we analyzed CY 2025 final claims data to determine the effects of actual behavior change on estimated aggregate expenditures. Again, that illustrative analysis included simulations that assumed the full permanent adjustments were already taken. We note that CMS implemented a payment adjustment of −1.975 percent for the

CY 2025 payment rate, rather than the −3.95 percent we calculated (89 FR 88373), so the calculations set forth later in this section reflect the remaining adjustments that still needed to be recognized.

Therefore, the calculation in this section includes any of the remaining adjustments not applied in previous years (that is, CYs 2020 through 2024 claims data), as well as the adjustment needed to account for CY 2025 claims. In calculating the full permanent adjustment needed to the CY 2027 30-day payment rate, we compare estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 2, we do not assume we made the full adjustment from prior years. This section also includes calculation of a permanent adjustment using the actual CY 2025 payment rate and the budget neutral rate for CY 2025 using the method discussed in the CY 2026 HH PPS final rule.

As discussed in section II.B.1.e. of this final rule, using the final dataset for CY 2025 (6,661,334 actual 30-day periods which made up the 3,917,201 simulated 60-day episodes) we determined the CY 2025 30-day base payment rate should have been $1,959.08 based on actual behavior. We then compared the repriced 30-day base payment rate based on actual behavior to the CY 2025 30-day base payment rate of $2,057.35 we paid based on assumed behaviors. The percent change, as summarized in table 3, between the actual CY 2025 base payment rate of $2,057.35 (based on assumed behaviors) and the CY 2025 recalculated base payment rate of $1,959.08 (based on actual behaviors) illustrates the total permanent adjustment that would reflect CY 2020 through CY 2025 claims. We conduct this calculation to satisfy the requirements described in section 1895(b)(3)(D)(ii) of the Act to illustrate what the permanent adjustment would be. We consider table 3 illustrative because we are limiting the calculation of the permanent adjustments to only include data from CYs 2020 through 2022 as finalized in the CY 2026 HH PPS final rule (90 FR 55365 through 55367).

TABLE 3: ILLUSTRATIVE TOTAL PERMANENT ADJUSTMENT FOR CYs 2020 THROUGH 2025 CLAIMS

Actual CY 2025 Base Payment Rate (Assumed Behavior)	Recalculated CY 2025 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
$2,057.35	$1,959.08	-4.777%*

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

* This is the total permanent adjustment based on CY 2025 data which includes the previous permanent adjustment of -1.975% applied. However, as described later, we recognized that for CY 2027 we must also account for adjustment made in CY 2026.

As shown in table 3, a permanent prospective adjustment of −4.777 percent to the CY 2027 30-day payment rate would be required to offset for such increases in estimated aggregate expenditures. To illustrate this calculation:

$$\frac{(\$1{,}959.08 - \$2{,}057.35)}{\$2{,}057.35} = -4.777\ \%$$

As we stated in the CY 2026 HH PPS final rule (90 FR 55357), applying a −1.975 percent (half of the proposed −3.95 percent) permanent adjustment to the CY 2025 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures in CYs 2020, 2021, 2022, and 2023. Using CY 2025 claims data, as shown in table 3, a permanent prospective adjustment of −4.777 percent to the CY 2027 30-day payment rate would offset for increases in estimated aggregate expenditures for CYs 2020 through 2025. We note that adjustment factors are multiplied in this payment system, and individual numbers (that is, percentages) cannot be added or subtracted together to determine the final adjustment. Therefore, we cannot determine the illustrative CY 2027 permanent adjustment, which would include estimated aggregate expenditures in CY 2025, by simply subtracting the −1.975 percent applied in CY 2025 and the −1.023 percent applied in CY 2026 from the total permanent adjustment of −4.777 percent as shown in table 3.

Instead, we account for the permanent adjustment applied in prior years when we calculate the CY 2027 permanent adjustment by solving the following equation $(1 - 0.01023) \times (1 - x) = (1 - 0.04777)$.

To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1-0.04777}{1-0.01023}\right)$$

$$x = 1 - 0.96207$$

$x = 0.03793$ (that is, 3.793 percent)

We note that the −3.793 percent is calculated as a permanent adjustment for CY 2027 illustrating what we would need if we were to offset the difference in aggregate expenditures between CY 2025 claims priced under the PDGM and the 153-group system and adjusting for the permanent adjustments applied in prior years.

We continue to apply the methodology finalized in the CY 2026 HH PPS final rule to determine what the permanent adjustment for CY 2025 claims would be even though we stopped comparing claims priced under the PDGM and the 153-group after CY 2022 claims for the purposes of applying a permanent adjustment in this final rule. As displayed in table 4, we calculate the permanent adjustment for CY 2025 by determining the percent change between the actual CY 2025 30-day payment rate ($2,057.35) and the budget neutral rate for CY 2025 ($2,036.29). The budget neutral rate for CY 2025 is the finalized CY 2024 budget neutral rate discussed in CY 2026 final rule ($1,977.43) multiplied by the CY 2025 case-mix weights recalibration neutrality factor (1.0039), the CY 2025 wage index budget neutrality factor (0.9988), and the CY 2025 home health payment update factor (1.027).

TABLE B4: ILLUSTRATIVE CY 2025 PERMANENT AND FINAL TEMPORARY ADJUSTMENT CALCULATIONS

	CY 2025 Nationalized Standardized 30-day Period Payment	CY 2025 Budget Neutral Payment Rate	CY 2025 Only Adjustment
Base Payment Rate	$2,057.35*	$2,036.29	**Permanent** -1.024%

Aggregate Expenditures	$ 16,957,268,010.43**	$ 16,802,166,149.24	**Temporary** -$ 155,101,861.19

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

* The $2,057.35 corresponds to the actual CY2025 payment rate. ** The estimated aggregate expenditures for assumed behavior ($16.6 billion), uses the actual CY 2025 payment rate of $2,057.35 as finalized in the CY 2025 HH PPS final rule.

In section II.C.1.d of CY 2027 HH PPS proposed rule, we discuss various trends that are part of monitoring changes related to the PDGM using analysis of CY 2025 claims. The data continues to show minimal changes that could be attributed to the PDGM implementation after CY 2022 by a large proportion of home health providers. We also continue to acknowledge the difficulty in attributing any behavior change occurring from CYs 2023 through 2025 directly to the PDGM implementation and its effects on expenditures from the other policy changes occurring in those years. As discussed in the CY 2026 HH PPS final rule, CMS introduced several policy changes that make isolating the effect of implementing a permanent adjustment, with claims data from CYs 2023 through 2025, for the PDGM difficult. These changes include recalibration of case-mix weights and LUPA visit thresholds finalized in the CY 2023, 2024, 2025, and 2026 final rules; reassignment of certain ICD-10-CM codes related to the PDGM clinical groups and comorbidity groups in the CY 2023 HH PPS final rule; finalized permanent adjustments in the CY 2023, 2024, and 2025 HH PPS final rules; the introduction of OASIS-E in 2023 and finalized mapping of OASIS-E to OASIS-D in the CY 2025 HH PPS final rule for calculating functional points for functional impairment levels during repricing; and the expanded HHVBP Model. For these reasons, we maintain that limiting the application of the permanent adjustment to analysis of data from CYs 2020 through 2022 continues to be the most accurate application of the law. However, as required by law, we will continue to analyze data through CY 2026 claims to determine if any additional permanent adjustments are needed to account for the impact of assumed versus actual behavior change related to the implementation of the PDGM and the change to a 30-day unit of payment on estimated aggregate expenditures.

The dollar amount that needs to be collected through the temporary adjustment increased when examining home health claims from CY 2025 because those claims were paid using the

actual 30-day payment rate ($2,057.35) instead of the calculated budget neutral payment rate for CY 2025 ($2,036.29). That is, had the payment rate in CY 2025 been $2,036.29, there would not be an increase in what needs to be collected through the temporary adjustment when examining home health claims from CY 2025. Because the 30-day payment rate was not budget neutral until the CY 2026 payment rate with the application of the −1.023 percent permanent adjustment, the temporary adjustment continued to accrue.

As described previously in this final rule, to account for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes in any given year from CY 2020 to CY 2026, we calculate the temporary prospective adjustment by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for that year. In other words, when determining the temporary retrospective dollar amount, we used the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims, the CY 2026 HH PPS final rule (90 FR 55366 through 55367) for analysis of CY 2023 and CY 2024 claims, and section II.C.1.d. of this final rule for the analysis of CY 2025 claims. Table 5 provides a summary of the temporary adjustment dollar amount for CYs 2020 through 2026.

TABLE 5: SUMMARY OF TEMPORARY ADJUSTMENTS DOLLAR AMOUNTS FOR CYs 2020 – 2026

Claims Analysis Year	Dollar Amount
CY 2020	-$873,073,121
CY 2021	-$1,211,002,953
CY 2022	-$1,405,447,290
CY 2023	- $836,208,180
CY 2024	- $430,435,218
CY 2025 – This final rule	-$155,101,861
CY 2026	TBD
Total (through CY 2025)	-$4,911,268,623

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW on July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed from the CCW on July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed from the CCW on July 15, 2023. CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed from the CCW on July 11, 2024. CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on July 11, 2025. CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.
Note: The anticipated temporary adjustments of approximately $4.9 billion (through CY 2025) will require temporary adjustment(s) to the base payment rate to offset for such increases in estimated aggregate expenditures. The dollar amount will be converted to a factor when implemented in future rulemaking.

Therefore, we exercise our authority under section 1895(b)(3)(D)(iii) of the Act to apply "one or more" temporary adjustments to continue recoupment of the retrospective overpayments for CYs 2020 through 2025. Specifically, we proposed implementing a 3.0 percent reduction in CY 2027, that is equivalent to a 0.9700 temporary adjustment factor, to the CY 2027 national, standardized payment rate. Using historical trends, we estimated 7,680,775 30-day periods would occur in CY 2027. Using this estimated utilization, a 3.0 percent reduction to the CY 2027 30-day payment rate would begin to collect approximately $500 million of the total temporary adjustment dollar amount, equating to about 10 percent of the total $4.9 billion shown in table 6. In doing so; however, we noted we would need to account for the remaining temporary adjustment dollar amount for CYs 2020 through 2026, plus any possible adjustments for CY 2027 and 2028, in future years. It is important to note that the estimated $500 million dollar amount anticipated to be collected by the implementation of the temporary adjustment factor is based on an estimate of the number of 30-day periods that would occur in CY 2027. It may not reflect the actual dollar amount to be collected if the actual number of 30-day periods and other utilization trends in CY 2027 differ from what was estimated. In other words, as noted in the proposed rule, CMS will calculate the actual amount collected from the temporary adjustment in CY 2027 and credit it to the overall cumulative temporary dollar amount.

In accordance with section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied on a prospective basis and shall apply only with respect to the year for which such temporary increase or decrease is made. This means we would not include the −3.0 percent temporary adjustment applied for CY 2027 when calculating the CY 2028 base payment rates. However, to continue recoupment of the retrospective overpayments, we may propose additional

temporary adjustments in future rulemaking and did not propose that the −3.0 percent temporary adjustment would be applied each year after CY 2027. Rather, as noted in the proposed rule, we will continue to analyze the data each year through CY 2026 claims as required by law, and in a time and manner deemed appropriate, we will propose one or more temporary adjustments to account for retrospective overpayments. We also note the $4.9 billion does not account for any monies recouped in CY 2026, as we do not have this dollar amount at the time of this CY 2027 rulemaking. In future rulemaking, we will show the remaining balance, accounting for the previous recoupment amount; however, there will be a lag. We refer readers to section II.E.3.b. for the CY 2027 base payment rates with and without the temporary adjustment.

We solicited comments on the proposals to not apply a permanent adjustment and to apply the −3.0 percent temporary adjustment to the CY 2027 home health base payment rate. The following is a summary of the comments we received and our responses.

Comment: One commenter, the Medicare Payment Advisory Commission (MedPAC), supported the proposed temporary payment adjustment for CY 2027. MedPAC stated that although the proposed payment update is larger than the Commission's recommendation for CY 2027, the proposed temporary behavioral adjustment would further align Medicare payments with providers' costs. They also stated that the home health base payment rate currently exceeds the estimated cost of a typical 30-day payment period by 34 percent.

Response: We thank MedPAC for their comment.

Comment: Several commenters recommended that CMS eliminate all permanent and temporary adjustments due to methodological flaws and data concerns, such as the inability to discern behavior related and unrelated to the PDGM. These commenters also recommended excluding anomalous data from areas with suspect billing patterns, similar to the policy finalized in The Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program (MSSP) Financial Calculations in Calendar Year 2023 final rule. Commenters also raised concerns about the anomalous data

having effects on varying case-mix weights, outlier calculations, PEPs changes in LUPAs and number of episodes.

Response: The methodological and data concerns raised by commenters were addressed in the CY 2026 HH PPS final rule (90 FR 55360 through 55365). As required by law, our methodology (that is, the repricing methodology) compares aggregate expenditures between the actual 30-day periods and simulated 60-day episodes paid under the prior payment system within a single claims' year to determine what the payment rate should be to ensure that payments under the two systems would be equal. When using the repricing methodology, we create simulated 60-day episodes to reprice the claims for CYs 2020 through 2022 and use the same claims data sets to calculate both pre-PDGM and PDGM payments. Regardless of the magnitude and frequency of individual behavior changes (for example, number of episodes, changes in LUPAs, therapy, PEPs, visits, etc.), the occurrence of any behavior change is captured by the methodology to determine the impact on aggregate expenditures.

Furthermore, not all anomalous billing patterns indicate fraudulent practices, and we would need further evidence to determine which providers with anomalous billing patterns could be connected to fraud and abuse. Excluding data some commenters view as “anomalous” from the calculation of the national 30-day base payment rate would require CMS to develop a new policy, including developing thresholds for determining deviations excluded from the analytical sample. Regarding the suggestion from commenters on the policy under which CMS made adjustments to Medicare Shared Savings Program (MSSP) financial benchmark calculations to account for significant, anomalous, and highly suspect billing activity in CY 2023 (89 FR 79156 through 79165), we lack the same statutory authority to apply a similar policy for setting the national standardized 30-day payment rate for HHAs as required by section 1895(b)(3) of the Act. In finalizing this policy, MSSP relied on statutory authority undersection 1899(d)(1)(B)(ii) of the Act, which permits the Secretary to adjust benchmark expenditures for beneficiary characteristics and such other factors as the Secretary determines appropriate. MSSP relied on

this authority to remove payments for the specified catheter codes from the determination of benchmark expenditures where CY 2023 serves as a benchmark year when establishing benchmarks for ACOs in agreement periods beginning in January 2024, January 2025, or January 2026. While we do not have similar statutory authority for the HH PPS, CMS continues to investigate anomalous providers and has made referrals to law enforcement and terminated certain suppliers and providers from the Medicare program. CMS also continues to work closely with the HHS-OIG and Department of Justice, as well as our Unified Program Integrity Contractors (UPIC), to investigate health care fraud activities.

Comment: Some commenters raised concerns regarding the way in which CMS was meeting the statutory requirements of section 1895(b)(3)(D) of the Act through the budget neutrality calculation methodology finalized in CY 2023 HH PPS final rule. Specifically, commenters raised concerns about repricing claims using simulated 60-day episodes stating that the methodology does not meet the statutory requirement, including how claims are excluded, structural LUPA differences between the pre-PDGM system and the PDGM, outlier assumptions for simulated 60-day episodes, and recalibrating pre-PDGM case-mix update factors. Commenters also raised concerns that recalibration did not control for the impact of COVID-19 and suggested these claims be excluded.

Response: The concerns raised by commenters were previously discussed in the CY 2023 HH PPS final rule (87 FR 66797 through 66804) and in the CY 2026 HH PPS final rule (90 FR 55362 through 55364). CMS continues to reiterate that the methodology is technically accurate in that it captures actual changes in behavior that have been explained in previous rulemaking, as well as this final rule. As required by law, our methodology compares aggregate expenditures between the actual 30-day periods and simulated 60-day episodes paid under the prior payment system within a single claims' year to determine what the payment rate should be to ensure that payments under the two systems would be equal. Regardless of the magnitude and frequency of individual behavior change (for example, changes in LUPAs, therapy, etc.), the occurrence of

any behavior change is captured by the methodology to determine the impact on aggregate expenditures.

We previously explained that the exclusion criteria in the finalized methodology dropped 30-day periods of care that had a claim occurrence code 50 after October 31, and before January 1 of the claims year we are analyzing, to ensure the 30-day period will not be part of a simulated 60-day period that began in the prior year and to ensure a simulated 60-day episode (simulated from two 30-day periods) does not overlap years (90 FR 29129). Additional exclusions include 60-day periods where no OASIS information was available, a recent SOC/ROC OASIS was not available, a wage index was not available, or the episode cannot be grouped to a HIPPS code due to a missing primary diagnosis or other reason. All the exclusion criteria are applied because the criteria are needed to appropriately price the simulated 60-day episodes for within the year the claims would have been paid. It is immaterial whether the 30-day periods that are excluded have different case-mix characteristics or higher visits if the 30-day periods are not able to be repriced accordingly as a simulated 60-day period. As stated in previous rulemaking (87 FR 66804), without these exclusions, we would not be confident we were appropriately grouping 30-day periods into simulated 60-day episodes. The permanent adjustment is based on the percentage change between the payment rates (which utilizes the same claims), and the temporary adjustment is based on the aggregate expenditures of all claims (that is, no exclusions) using the two payment rates (that is, the actual payment rate and the budget neutral payment rate with the permanent adjustment applied). Therefore, we do not believe that the small portion of excluded claims significantly biased our results.

Excluding claims with COVID-19 as a diagnosis lacks a clear rationale. Simulated 60-day episodes with a primary diagnosis of COVID-19 would still be assigned a HIPPS under the V8219 Home Health Grouper and would not have been excluded from the repricing analysis unless there was another unrelated issue with the claim that prevented grouping. As described in the CY 2023 HH PPS final rule (87 FR 66800), our methodology includes the effect of the

COVID-19 public health emergency (PHE) and ensures that any difference between the two calculated spending amounts for estimated budget-neutral amount and actual home health expenditures is not attributable to the PHE.

Recalibrating the pre-PDGM case-mix weights to reflect changes due to the COVID-19 PHE would not increase the aggregate payments estimated for simulated 60-day periods paid under the pre-PDGM case-mix system. Because we are comparing a single year of data priced under the PDGM and the 153-group case-mix system, the COVID-19 PHE would not bias the PDGM payments differently than the 153-group or vice-versa. Our methodology ensured that we used actual claims with the same episodes, same diagnoses, same therapy and non-therapy visit counts, same clinical documentation, same LUPA patterns, all shaped by the COVID-19 PHE — and ran them through two different payment calculations: (1) actual payment under PDGM's case-mix methodology, and (2) a hypothetical repricing under the prior 153-group system's case-mix methodology. Because both calculations draw on the identical underlying utilization data, any COVID-19 PHE-driven change in the volume or intensity of care (fewer visits, shorter episodes, telehealth substitution, deferred admissions) shows up in both the actual and the counterfactual payment amount. If we were to implement recalibration of case-mix weights (including early vs. late visits or admission source) when determining aggregate payments under the 60-day payment system, the aggregate expenditures would not change because we would implement the recalibration of case-mix weights in a budget neutral manner.

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. We continue to believe that the COVID-19 PHE would have impacted utilization within all case-mix groups similarly. We acknowledge that the COVID-19 PHE changed the underlying clinical picture in 2020 (more respiratory diagnoses, fewer therapy visits, more skilled nursing visits,

altered LUPA thresholds, telehealth-driven changes in visit patterns, etc.). However the PHE would have affected care patterns regardless of whether payment was made under the 153-group system or the PDGM. However, the impact of the COVID-19 PHE contributes to case-mix changes and changes in utilization that will be reflected in the single year of claims that is priced as the simulated 60-day episodes in our repricing methodology. When we compare the aggregate expenditures between the two payment systems that are similarly affected by the COVID-19 PHE, we determine the difference in aggregate expenditures that can be attributed to the PDGM. In addition, when we create the case-mix weight for each 30-day period under PDGM, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression model for recalibration. 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 minimal since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight.

We previously explained the outlier assumptions for simulated 60-day episodes in the CY 2026 HH PPS final rule (90 FR 55363). If we were to implement an updated FDL instead of using the finalized CY 2020 FDL to determine outlier payments under the simulated episodes, it is unclear whether retrospectively assigning the necessary FDL to hit a 2.5 percent target for the years after CY 2020 would be an accurate representation of what would happen under the previous payment system as discussed previously in the CY 2026 HH PPS final rule (90 FR 55363). In addition, updating the FDL for the 153-group payment system would require an iterative process to adjust the PDGM FDL used in repricing to also hit the 2.5 percent target of total PDGM expenditures. We note that the 2.5 percent is only a target amount that is set prospectively and is never reconciled and adjusted for.

Comment: Some commenters reminded CMS of its legal responsibilities under the Administrative Procedure Act to exercise informed decision-making that includes public input and for the Agency to ensure that consideration is given to data and perspectives that the Agency

may not have considered or overlooked. These same commenters referenced *Loper Bright Enterprises v. Raimondo,* 603 U.S. 369 (2024), which reinforced the principle that courts must exercise independent judgment to ensure Agency actions are lawful and within their statutory authority. These commenters noted that *Loper Bright* shifted the focus away from deference to Agency interpretations of statutes, and gaps in them, and solidified the requirement for agencies to engage in reasoned decision making, including considering and responding to public comments, as a foundational aspect of the regulatory process. Using these legal foundational principles, the commenters stated that their recommendations regarding flaws in CMS's approach related to the calculation of the permanent and temporary adjustments must be addressed.

Response: CMS has responded, in this and prior HH PPS final rules (for example, 90 FR 55342), to the substance of the commenters' recurring methodological objections, including through the previous detailed responses. The APA requires reasoned engagement with significant comments, not acceptance of a commenter's preferred outcome, and CMS's obligation to explain its reasoning is unchanged by *Loper Bright*. *Loper Bright* addresses the standard courts apply when reviewing an agency's interpretation of statutory text; it does not impose a new or heightened comment-response obligation beyond existing APA requirements. CMS maintains that its interpretation of section 1895(b)(3)(A)(iv) of the Act— which requires that the estimated aggregate amount of expenditures under the PDGM be equal to the estimated aggregate amount of expenditures under the previous 153-group payment system — reflects the best reading of the statutory text, which is the standard *Loper Bright* directs courts to apply independently.

Comment: Some commenters stated that simulating 60-day episodes may understate differences, including differences in clinical group assignments between the pre-PDGM and the PDGM systems. They stated that because CMS assigns the first period's diagnosis and clinical group to the entire episode, it may understate counterfactual case mix when the second period

reflects greater acuity and does not capture mid-episode case-mix changes permitted under the former system.

Response: Any change in the average case-mix weight is counteracted through a corresponding change in the payment rate so that aggregate expenditures are budget neutral regardless of whether there are clinical group differences. Recalibration ensures that payment incentives for future utilization are aligned with the design of the payment system (for example, recalibration ensures roughly a third of periods and episodes are in a particular functional level grouping). Any differences, such as clinical group assignments, that are part of the changes attributed to the PDGM are accounted for when we compare the aggregate expenditures from pre-PDGM and PDGM claims.

Comment: Some commenters raised concerns about the assumptions CMS used to crosswalk the Outcome and Assessment Information (OASIS)-E to OASIS-D during repricing. They believe that mapping OASIS-E responses back to earlier OASIS-E specifications could understate severity or misclassify counterfactual case-mix groups.

Response: As discussed in the CY 2025 HH PPS final rule (89 FR 88361), in response to an update of the OASIS instrument, we updated two minor technical parts and added new assumptions in the first repricing step (creating simulated 60-day episodes from 30-day periods). However, in the CY 2026 HH PPS final rule (90 FR 55364), we acknowledged that because it is difficult to definitively isolate the behaviors directly related to the PDGM implementation after CY 2022, we were only finalizing a permanent adjustment based on data from CYs 2020 through 2022. Because of that decision, the finalized mapping of OASIS-E to OASIS-D is not used for calculations related to the proposed payment adjustments in this final rule. While we are not implementing a permanent adjustment in this final rule, we still follow this process to provide the calculation for the illustrative permanent adjustments presented in tables 2 and 3, in order to comply with statutory requirements.

Comment: Several commenters stated that data from CYs 2020 through 2022 should also not be used to isolate PDGM-related behavior change and that consequently, those years should not be used to calculate permanent or temporary adjustments. Other commenters suggested that CMS not use CY 2022 claims as part of the repricing methodology. Commenters stated that annual recalibration began in CY 2022, not CY 2023 using disrupted CY 2020 data and that CMS should recalculate the total permanent adjustments excluding 2022 claims. Commenters noted their belief that CMS should at a minimum, not finalize the proposed -3.0 percent temporary adjustment for CY 2027, exclude the data for CY 2022, and recalculate the total permanent adjustments determined based on only the data from CYs 2020 and 2021.

Response: We remind commenters that repricing compares expenditures paid under the PDGM and pre-PDGM systems to determine if we are paying differently under the PDGM than we otherwise would have absent the new payment system (that is, the 153-group system). In the CY 2023 HH PPS proposed rule (87 FR 37615), we described an analysis that showed the decline in the average case-mix weight for simulated 60-day episodes was largely driven by reductions in therapy utilization instead of the clinical score (which may be impacted by diagnoses).

We acknowledge that the CY 2022 HH PPS final rule included recalibration of case-mix weights using CY 2020 claims and reassignment of certain ICD-10-CM codes to PDGM clinical and comorbidity groups. It is important to note that these policy changes do not affect aggregate expenditures under the PDGM. In contrast, updating LUPA visit thresholds in the CY 2023 HH PPS final rule (87 FR 66815 through 66816) did affect aggregate expenditures. In the CY 2023 final rule, we finalized our proposal to recalibrate the PDGM case-mix weights, updated points for functional impairment levels, reassigned certain ICD-10-CM codes related to the PDGM clinical groups and comorbidity groups, and updated LUPA visit thresholds using CY 2021 data (87 FR 66815 through 66846). Our data analysis indicated that visits in CY 2021 were similar to visits in CY 2020. We believed that CY 2021 data would be more indicative of visit patterns in

CY 2023 rather than continuing to use the LUPA thresholds derived from the CY 2018 data pre-PDGM. Therefore, we finalized updates to the LUPA thresholds for CY 2023 using data from CY 2021.

We also remind commenters that recalibration is done in a budget neutral manner, as we apply a case-mix weight recalibration budget neutrality factor to the national standardized 30-day payment rate. Regarding concerns from commenters about using claims data from CY 2022, we provided analysis in the CY 2026 HH PPS final rule (90 FR 55364 through 55366) that suggested that provider behavior changed more significantly in the years immediately following the implementation of the PDGM, but decreased in magnitude overall starting in CY 2023. These changes, that may indicate HHAs were adapting to the implementation of a new case-mix system, have decreased in magnitude (90 FR 29121 through 29125) to the extent that we believe the implementation of the PDGM is the reason for these changes through CY 2022.

We remind commenters when analyzing the overall home health trends, such as the distribution of 30-day periods of care by the twelve PDGM clinical groups, distribution of 30-day periods of care by admission source and timing, distribution of 30-day periods of care by functional impairment level, distribution of 30-day periods with therapy and non-therapy visits, and average therapy visits per 30-day period by clinical group (Tables 6, 8, 9, and 10 and Figure 3 in the CY 2026 HH PPS proposed rule (90 FR 29121 through 29125)), we see indicators that suggest provider behavior changed more significantly in the years immediately following the implementation of the PDGM, but has decreased in magnitude overall starting in CY 2023.

MedPAC's analysis of home health trends after implementation of the PDGM is consistent with our findings. In its March 2026 Report to Congress, MedPAC provided a mandated report on the impact of the implementation of the PDGM.[4] The report examined outcomes from home health care services regardless of whether they were preceded by a hospitalization. MedPAC stated that fewer therapy visits per episode were directionally

[4] https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch14_MedPAC_Report_To_Congress_SEC.pdf.

consistent with the PDGM's exclusion of the number of therapy visits as a payment factor and referenced CMS's concern for how the prior payment system encouraged therapy provision through financial incentives rather than patient need. Overall, MedPAC found that the implementation of the PDGM did not substantially affect overall access to home health care and that the transition to the new case-mix system did not negatively affect beneficiaries. As presented in Figures 14-3 and 14-4 of the report, our conclusion regarding the majority of behavior change occurring in CYs 2020 through 2022 is supported by MedPAC's findings, with declining trends for the share of Medicare beneficiaries with at least one home health stay and reduction of average number of visits per stay during CYs 2020 through 2022. That is, the most substantial declines occurred in the first few years after the implementation of the PDGM (that is, CYs 2020-2022).

For the reasons discussed earlier, we continue to acknowledge the difficulty in attributing any behavior change occurring from CYs 2023 through 2025 directly to the PDGM implementation and its effects on expenditures from the other policy changes occurring in those years. As discussed in the CY 2026 final rule (90 FR 55365), our analysis supports that the observed behavior changes in CYs 2020 through 2022 are attributable to the implementation of the PDGM and the 30-day unit of payment. Therefore, since the observed behavior changes directly attributable to the implementation of the PDGM occurred in CYs 2020 through 2022, we will continue to calculate the permanent adjustment for CYs 2020 through 2022. In response to commenters' request that CMS not finalize the proposed -3 percent temporary adjustment in CY 2027, we decline to do so as we continue to believe that applying a temporary adjustment in CY 2027 mitigates the need for a larger temporary adjustment in the future. Finalizing a -3 percent temporary adjustment ensures that CMS continues to recoup retrospective overpayments as required by law and ensures financial stewardship of the Medicare Trust Funds.

Final Decision: We continue to adhere to the methodology finalized in the CY 2026 HH PPS final rule (90 FR 55365 through 55367) and reiterate that it complies with the statutory

requirement to evaluate and adjust payments based on actual behavior changes on estimated aggregate expenditures. In this final rule, we exercise our authority under section 1895(b)(3)(D)(iii) of the Act to apply "one or more" temporary adjustments to begin recoupment of the retrospective overpayments for CYs 2020 through 2025. We are finalizing a 3.0 percent temporary reduction in CY 2027, that is equivalent to a 0.9700 temporary adjustment factor, to the CY 2027 national, 30-day payment rate. By implementing a −3.0 percent temporary adjustment, we can begin recoupment of retrospective overpayments. We determined that the total temporary adjustment dollar amount is approximately $4.9 billion through CY 2025, and we estimate that implementing a −3.0 percent temporary adjustment will allow us to recoup $500 million of this total dollar amount.

C. CY 2027 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights.

1. Final CY 2027 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 a policy setting the LUPA thresholds at the 10th percentile of visits or two visits, whichever is higher, for each PDGM payment group. This means 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 will be paid the full 30-day period case-mix adjusted payment amount (subject to any partial payment adjustment 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 per-visit payment amounts as described in section II.E.4.c. 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 fewer 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 will be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, as CY 2020 was the first year of the new case-mix adjustment methodology, we stated in the CY 2021 HH PPS final rule (85 FR 70305, 70306) that we will 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. We stated that at that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

In the CY 2022 HH PPS final rule with comment period (86 FR 62249), we finalized the proposal to recalibrate the PDGM case-mix weights, functional impairment levels, and comorbidity subgroups while maintaining the LUPA thresholds for CY 2022. We stated that because 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, we believe 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 will be minimized since the impact will 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 will control for the impacts of the COVID-19 PHE. We noted that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID-19 PHE, we finalized the proposal 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.

For CY 2024, we proposed to update the LUPA thresholds using CY 2022 Medicare home health claims (as of March 17, 2023) linked to OASIS assessment data. We believed that CY 2022 data would be more indicative of visit patterns in CY 2024 rather than continuing to use the LUPA thresholds derived from the CY 2018 data pre-PDGM. Therefore, we finalized a policy to update the LUPA thresholds for CY 2024 using data from CY 2022.

For CY 2027, we proposed to update the LUPA thresholds using CY 2025 home health claims utilization data (using more complete CY 2025 claims data as of July 14, 2026), in accordance with our policy to annually recalibrate the case-mix weights and update the LUPA thresholds, functional impairment levels, and comorbidity subgroups. After reviewing the CY 2025 home health claims utilization data, we determined that LUPA visit patterns in 2025 were similar to visits in 2024 and a total of 10 case-mix groups had a decline in their LUPA threshold of a single visit and one case-mix group had their LUPA threshold increase by a single visit. The proposed LUPA thresholds for the CY 2027 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights can be found in the CY 2027 HH PPS proposed rule (91 FR 41255).

We solicited public comment on the proposed updates to the LUPA thresholds for CY 2027. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for CMS's continued practice of annually recalibrating LUPA thresholds using the most recent complete claims data and characterized the proposed threshold reductions across 18 payment groups as "modest but directionally favorable". Two commenters identified a proposed LUPA threshold of 3.5 visits for HIPPS Code 4LC11 in the "CY 2027 Proposed HH PDGM Case Mix Weights and LUPA Thresholds" file (as posted on the HHA Center web page, located at *https://www.cms.gov/medicare/enrollment-*

renewal/providers-suppliers/home-health-agency-center), and asked CMS to clarify whether this should be read as 3 visits, 4 visits, or whether it reflects a true partial threshold.

Response: We thank commenters for their support and feedback on the annual recalibration for LUPA thresholds. We calculated the proposed CY 2027 LUPA thresholds using CY 2025 home health claims utilization data as of March 15, 2026, which identified 18 case-mix groups with a one-visit decrease. We are finalizing CY 2027 LUPA thresholds using more complete CY 2025 home health claims utilization data as of July 14, 2026, which shifted the visit distribution for eight of the 18 proposed groups and reduced the final count to 10 case-mix groups with a one-visit decrease.

Additionally, we reviewed the case-mix weight and LUPA thresholds published in the CY 2027 HH PPS proposed rule (91 FR 41261) in response to these comments and can confirm that the value of 3.5 visits listed for HIPPS Code 4LC11 was the result of an inadvertent technical error. LUPA visit thresholds are calculated as whole numbers, consistent with all other case-mix groups. We are publishing the corrected, finalized whole number LUPA threshold for HIPPS Code 4LC11 of three for CY 2027 in this final rule and are correcting this error in the technical files accompanying the final rule. We are otherwise finalizing the LUPA thresholds contained in table 11 using more complete CY 2025 claims data as of July 14, 2026.

Comment: Some commenters raised concerns that CMS is basing updates to the proposed LUPA thresholds on potentially fraudulent data, pointing specifically to clinically complex, short duration episodes and what they describe as high fraud areas such as Los Angeles County. These commenters stated that this distortion disadvantages legitimate HHAs that serve genuinely high-cost patients as fraudulent, low-acuity, high-volume billing skews the ratio's underlying data.

Response: We appreciate commenters' concerns about potential fraudulent billing and its impact on the proposed LUPA thresholds. However, we remind commenters that outlier billing patterns do not necessarily indicate fraudulent practice. We did not propose, and are not adopting, a geographic exclusion or separate modeling approach for identified outliers in

calculating the CY 2027 LUPA thresholds. As such, we include the most recent and complete claims data available when it updates the LUPA thresholds. Nevertheless, we thank commenters for sharing their insight on how CMS can address fraud concerns in the home health market. Depending on the circumstances, an anomalous pattern can prompt further review and may trigger an investigation into fraud, waste, and abuse. Specifically, cost report fraud and abusive billing behavior require action through the appropriate channels that hold enforcement authority and we encourage commenters to report suspected fraud at: *https:// www.cms.gov/medicare/medicaid- coordination/center-program-integrity/ reporting-fraud*.

Comment: One commenter recommended that when CMS adjusts clinical group assignments or comorbidity subgroups affecting LUPA thresholds, CMS should release revised grouper specifications and testing files at least 90–120 days prior to the January 1 effective date, to prevent claims disruption across clearinghouses and billing vendors.

Response: We thank the commenter for this feedback. The ICD-10-CM diagnosis code mappings used by the grouper (clinical groupings, comorbidity adjustments) and the LUPA thresholds are typically previewed in the proposed rule (published around late June/early July) so stakeholders can comment, and are then finalized in the final rule (published in early November). Each update of the Home Health Grouper software is available for beta testing approximately 6-8 weeks prior to the implementation date, and shortly before the final rule is published. To sign up to beta test the home health software release, stakeholders can email hhppsgrouperemail@solventum.com and provide their contact information. However, because we are still finalizing edits to diagnosis mapping based on comments received on the elements that make up the home health grouper that are previewed in the proposed rule, CMS cannot release the beta testing any sooner than 6-8 weeks prior to the implementation date.

Final Decision: We are finalizing the LUPA threshold updates as proposed for CY 2027 using CY 2025 home health claims utilization data (using more complete CY 2025 claims data as of July 14, 2026), including the one-visit decrease for ten case-mix groups and the one-visit

increase for one case-mix group. The final LUPA thresholds for the CY 2027 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in table 11 and are also available on the HHA Center web page, located at *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center*. We will continue to monitor national LUPA rates and data indicators through routine program monitoring.

2. Final CY 2027 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 M1033. 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 these points results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the more the response is associated with increased resource use, or increased impairment. The three functional impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each clinical group falls within each level. This means 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 2027, we proposed using CY 2025 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 technical report from December 2016, posted on the Home Health PPS Archive web page, located at *https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive*, provide a more detailed explanation as to the construction of the functional impairment levels

using the OASIS items. We proposed to use the same methodology previously finalized to update the functional impairment levels for CY 2027. The final updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2027 are listed in tables 6 and 7, respectively.

TABLE 6: FINAL OASIS POINTS TABLE FOR CY 2027

	Responses	CY 2027 Points	Percent of Periods with this Response Category*
M1800: Grooming	0 or 1	**0**	**21.5%**
	2 or 3	**3**	**78.5%**
M1810: Current Ability to Dress Upper Body	0 or 1	**0**	**15.9%**
	2 or 3	**5**	**84.1%**
M1820: Current Ability to Dress Lower Body	0 or 1	**0**	**7.7%**
	2	**4**	**63.5%**
	3	**11**	**28.8%**
M1830: Bathing	0 or 1	**0**	**2.0%**
	2	**2**	**8.6%**
	3 or 4	**8**	**48.0%**
	5 or 6	**16**	**41.3%**
M1840: Toilet Transferring	0 or 1	**0**	**58.3%**
	2, 3 or 4	**6**	**41.7%**
M1850: Transferring	0	**0**	**1.0%**
	1	**3**	**16.4%**
	2, 3, 4 or 5	**5**	**82.6%**
M1860: Ambulation/Locomotion	0 or 1	**0**	**2.7%**
	2	**4**	**13.3%**
	3	**0**	**66.2%**
	4, 5 or 6	**19**	**17.8%**
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	**0**	**52.9%**
	Four or more items marked (Excluding responses 8, 9 or 10)	**11**	**47.1%**

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.
Note: *For item M1860, the point values for response 2 is worth more than the point values for response 3. There may be times in which the resource use for certain OASIS items associated with functional impairment will result in a seemingly inverse relationship to the response reported. However, this is the result of the direct association between the responses reported on the OASIS items and actual resource use. For item M1033, responses 8,9 and 10 represent "currently reports exhaustion", "other risk(s) not listed in 1-8", and "none of the above", respectively.*

TABLE 7: FINAL THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, FOR CY 2027

Clinical Group	Level of Impairment	CY 2027 Points
MMTA - Other	Low	**0-30**
	Medium	**31-42**
	High	**43+**
Behavioral Health	Low	**0-31**
	Medium	**32-44**
	High	**45+**
Complex Nursing Interventions	Low	**0-31**
	Medium	**32-55**
	High	**56+**

Clinical Group	Level of Impairment	CY 2027 Points
Musculoskeletal Rehabilitation	Low	**0-31**
	Medium	**32-44**
	High	**45+**
Neuro Rehabilitation	Low	**0-33**
	Medium	**34-50**
	High	**51+**
Wound	Low	**0-32**
	Medium	**33-50**
	High	**51+**
MMTA - Surgical Aftercare	Low	**0-30**
	Medium	**31-42**
	High	**43+**
MMTA - Cardiac and Circulatory	Low	**0-29**
	Medium	**30-42**
	High	**43+**
MMTA - Endocrine	Low	**0-27**
	Medium	**28-42**
	High	**43+**
MMTA - Gastrointestinal tract and Genitourinary system	Low	**0-33**
	Medium	**34-46**
	High	**47+**
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	**0-31**
	Medium	**32-44**
	High	**45+**
MMTA - Respiratory	Low	**0-32**
	Medium	**33-44**
	High	**45+**

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

We solicited public comment on the proposed updates to the functional points and the functional impairment levels by clinical group. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed CMS's proposal to reduce the point value assigned to OASIS item M1860 response "3" (*for "able to walk only with the supervision or assistance of another person at all times"*) to zero points for CY 2027, which is down from 1 point in CY 2026 and down from 6 points as recently as CY 2022. These commenters stated that M1860 response "3" covers a wide and clinically meaningful range of ambulation impairment (ranging from contact guard assistance to maximum assist) and that collapsing it to zero points equates it with no impairment at all and resultingly makes it appear progressively less resource intensive solely as a result of annual recalibration. Commenters requested that CMS explain the basis for the change and commit to a stable and anchored scoring approach for M1860 response "3" going forward. Other commenters raised similar concerns that the proposed functional

impairment thresholds could shift a meaningful number of patient episodes from high to medium and medium to low functional impairment classifications, even though the underlying clinical needs of those patients have not changed. A few commenters identified specific proposed point reductions, including point values for M1830 (*bathing*) and for M1820 (*ability to dress lower body*) at low to moderate impairment levels, while severe impairment levels remain largely unchanged.

Commenters stated that this pattern in which response categories that encompass wide and clinically meaningful ranges of impairment are reduced in points, effectively equating those levels of impairment with no impairment at all and, consequently, making them appear progressively less resource intensive even though the underlying clinical needs of the patients have not changed concentrates payment recognition only on the most severely dependent patients and undervalues resources devoted to patients with low to moderate limitations. To counter this, commenters recommended CMS implement greater stability in the functional scoring methodology by implementing fixed functional point values for a multiyear period, recalibrating only when CMS identifies statistically/clinically meaningful changes in patient needs rather than through full annual recalibration.

Response: We proposed the revised M1860, M1830 and M1820 point values based on updated regression analysis of CY 2025 claims and OASIS data reflecting the empirical association between OASIS responses and resource utilization, consistent with the same methodology CMS has applied in each annual PDGM recalibration cycle since implementation. CMS recognizes that HHAs whose patient populations differ from the national distribution may experience varied effects from the nationally calibrated set of functional impairment thresholds. However, functional impairment levels are calibrated using national data to ensure the methodology reflects resource use across the Medicare home health population as a whole, as we believe annual recalibration using the most recent complete data year is necessary to ensure functional impairment scoring continues to reflect current clinical and utilization patterns. As

such CMS declines to propose or implement a floor or multiyear fix on point values for any individual OASIS response.

Comment: Several commenters recommended that CMS transition away from OASIS M items toward the exclusive use of GG functional items in order to determine functional impairment levels, highlighting that GG items would provide more clinically precise measurement and would better differentiate differences in resource use that the current OASIS M item categories collapse into a single data point.

Response: We appreciate commenters' interest in a potential transition to Section GG items for functional impairment scoring. We will continue to evaluate the feasibility of using the GG items for payment.

Comment: A few commenters challenged the structural basis of CMS's functional impairment methodology, under which point values and thresholds are calibrated so that approximately one third of periods within each clinical group fall into the low, medium, and high functional impairment categories, characterizing this as "arbitrary".

Response: We thank commenters for their feedback and note that the functional impairment levels are structured so that approximately one-third of periods within each clinical group are assigned to low, medium, and high categories, as this ensures that the case-mix system appropriately reflects differences in functional impairment. This classification of functional impairment has been a fundamental component of the HH PPS since its implementation and remains essential under the PDGM. Previously, the HH PPS grouped home health episodes using functional scores based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low, a third classified as medium, and a third classified as high functional impairment. Likewise, the PDGM groups home health periods of care using functional impairment scores based on functional OASIS items with similar resource use and has three levels of functional impairment severity: low, medium, and high. However, the PDGM differs from the previous HH PPS functional variable in

that the three functional impairment level thresholds in the PDGM vary between the clinical groups. As such, the PDGM functional impairment structure accounts for patient characteristics within each clinical group that are associated with increased resource use due to functional impairment. This ensures that payment is more accurately aligned with patient characteristics, including beneficiaries who have greater need with activities of daily living (ADLs) and who are more functionally impaired. Updating the functional impairment levels based on the most current OASIS and claims data ensures that the payment system captures changes in functional impairment and the associated increases in resource use. Regardless of whether patients entering home health are more impaired due to shifts in the broader health care system or any other influence, the functional levels capture the relationship between functional status as indicated on the OASIS with resource use captured on claims. While we acknowledge commenters' concerns, we emphasize that the proposed recalibration is designed to strengthen the alignment between payment and patient characteristics, not to diminish access to medically necessary services. As such, updating the functional levels would specifically capture any changes in functional impairment and any changes in resource use associated with ADLs.

Final Decision: We are finalizing the functional points and functional impairment level updates for CY 2027 as proposed, using updated CY 2025 claims data (as of July 14, 2026).

3. Final CY 2027 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 diagnoses 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:

- *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 when they are reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.

- *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or do not 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 will continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of providing care. For CY 2027, we proposed to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2025 home health data with linked OASIS data.

For CY 2027, we proposed to update the comorbidity subgroups to include 21 low comorbidity adjustment subgroups and 100 high comorbidity adjustment interaction subgroups. The proposed CY 2027 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments were included in tables 21 and 22 in the CY 2027 HH PPS proposed rule (91 FR 41245).

Using more updated claims data for this final rule, there are 22 low comorbidity subgroups, and 103 high comorbidity subgroups for CY 2027 as shown in tables 8 and 9.

TABLE 8: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2027

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 10	Varicose Veins and Lymphedema
Circulatory 2	Hemolytic, Aplastic, and Other Anemias
Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
Circulatory 9	Other Venous Embolism and Thrombosis
Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Gastrointestinal 2	Intestinal Obstruction and Ileus

Low Comorbidity Subgroup	Description
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Heart 5	Atherosclerotic Heart Disease with Angina
Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neurological 10	Diabetes with neuropathy
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
Respiratory 10	2019 Novel Coronavirus
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-Four and unstageable pressure ulcers by site

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

TABLE 9: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2027

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
1	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
2	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
4	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
5	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
6	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
7	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
8	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
9	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
10	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
11	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
12	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 9	Other Venous Embolism and Thrombosis
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
16	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure
17	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Infectious 1	C-diff, MRSA, E-coli
18	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with neuropathy
19	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
20	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
21	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
22	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
23	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
24	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
25	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
26	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
27	Circulatory 10	Varicose Veins and Lymphedema	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
28	Circulatory 10	Varicose Veins and Lymphedema	Heart 12	Other Heart Diseases
29	Circulatory 10	Varicose Veins and Lymphedema	Heart 8	Other Pulmonary Heart Diseases
30	Circulatory 10	Varicose Veins and Lymphedema	Infectious 1	C-diff, MRSA, E-coli
31	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 2	Rheumatoid Arthritis
32	Circulatory 10	Varicose Veins and Lymphedema	Neurological 12	Nondiabetic neuropathy
33	Circulatory 10	Varicose Veins and Lymphedema	Renal 1	Chronic kidney disease and ESRD
34	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
35	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
36	Circulatory 10	Varicose Veins and Lymphedema	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
37	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neoplasms 9	Malignant neoplasm of breast
38	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
39	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
40	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
41	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
42	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
43	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
44	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
45	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
46	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
47	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
48	Circulatory 9	Other Venous Embolism and Thrombosis	Heart 11	Heart Failure
49	Circulatory 9	Other Venous Embolism and Thrombosis	Musculoskeletal 4	Lumbar Spinal Stenosis
50	Circulatory 9	Other Venous Embolism and Thrombosis	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease
51	Circulatory 9	Other Venous Embolism and Thrombosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
52	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
53	Endocrine 1	Hypothyroidism	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
54	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
55	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
56	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
57	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
58	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
59	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
60	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
61	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
62	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
63	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
64	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
65	Gastrointestinal 4	Alcoholic Liver Disease, Chronic Hepatitis, Fibrosis and Cirrhosis of the Liver	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
66	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
67	Heart 11	Heart Failure	Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
68	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
69	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
70	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
71	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
72	Heart 7	Chronic Ischemic Heart Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
73	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
74	Heart 9	Valve Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
75	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
76	Infectious 1	C-diff, MRSA, E-coli	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
77	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
78	Musculoskeletal 3	Joint Pain	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
79	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
80	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
81	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
82	Neurological 10	Diabetes with neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
83	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
84	Neurological 12	Nondiabetic neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
85	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
86	Neurological 4	Alzheimer's disease and related dementias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
87	Neurological 4	Alzheimer's disease and related dementias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
88	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Renal 1	Chronic kidney disease and ESRD
89	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 9	Respiratory Failure and Atelectasis
90	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
91	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
92	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
93	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 9	Respiratory Failure and Atelectasis
94	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
95	Neurological 8	Epilepsy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
96	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
97	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
98	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
99	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
100	Respiratory 9	Respiratory Failure and Atelectasis	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
101	Respiratory 9	Respiratory Failure and Atelectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
102	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
103	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.

We invited comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2027. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed general support for CMS's proposed CY 2027 comorbidity subgroup structure, agreeing the proposed changes generally align payment with the cost of caring for patients with multiple interacting diagnoses and recommended CMS continue evaluating the reimbursement impact of comorbidity revisions for diabetes and chronic wound patients.

Response: We appreciate commenters' support and comments regarding the reimbursement impacts of the proposed comorbidity revisions for patients with diabetes and chronic wounds. CMS will continue to evaluate the effects of these revisions through annual recalibration using the most recently available data.

Comment: Some commenters raised concerns regarding proposed modifications that would lower certain wound-related high comorbidity interactions and stated this may not fully account for the skilled nursing resources required to manage patients with chronic wounds who also have diabetes, peripheral vascular disease, or renal disease, since such conditions significantly influence wound healing/hospitalization risk and require frequent clinical assessment and medication management. These commenters noted this may disproportionately affect HHAs serving medically complex wound care populations if the final subgroup structure does not adequately capture such interactions.

Response: We appreciate commenters' concerns regarding resource needs of certain patient populations. However, we proposed the revised high comorbidity interaction subgroups based on updated analysis of CY 2025 claims data, which is most appropriate as it reflects the current empirical relationship between specific diagnosis combinations and resource utilization across the Medicare home health population. We also note that the Wounds clinical group still has some of the highest case-mix weights, which should account for the resource intensity of

caring for patients with wounds. We will continue to annually analyze the reported comorbidities along with the associated resource use to determine if any policy changes are necessary and appropriate in the future.

Final Decision: We are finalizing the updated comorbidity adjustment subgroups and the high comorbidity adjustment interactions using CY 2025 home health data. For CY 2027, the final updated comorbidity adjustment subgroups include 22 low comorbidity adjustment subgroups as identified in table 8 and 103 high comorbidity adjustment interaction subgroups as identified in table 9. The final CY 2027 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will also be posted on the HHA Center web page at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center*.

4. Final CY 2027 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). We also finalized a policy in the CY 2019 HH PPS final rule with comment period (83 FR 56515) 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 2027 case-mix weights, we used CY 2025 home health claims data with linked OASIS data (as of March 15, 2026). We included the proposed case-mix weights in table 11 of the proposed rule (91 FR 41255). In this final rule, we updated these case-

mix weights with claims data as of July 14, 2026, as shown in table 11. These data are the most current and complete data available at the time of this rulemaking.

The claims data provide visit-level data and data on whether non-routine supplies (NRS) were 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 12 of the proposed rule 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 2022 home health cost reports. Other variables in the regression model include the 30-day period's admission source, clinical group, and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium, or high functional impairment level. We set those thresholds so that we assign roughly a third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

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

Step 4: 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 10 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

TABLE 10: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE

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	$132.26	1.3%	0.0779
MMTA - Other - High Functional	$291.87	1.3%	0.1718
MMTA - Surgical Aftercare - Low Functional	-$36.01	1.2%	-0.0212
MMTA - Surgical Aftercare - Medium Functional	$142.03	1.2%	0.0836
MMTA - Surgical Aftercare - High Functional	$352.51	1.1%	0.2075
MMTA - Cardiac and Circulatory - Low Functional	-$23.85	5.7%	-0.0140
MMTA - Cardiac and Circulatory - Medium Functional	$127.63	5.9%	0.0751
MMTA - Cardiac and Circulatory - High Functional	$301.22	5.5%	0.1773
MMTA - Endocrine - Low Functional	$466.30	2.6%	0.2745
MMTA - Endocrine - Medium Functional	$547.02	2.6%	0.3220
MMTA - Endocrine - High Functional	$697.64	2.2%	0.4107
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$38.73	1.8%	-0.0228
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$125.51	1.6%	0.0739
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$294.04	1.7%	0.1731
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$7.38	1.6%	-0.0043
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$144.32	1.7%	0.0850
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$364.31	1.5%	0.2144
MMTA - Respiratory - Low Functional	-$21.03	2.2%	-0.0124
MMTA - Respiratory - Medium Functional	$146.62	2.3%	0.0863
MMTA - Respiratory - High Functional	$310.30	2.1%	0.1826
Behavioral Health - Low Functional	-$97.93	0.8%	-0.0576
Behavioral Health - Medium Functional	$120.06	0.7%	0.0707
Behavioral Health - High Functional	$244.39	0.7%	0.1439
Complex - Low Functional	-$25.88	0.9%	-0.0152
Complex - Medium Functional	$161.43	0.9%	0.0950
Complex - High Functional	$123.33	0.9%	0.0726
MS Rehab - Low Functional	$47.59	7.7%	0.0280
MS Rehab - Medium Functional	$188.20	7.5%	0.1108
MS Rehab - High Functional	$410.51	6.3%	0.2416
Neuro - Low Functional	$185.07	3.6%	0.1089
Neuro - Medium Functional	$350.88	4.0%	0.2065
Neuro - High Functional	$592.50	3.2%	0.3488
Wound - Low Functional	$620.23	4.8%	0.3651
Wound - Medium Functional	$780.37	4.9%	0.4593
Wound - High Functional	$995.20	4.6%	0.5858
Admission Source with Timing (Community Early is excluded)			
Community - Late	-$549.30	64.2%	-0.3233
Institutional - Early	$360.59	18.3%	0.2123
Institutional - Late	$237.01	6.1%	0.1395
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$96.98	58.7%	0.0571
Comorbidity Adjustment - Has at least one interaction from interaction list	$354.77	16.7%	0.2088
Constant	$1,554.78		
Average Resource Use	$1,698.88		

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Number of 30-day Periods	7,795,221		
Adjusted R-Squared	0.3142		

Source: *CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.*

The final updated case-mix weights for CY 2027 are listed in table 11 and will also be posted on the HHA Center web page upon display of this final rule.

TABLE B11: CASE-MIX WEIGHTS AND LUPA THRESHOLDS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.0590	4
1FC21	Behavioral Health - High	Early - Community	1	1.1161	4
1FC31	Behavioral Health - High	Early - Community	2	1.2679	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.2713	3
2FC21	Behavioral Health - High	Early - Institutional	1	1.3284	3
2FC31	Behavioral Health - High	Early - Institutional	2	1.4801	4
3FC11	Behavioral Health - High	Late - Community	0	0.7357	2
3FC21	Behavioral Health - High	Late - Community	1	0.7928	2
3FC31	Behavioral Health - High	Late - Community	2	0.9445	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.1985	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2556	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4074	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8575	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9146	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0664	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0698	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1269	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2786	3
3FA11	Behavioral Health - Low	Late - Community	0	0.5342	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5913	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7430	2
4FA11	Behavioral Health - Low	Late - Institutional	0	0.9970	3
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0541	2
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2059	3
1FB11	Behavioral Health - Medium	Early - Community	0	0.9859	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0429	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.1947	3
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.1981	3
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2552	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4069	4
3FB11	Behavioral Health - Medium	Late - Community	0	0.6625	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.7196	2
3FB31	Behavioral Health - Medium	Late - Community	2	0.8713	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1254	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1824	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3342	3
1DC11	Complex - High	Early - Community	0	0.9878	2
1DC21	Complex - High	Early - Community	1	1.0449	2
1DC31	Complex - High	Early - Community	2	1.1966	2
2DC11	Complex - High	Early - Institutional	0	1.2000	3
2DC21	Complex - High	Early - Institutional	1	1.2571	3
2DC31	Complex - High	Early - Institutional	2	1.4089	3
3DC11	Complex - High	Late - Community	0	0.6644	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3DC21	Complex - High	Late - Community	1	0.7215	2
3DC31	Complex - High	Late - Community	2	0.8733	2
4DC11	Complex - High	Late - Institutional	0	1.1273	2
4DC21	Complex - High	Late - Institutional	1	1.1844	2
4DC31	Complex - High	Late - Institutional	2	1.3361	2
1DA11	Complex - Low	Early - Community	0	0.8999	2
1DA21	Complex - Low	Early - Community	1	0.9570	2
1DA31	Complex - Low	Early - Community	2	1.1088	2
2DA11	Complex - Low	Early - Institutional	0	1.1122	3
2DA21	Complex - Low	Early - Institutional	1	1.1693	3
2DA31	Complex - Low	Early - Institutional	2	1.3210	3
3DA11	Complex - Low	Late - Community	0	0.5766	2
3DA21	Complex - Low	Late - Community	1	0.6337	2
3DA31	Complex - Low	Late - Community	2	0.7854	2
4DA11	Complex - Low	Late - Institutional	0	1.0395	3
4DA21	Complex - Low	Late - Institutional	1	1.0965	2
4DA31	Complex - Low	Late - Institutional	2	1.2483	2
1DB11	Complex - Medium	Early - Community	0	1.0102	2
1DB21	Complex - Medium	Early - Community	1	1.0673	2
1DB31	Complex - Medium	Early - Community	2	1.2190	2
2DB11	Complex - Medium	Early - Institutional	0	1.2225	3
2DB21	Complex - Medium	Early - Institutional	1	1.2795	3
2DB31	Complex - Medium	Early - Institutional	2	1.4313	3
3DB11	Complex - Medium	Late - Community	0	0.6869	2
3DB21	Complex - Medium	Late - Community	1	0.7440	2
3DB31	Complex - Medium	Late - Community	2	0.8957	2
4DB11	Complex - Medium	Late - Institutional	0	1.1497	3
4DB21	Complex - Medium	Late - Institutional	1	1.2068	3
4DB31	Complex - Medium	Late - Institutional	2	1.3585	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.0925	4
1HC21	MMTA - Cardiac - High	Early - Community	1	1.1496	4
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3013	3
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3047	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3618	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5136	4
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7691	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8262	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9780	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2320	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.2891	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4408	3
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9011	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9582	3
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1100	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1134	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1705	3
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3222	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5778	3
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6349	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7866	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0406	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0977	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2495	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	0.9903	4
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0474	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.1991	3
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2026	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.2596	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4114	4
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6670	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7241	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8758	2
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1298	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.1869	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3386	3
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3258	4
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3829	4
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5347	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5381	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.5952	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7469	4
3IC11	MMTA - Endocrine - High	Late - Community	0	1.0025	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0596	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.2113	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4653	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5224	4
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6742	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1897	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2467	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3985	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.4019	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4590	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.6107	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.8663	3
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.9234	3
3IA31	MMTA - Endocrine - Low	Late - Community	2	1.0752	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.3292	4
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3863	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.5380	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2372	5

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.2943	4
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4460	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4494	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5065	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6582	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.9138	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9709	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.1227	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3767	4
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4338	4
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.5855	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.0883	3
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1453	2
1JC31	MMTA - GI/GU - High	Early - Community	2	1.2971	2
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3005	3
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.3576	3
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5093	3
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7649	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8220	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9738	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2278	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.2849	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4366	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8924	3
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9495	2
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1012	2
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1046	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1617	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3135	3
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5691	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.6261	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7779	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0319	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0890	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2407	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	0.9891	3
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0461	3
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.1979	3
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2013	3
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.2584	3
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4101	3
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6657	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7228	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8746	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1286	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.1857	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3374	3
1KC11	MMTA - Infectious - High	Early - Community	0	1.1296	2
1KC21	MMTA - Infectious - High	Early - Community	1	1.1867	2
1KC31	MMTA - Infectious - High	Early - Community	2	1.3384	2
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3419	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.3990	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5507	3
3KC11	MMTA - Infectious - High	Late - Community	0	0.8063	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8634	2
3KC31	MMTA - Infectious - High	Late - Community	2	1.0151	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2691	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3262	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4780	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9108	2
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9679	2
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1197	2
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1231	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1802	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3319	3
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5875	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6446	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7963	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0503	3
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.1074	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2592	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0001	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.0572	2
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2090	2
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2124	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.2695	3
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4212	3
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6768	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7339	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8856	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1396	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.1967	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3485	3
1AC11	MMTA - Other - High	Early - Community	0	1.0870	4
1AC21	MMTA - Other - High	Early - Community	1	1.1441	3
1AC31	MMTA - Other - High	Early - Community	2	1.2958	3
2AC11	MMTA - Other - High	Early - Institutional	0	1.2992	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.3563	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.5081	4
3AC11	MMTA - Other - High	Late - Community	0	0.7636	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3AC21	MMTA - Other - High	Late - Community	1	0.8207	2
3AC31	MMTA - Other - High	Late - Community	2	0.9725	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2265	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.2836	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.4353	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9152	3
1AA21	MMTA - Other - Low	Early - Community	1	0.9723	3
1AA31	MMTA - Other - Low	Early - Community	2	1.1240	3
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1274	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.1845	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3363	4
3AA11	MMTA - Other - Low	Late - Community	0	0.5918	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6489	2
3AA31	MMTA - Other - Low	Late - Community	2	0.8007	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0547	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1118	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2635	3
1AB11	MMTA - Other - Medium	Early - Community	0	0.9930	4
1AB21	MMTA - Other - Medium	Early - Community	1	1.0501	4
1AB31	MMTA - Other - Medium	Early - Community	2	1.2019	4
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2053	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.2624	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4141	4
3AB11	MMTA - Other - Medium	Late - Community	0	0.6697	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7268	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8785	2
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1325	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.1896	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3414	4
1LC11	MMTA - Respiratory - High	Early - Community	0	1.0978	3
1LC21	MMTA - Respiratory - High	Early - Community	1	1.1549	3
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3067	3
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3101	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.3672	3
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5189	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7745	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8316	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9833	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2373	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.2944	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4462	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9028	3
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9599	2
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1116	2
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1151	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1721	3
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3239	3
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5795	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6366	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7883	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0423	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.0994	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2511	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0015	3
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0586	3
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2103	3
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2137	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.2708	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4226	4
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6781	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7352	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8870	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1410	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.1981	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3498	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.1227	3
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.1798	2
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3315	2
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3349	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.3920	4
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5438	4
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.7993	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8564	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0082	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2622	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3193	3
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4710	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8940	2
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9511	2
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1028	2
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1062	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1633	3
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3151	4
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.5706	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.6277	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7795	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0335	2
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.0906	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2423	3
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	0.9988	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.0559	2
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2076	2
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2110	3
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2681	4
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4199	4
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6755	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7325	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8843	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1383	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.1954	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3471	4
1EC11	MS Rehab - High	Early - Community	0	1.1568	5
1EC21	MS Rehab - High	Early - Community	1	1.2139	4
1EC31	MS Rehab - High	Early - Community	2	1.3656	4
2EC11	MS Rehab - High	Early - Institutional	0	1.3691	5
2EC21	MS Rehab - High	Early - Institutional	1	1.4262	5
2EC31	MS Rehab - High	Early - Institutional	2	1.5779	5
3EC11	MS Rehab - High	Late - Community	0	0.8335	2
3EC21	MS Rehab - High	Late - Community	1	0.8906	2
3EC31	MS Rehab - High	Late - Community	2	1.0423	3
4EC11	MS Rehab - High	Late - Institutional	0	1.2963	4
4EC21	MS Rehab - High	Late - Institutional	1	1.3534	4
4EC31	MS Rehab - High	Late - Institutional	2	1.5051	4
1EA11	MS Rehab - Low	Early - Community	0	0.9432	4
1EA21	MS Rehab - Low	Early - Community	1	1.0003	4
1EA31	MS Rehab - Low	Early - Community	2	1.1520	4
2EA11	MS Rehab - Low	Early - Institutional	0	1.1554	4
2EA21	MS Rehab - Low	Early - Institutional	1	1.2125	4
2EA31	MS Rehab - Low	Early - Institutional	2	1.3643	5
3EA11	MS Rehab - Low	Late - Community	0	0.6199	2
3EA21	MS Rehab - Low	Late - Community	1	0.6769	2
3EA31	MS Rehab - Low	Late - Community	2	0.8287	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.0827	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.1398	4
4EA31	MS Rehab - Low	Late - Institutional	2	1.2915	4
1EB11	MS Rehab - Medium	Early - Community	0	1.0260	5
1EB21	MS Rehab - Medium	Early - Community	1	1.0830	4
1EB31	MS Rehab - Medium	Early - Community	2	1.2348	4
2EB11	MS Rehab - Medium	Early - Institutional	0	1.2382	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.2953	5
2EB31	MS Rehab - Medium	Early - Institutional	2	1.4470	5
3EB11	MS Rehab - Medium	Late - Community	0	0.7026	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7597	2
3EB31	MS Rehab - Medium	Late - Community	2	0.9115	2
4EB11	MS Rehab - Medium	Late - Institutional	0	1.1655	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2226	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.3743	4
1BC11	Neuro - High	Early - Community	0	1.2639	4
1BC21	Neuro - High	Early - Community	1	1.3210	4
1BC31	Neuro - High	Early - Community	2	1.4728	4
2BC11	Neuro - High	Early - Institutional	0	1.4762	4
2BC21	Neuro - High	Early - Institutional	1	1.5333	4
2BC31	Neuro - High	Early - Institutional	2	1.6850	4
3BC11	Neuro - High	Late - Community	0	0.9406	2
3BC21	Neuro - High	Late - Community	1	0.9977	3
3BC31	Neuro - High	Late - Community	2	1.1494	3
4BC11	Neuro - High	Late - Institutional	0	1.4034	4
4BC21	Neuro - High	Late - Institutional	1	1.4605	4
4BC31	Neuro - High	Late - Institutional	2	1.6123	4
1BA11	Neuro - Low	Early - Community	0	1.0241	4
1BA21	Neuro - Low	Early - Community	1	1.0812	4
1BA31	Neuro - Low	Early - Community	2	1.2329	4
2BA11	Neuro - Low	Early - Institutional	0	1.2364	4
2BA21	Neuro - Low	Early - Institutional	1	1.2935	4
2BA31	Neuro - Low	Early - Institutional	2	1.4452	4
3BA11	Neuro - Low	Late - Community	0	0.7008	2
3BA21	Neuro - Low	Late - Community	1	0.7579	2
3BA31	Neuro - Low	Late - Community	2	0.9096	2
4BA11	Neuro - Low	Late - Institutional	0	1.1636	3
4BA21	Neuro - Low	Late - Institutional	1	1.2207	3
4BA31	Neuro - Low	Late - Institutional	2	1.3724	3
1BB11	Neuro - Medium	Early - Community	0	1.1217	4
1BB21	Neuro - Medium	Early - Community	1	1.1788	4
1BB31	Neuro - Medium	Early - Community	2	1.3305	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3340	4
2BB21	Neuro - Medium	Early - Institutional	1	1.3911	4
2BB31	Neuro - Medium	Early - Institutional	2	1.5428	4
3BB11	Neuro - Medium	Late - Community	0	0.7984	2
3BB21	Neuro - Medium	Late - Community	1	0.8555	2
3BB31	Neuro - Medium	Late - Community	2	1.0072	2
4BB11	Neuro - Medium	Late - Institutional	0	1.2612	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3183	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4701	4
1CC11	Wound - High	Early - Community	0	1.5010	4
1CC21	Wound - High	Early - Community	1	1.5581	4
1CC31	Wound - High	Early - Community	2	1.7098	4
2CC11	Wound - High	Early - Institutional	0	1.7132	4
2CC21	Wound - High	Early - Institutional	1	1.7703	4
2CC31	Wound - High	Early - Institutional	2	1.9221	4
3CC11	Wound - High	Late - Community	0	1.1776	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2027	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3CC21	Wound - High	Late - Community	1	1.2347	3
3CC31	Wound - High	Late - Community	2	1.3865	3
4CC11	Wound - High	Late - Institutional	0	1.6405	4
4CC21	Wound - High	Late - Institutional	1	1.6976	4
4CC31	Wound - High	Late - Institutional	2	1.8493	4
1CA11	Wound - Low	Early - Community	0	1.2803	4
1CA21	Wound - Low	Early - Community	1	1.3373	4
1CA31	Wound - Low	Early - Community	2	1.4891	4
2CA11	Wound - Low	Early - Institutional	0	1.4925	4
2CA21	Wound - Low	Early - Institutional	1	1.5496	4
2CA31	Wound - Low	Early - Institutional	2	1.7013	4
3CA11	Wound - Low	Late - Community	0	0.9569	2
3CA21	Wound - Low	Late - Community	1	1.0140	3
3CA31	Wound - Low	Late - Community	2	1.1658	3
4CA11	Wound - Low	Late - Institutional	0	1.4198	4
4CA21	Wound - Low	Late - Institutional	1	1.4769	4
4CA31	Wound - Low	Late - Institutional	2	1.6286	4
1CB11	Wound - Medium	Early - Community	0	1.3745	4
1CB21	Wound - Medium	Early - Community	1	1.4316	4
1CB31	Wound - Medium	Early - Community	2	1.5833	4
2CB11	Wound - Medium	Early - Institutional	0	1.5868	4
2CB21	Wound - Medium	Early - Institutional	1	1.6439	4
2CB31	Wound - Medium	Early - Institutional	2	1.7956	4
3CB11	Wound - Medium	Late - Community	0	1.0512	3
3CB21	Wound - Medium	Late - Community	1	1.1083	3
3CB31	Wound - Medium	Late - Community	2	1.2600	3
4CB11	Wound - Medium	Late - Institutional	0	1.5140	4
4CB21	Wound - Medium	Late - Institutional	1	1.5711	4
4CB31	Wound - Medium	Late - Institutional	2	1.7229	4

Source: *CY 2025 Home Health Claims Data, Periods that end in CY 2025 accessed from the CCW on July 14, 2026.*

Changes to the PDGM case-mix weights are implemented in a budget neutral manner by multiplying the CY 2027 national standardized 30-day period payment rate by a case-mix budget neutrality factor. Typically, the case-mix weight budget neutrality factor is also calculated using the most recent, complete home health claims data available. For CY 2027, we will continue the practice of using the most recent complete home health claims data at the time of rulemaking, which is CY 2025 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 2027 PDGM case-mix weights (developed using CY 2025 home health claims data) are applied to CY 2025 utilization (claims) data are equal to total payments when CY 2026 PDGM case-mix weights (developed using CY 2024 home health claims data) are applied to CY 2025 utilization data. This produces a case-mix budget neutrality factor for CY 2027 of 1.0045.

We invited public comments on the CY 2027 proposed case-mix weights and proposed case-mix weight budget neutrality factor. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed support for CMS's practice of annually recalibrating case-mix weights using the most recent complete claims and OASIS data and generally agreed this practice is necessary to keep payment aligned with current utilization and clinical patterns.

Response: CMS appreciates commenters' support for the annual recalibration methodology required to maintain payment accuracy under the PDGM.

Comment: Some commenters raised concerns that recalibration may systematically underpay for high complexity, caregiver intensive patients (Alzheimer's disease and related dementias, wound care, high-acuity/dual-eligible populations), potentially discouraging HHAs from accepting them. Specifically, a commenter stated that the Wound clinical group, a high-acuity home health population, appears to take the largest case-mix cut. While, by contrast, MMTA–Endocrine sees a comparatively favorable increase. This commenter expressed concern

that this shifts care away from HHAs who accept more complex patients, while rewarding low-acuity billing patterns.

Commenters also suggested that historical claims data used for recalibration may be distorted by what they describe as fraud/outlier billing (particularly in Los Angeles County) and COVID-19 PHE anomalies, which results in annual volatility in thresholds that ultimately creates operational/planning challenges. Commenters stated that this is especially the case for those HHAs whose patients differ from national averages leading to disproportionate payment shifts unrelated to actual patient needs.

Response: CMS notes that case-mix weights are derived from resource use patterns reflected in the most recent complete claims and assessment data, consistent with the statutory requirement to base weights on actual utilization. CMS also reminds stakeholders that the use of percentile trimming methodologies currently applied to claims data are designed to limit the influence of individual outlier claims. That said, for CY 2027, the use of CY 2025 claims represents the most complete and current data available. Also, as it relates to stakeholders' concerns regarding fraudulent/anomalous claims, we note that the recalibration methodology finalized in the CY 2019 HH PPS rule (83 FR 56502) is applied nationally and is based on the aggregate relationship between patient characteristics and observed resource use. To add, the program integrity issues are addressed through separate oversight channels and do not alter the statutory requirement for recalibrations to be implemented in a budget-neutral manner, as required by section 1895(b)(3)(A)(i) of the Act. We acknowledge that annual recalibration may contribute to year-to-year variability, but the overarching intent is to align payments as closely as possible with actual resource use. Finally, we note that the case-mix weights for high-intensity clinical and functional groups such as complex nursing, wound care, and the rehabilitation groups remain among the highest weighted case-mix weight categories for the finalized CY 2027 Home Health recalibration update. For example, the Wound-High Functional Impairment-Early-Institutional-High Comorbidity carries a case-mix weight of 1.9221, and the MMTA-Endocrine-

High Functional Impairment-Early-Institutional-High Comorbidity has a case-mix weight of 1.7469. This indicates that recalibrated weights continue to account for the increased resource needs and costs associated with providing care to high-acuity patients, helping to ensure the adequate provision of needed home health services. Moreover, fraud, waste and abuse cannot be determined through claims data analysis alone. Thus, targeted program integrity efforts (which may involve examining individual providers and claims via established processes) remain the appropriate mechanism to identify and address fraud, waste and abuse. When providers are removed from the Medicare program, their claims are no longer reflected in subsequent rate-setting data. However, removal from the Medicare program for fraud, waste and abuse requires adjudicatory process. CMS cannot presumptively exclude all claims from the recalibration data set based on geographic location (such as Los Angeles County, as raised by commenters) or general utilization patterns (such as anomalous or outlier claims), and deem them as fraudulent absent this adjudicatory process or simply because of stakeholders' assertions alone. Nevertheless, CMS will continue to evaluate ways to improve transparency while monitoring broader system trends such as rising acuity, workforce shortages, and operational costs, as appropriate.

Comment: One commenter raised a distinct case-mix-adjacent concern regarding the admission-source variable used in the HH PPS case-mix adjustment methodology. This commenter noted that the CY 2026 Hospital Outpatient Prospective Payment System final rule finalized a three-year phasing out of the inpatient only list with an expansion of procedures permitted in ambulatory surgical centers. The commenter stated that as care continues shifting from inpatient to outpatient settings, the admission source distribution used in case-mix adjustment will change in ways not fully captured by historical home health claims data, and asked CMS to continue monitoring and assessing whether refinements to the admission-source variable are warranted.

Response: We acknowledge this comment and reiterate our commitment to continue monitoring whether refinements to the admission-source variable are warranted for consideration in future rulemaking as appropriate.

Final Decision: We are finalizing the recalibrated case-mix weights for CY 2027, updated with claims data as of July 14, 2026. We did not receive any comments on the proposed case-mix weight budget neutrality factor. Therefore, we are 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 2027 national, standardized 30-day period payment rate. As stated previously, the final case-mix budget neutrality factor for CY 2027 is 1.0047.

E. Final CY 2027 Home Health Payment Rate Updates

1. Final CY 2027 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 2024 HH PPS final rule (88 FR 77726), we finalized a rebasing of the home health market basket to reflect 2021 cost report data. We also finalized a policy for CY 2024 and subsequent years that the labor-related share is 74.9 percent, and the non-labor-related share is 25.1 percent. A detailed description of how we rebased the home health market basket and labor-related share is available in the CY 2024 HH PPS final rule (88 FR 77726 through 77742).

In the CY 2015 HH PPS final rule (79 FR 38384), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) 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 Balanced Budget Act of 2018)), the market basket percentage under the HH PPS 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 as equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (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) publishes the official measures of productivity for the United States economy. The productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is published by BLS as private nonfarm business total factor productivity (TFP) (previously referred to as multifactor productivity)[5]. We refer readers to https://www.bls.gov/productivity for the BLS historical published TFP data. A complete description of IHS Global Inc.'s (IGI) TFP projection methodology is available on the CMS website at https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.

The proposed home health update percentage for CY 2027 was based on the estimated home health market basket percentage increase, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.1 percent (based on IHS Global Inc.'s first quarter 2026 forecast with historical data through fourth quarter 2025). The estimated CY 2027 proposed home health market basket percentage increase of 3.1 percent was then reduced by a productivity adjustment, in accordance with section 1895(b)(3)(B)(vi) of the Act. Based on IGI's first quarter 2026 forecast, the proposed productivity adjustment was estimated to be 1.0 percentage point for CY 2027. Therefore, the proposed productivity-adjusted CY 2027 home health market basket update was 2.1 percent (proposed 3.1 percent market basket percentage increase, reduced by a proposed 1.0 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available (for example, a more recent estimate of the market basket percentage increase and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2027 market basket percentage increase and productivity adjustment in the final rule.

[5] https://www.bls.gov/productivity/notices/2021/mfp-to-tfp-term-change.htm.

Section 1895(b)(3)(B)(v) of the Act requires that the home health percentage 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 2027, the proposed home health payment update percentage was 0.1 percent (2.1 percent minus 2 percentage points).

We invited public comments on the proposed CY 2027 home health market basket percentage increase and productivity adjustment.

We received public comments on the proposed home health update percentage. The following is a summary of the comments we received and our responses.

Comment: While several commenters expressed support for the proposed 2.1 percent market basket update, many expressed that the proposed market basket percentage increase is inadequate to offset actual growth in the cost of furnishing home health care. Commenters most frequently cited rising labor costs (including wages, benefits, and recruitment/retention expenses), transportation and fuel costs, medical supply and pharmaceutical costs, and technology, cybersecurity, and regulatory compliance costs as exceeding the rate of the proposed market basket update.

A few commenters noted that cumulative market basket updates from CY 2020 through CY 2027 have lagged behind overall inflation indices such as the Employer Cost Index for Total Compensation and the Producer Price Index for All Commodities over the same period.

A few commenters requested that CMS clarify its market basket forecasting methodology and publish underlying data supporting the update calculation.

Response: Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts 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. The home health market basket is a fixed-weight, Laspeyres-type price index, which measures the change in price, over time, of the mix of goods and services included in home health services that were purchased in the base period. Therefore, the market basket is designed to measure price inflation for HHAs

and does not reflect increases in costs associated with changes in the volume or intensity of input goods and services. The home health market basket was last rebased to reflect a 2021 base year effective for CY 2024. We refer commenters to the CY 2024 HH PPS final rule (88 FR 77726) for a detailed description of the methodology used to rebase the home health market basket.

CMS understands that the market basket updates may differ from other overall inflation indexes; however, we reiterate that these topline indexes are not comparable since they measure different mixes of products, services, or wages than the legislatively defined CMS home health market basket. CMS welcomes feedback on alternative data sources for the market basket price proxies that appropriately measure price inflation and not costs. Suggestions can be emailed to cmsdnhs@cms.hhs.gov.

We acknowledge commenters' requests for CMS to provide additional information on the assumptions and inputs that go into developing a market basket update. As previously noted, the detailed market basket cost weights (including the methodology) and price proxies used in the market baskets were set forth in the CY 2024 HH PPS final rule (88 FR 77726). Additionally, we continually make available on the CMS website (https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data) the detailed historical growth rates for the market baskets as well as price forecasts for the aggregated cost weights (such as compensation and utilities). We reiterate that the price proxy forecasts that underlie the home health market basket percentage increase (and all CMS market baskets) are derived from proprietary data produced by IHS Global Inc. (IGI), a nationally recognized economic and financial forecasting firm. Because these forecasts are proprietary to IGI, CMS cannot make the full underlying data publicly available. CMS uses independent, third-party forecasting services such as IGI specifically to ensure that the market basket projections reflect sound, objective economic analysis. We also note that when developing its forecast for the various price indexes used in the home health market basket, IGI considers industry-specific and overall macroeconomic factors that influence pricing trends. We strive for transparency regarding our

methods and note that general inquiries on the forecasting methodology can be emailed to cmsdnhs@cms.hhs.gov.

Comment: Several commenters identified a cumulative home health market basket forecast error of approximately 7.3 to 7.6 percentage points for calendar years 2021 through 2025. Commenters assert that this forecast error has been permanently embedded in the home health payment rates contributing to the chronic underfunding of home health services relative to actual costs incurred.

Some commenters requested that CMS finalize a one-time forecast error correction of approximately 7.6 percentage points to remedy this cumulative underpayment.

Response: While the projected home health market basket updates have recently been underforecast (actual increases less forecasted increases were positive), over longer periods the forecasts have generally averaged close to the historical measures. The cumulative forecast error since HH PPS inception (fiscal year 2002 to CY 2025, excluding CY 2018 and CY 2020 when the market basket update was statutorily mandated) is 0.5 percent. CMS will continue to monitor the methods associated with the market basket forecasts as appropriate to ensure there are not underlying systematic issues in the forecasting approach.

We note that the recent underforecast of the home health market basket increase was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE. However, an analysis of the forecast error of the home health market basket over a longer period of time shows the forecast error has been both positive and negative. Only considering the forecast error for years when the final home health market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error, in particular the numerous years that providers benefited from the forecast error.

For these reasons, we continue to believe it is not appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years.

Comment: Several commenters stated that the statutorily required 1.0 percentage point productivity adjustment does not reflect the operational realities of home health care delivery. These commenters characterized home health as a labor-intensive service delivered to one patient at a time in dispersed geographic settings, arguing that meaningful productivity gains of the magnitude assumed by the broader economy-wide total factor productivity measure are not achievable in this care setting.

A few commenters cited an analysis by the CMS Office of the Actuary suggesting that only approximately 0.1 percentage point of productivity gain is realistically achievable for home health, which is substantially less than the proposed 1.0 percentage point reduction.

A few commenters noted that the proposed 1.0 percent home health productivity adjustment is inconsistent with the 0.9 percent productivity adjustment applied to hospice payments, despite the similarity of the two programs' labor-intensive, in-home workforce models, and requested that CMS reconcile this discrepancy.

One commenter stated that the productivity adjustment has been applied asymmetrically over time, noting that CMS set the productivity adjustment to zero in FY 2021 a year when application of the standard methodology would have increased (not decreased) payments, and asserted that this asymmetry has widened the gap between home health payments and actual provider costs over time.

A few commenters suggested that CMS work with Congress or use its "special exceptions and adjustments" authority to reduce or waive the 1.0 percent productivity adjustment for CY 2027 in light of workforce shortages and rising patient acuity.

Response: Section 1895(b)(3)(B)(vi) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HH PPS

market basket increase factor. As required by statute, the CY 2027 productivity adjustment is derived based on the 10-year moving average growth in economy-wide nonfarm business TFP for the period ending in CY 2027. We recognize the concerns of commenters regarding the appropriateness of the productivity adjustment; however, we are required under section 1895(b)(3)(B)(vi) of the Act to apply the specific productivity adjustment described here. We note that the differing productivity adjustments between home health and hospice that commenters identified are due to timing and data availability rather than industry characteristics. Both productivity adjustments use the most recent published BLS historical TFP data (https://www.bls.gov/productivity) at the time of rulemaking, and IGI's projection model (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf) is used to derive annual TFP growth rates for 2026 and 2027. The annual index level derived from this method is then interpolated to quarterly levels, and the FY 2027, or hospice, productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending September 30, 2027 relative to the 40-quarter moving average projected level for the period ending September 30, 2026. For more information on the FY 2027 productivity adjustment used to update hospice rates, refer to the FY 2027 Hospital Inpatient Prospective Payment System Final Rule (91 FR 49931). Similarly, the CY 2027, or home health, productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending December 31, 2027 relative to the 40-quarter moving average projected level for the period ending December 31, 2026. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the 2027 productivity adjustment reflects BLS historical TFP data through 2025 (released on March 19, 2026) and IGI's forecasted TFP growth for 2026 and 2027. The average annual growth rate of historical TFP published by BLS for 2018 through 2025 is currently 1.0 percent and IGI is projecting average TFP growth of about 0.9 percent for 2026 and 2027 based on IGI's third quarter 2026 forecast. Combining the historical and projected TFP data over the entire 10-year time period and interpolating into quarterly index levels results in a 10-year moving average growth rate of TFP of 1.0 percent for CY 2027 (unchanged from the CY 2027 HH PPS proposed rule).

In response to commenters' concerns about the productivity adjustment only being applied if it reduces the payment update, we note that the productivity adjustment was established under the Affordable Care Act with a specific policy intent to encourage efficiency improvements in healthcare delivery by linking Medicare payment updates to economy-wide productivity gains. The statutory language in section 1895(b)(3)(B)(vi) of the Act requires that the Secretary reduce the market basket percentage increase by changes in economy-wide productivity; therefore, only productivity adjustments that reduce the market basket percentage increase in a given year are applied.

Furthermore, we appreciate the commenters' recommendations for CMS to work with Congress or use its "special exceptions and adjustments" authority to reduce or waive the 1.0 percent productivity adjustment for CY 2027 in light of workforce shortages and rising patient acuity. However, the productivity adjustment is required by statute and is not subject to the Secretary's discretion. Any change to how the productivity adjustment is calculated or applied would require a legislative change, not a regulatory one.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing, as proposed, to use more recent data to determine the CY 2027 productivity adjustment for the final rule.

Final Decision: Consistent with section 1895(b)(3)(B)(vi) of the Act, we are finalizing the home health payment update methodology. The market basket percentage increase for CY 2027 for the HH PPS is based on IGI's third quarter 2026 forecast of the home health market basket percentage increase, which is estimated to be 3.1 percent. As outlined earlier in this section, we are applying a 1.0 percentage point productivity adjustment to the CY 2027 home health market basket percentage increase. Therefore, the final CY 2027 home health market basket update is equal to 2.1 percent for HHAs that submit quality data and 0.1 percent for HHAs that do not submit quality data.

2. Final CY 2027 Home Health Wage Index

a. Background

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 health payments. We proposed to continue this practice for CY 2027, as it is our belief that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data, including taking into account any changes made by the Office of Management and Budget (OMB) to Metropolitan Statistical Area (MSA) definitions, is appropriate and reasonable for the HH PPS.

In general, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. 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.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf. In the CY 2021 HH PPS final rule (85 FR 70298), we finalized our proposal to adopt the revised OMB delineations with a 5 percent cap on wage index decreases in CY 2021.

On July 21, 2023, OMB issued Bulletin No. 23-01, which updates and supersedes OMB Bulletin No. 20-01, issued on March 6, 2020. OMB Bulletin No. 23-01 establishes revised delineations for the MSAs, Micropolitan Statistical Areas, Combined Statistical Areas, and Metropolitan Divisions, collectively referred to as Core Based Statistical Areas (CBSAs). A copy of OMB Bulletin No. 23-01 is available online at https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.

According to OMB, the delineations from OMB Bulletin 23-01 reflect the 2020 Standards for Delineating Core Based Statistical Areas (CBSAs) (the "2020 Standards"), which appeared in the **Federal Register** (86 FR 37770 through 37778) on July 16, 2021, and application of those standards to Census Bureau population and journey-to-work data (for example, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). The OMB ''2020 Standards'' define a "Metropolitan Statistical Area" as being associated with at least one Urban Area that has a population of at least 50,000 and a ''Micropolitan Statistical Area'' as being associated with at least one Urban Area that has a population of at least 10,000, but less than 50,000 (86 FR 37778).

In the CY 2025 HH PPS final rule (89 FR 88354), we finalized our proposal to adopt the revised OMB delineations from OMB Bulletin 23-01 with a 5 percent cap on wage index decreases at the CBSA level as well as at the county level. In that final rule we stated that we believe it is important for the HH PPS wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We also stated that we believe using the most

current OMB delineations will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. In conjunction with our implementation of the revised labor market delineations beginning in CY 2025, and consistent with the treatment of Micropolitan Statistical Areas under the Inpatient Prospective Payment System (IPPS), we also finalized continuing to treat Micropolitan Statistical Areas as ‘‘rural’’ and including Micropolitan Statistical Areas in the calculation of each state’s statewide rural wage index. Therefore, the HH PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in Micropolitan Statistical Areas and the HH PPS wage index for each CBSA is determined using IPPS hospital data from hospitals located in Metropolitan Statistical Areas.

b. Five Percent Cap on Wage Index Decreases

In the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we finalized a policy that the CY HH PPS wage index will include a permanent 5 percent cap on wage index decreases for CY 2023 and each subsequent year. Specifically, we finalized, for CY 2023 and subsequent years, the application of a permanent 5 percent cap on any decrease to a geographic area’s wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we finalized a policy requiring that a geographic area’s wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area’s wage index will not be less than 95 percent of its wage index calculated in the prior CY.

Previously this methodology was applied to all counties that make up a CBSA or statewide rural area. However, in the CY 2025 HH PPS final rule (89 FR 88418 through 88421), because of the adoption of the revised OMB delineations from OMB Bulletin 23-01, we finalized a policy applying this methodology to individual counties. Specifically, we finalized a policy applying the 5 percent cap to counties that moved from a CBSA or statewide rural area with a higher wage index value into a new CBSA or statewide rural area with a lower wage index value,

so that the county's CY 2025 wage index would not be less than 95 percent of the county's CY 2024 wage index value under the old delineation despite moving into a new delineation with a lower wage index.

Due to the way that we proposed calculating the 5 percent cap for counties that experienced an OMB designation change, some CBSAs and statewide rural areas could have had more than one wage index value. Specifically, some counties that changed OMB designations had a wage index value that was different than the wage index value assigned to the other constituent counties that made up that CBSA or statewide rural area that they moved into after the application of the 5 percent cap. However, for home health claims processing, each CBSA or statewide rural area can have only one wage index value assigned to that CBSA or statewide rural area. Therefore, we finalized a policy, beginning in CY 2025, that counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5 percent cap will use a wage index transition code. These special codes are five digits in length and begin with "50" and the remaining digits are unique for that code. The 50XXX wage index transition codes are used only in specific counties; counties located in CBSAs and rural areas that do not correspond to a different transition wage index value will still use the CBSA number.

We also finalized a policy applying the 5 percent cap to these specific counties that correspond to a different wage index value due to a delineation change until the county's new wage index is more than 95 percent of the wage index from the previous calendar year. In order to capture the correct wage index value, an HHA will continue to use the assigned 50XXX transition code on home health claims for services in these counties until the county's wage index value calculated for that calendar year using the new OMB delineations is not less than 95 percent of the county's capped wage index from the previous calendar year.

For CY 2027, the 5 percent cap on wage index decreases will continue to be calculated at the county level as well as the CBSA and statewide rural area level. While some counties that

required a transition code for CY 2025 and CY 2026 will continue to use the same transition code for CY 2027, other counties that required a transition code in CY 2025 and CY 2026 will no longer require a transition code in CY 2027. The counties that will no longer require a transition code beginning in CY 2027 have a CY 2027 wage index value in the CBSA or rural area that the county was redesignated into that is higher than 95 percent of the county's CY 2026 wage index. Therefore, these counties will use the CBSA or rural county code of the area into which they were redesignated based on OMB Bulletin No. 23-01.

While we did not propose any changes to the 5 percent cap policy for CY 2027, we did receive a few comments on the finalized policies. The following is a summary of the comments we received and our responses:

Comment: A few commenters expressed support for the finalized 5 percent cap policy.

Response: We thank the commenters for their support.

Comment: Some commenters recommended changes to the finalized cap percentage. Specifically, some commenters suggested reducing the cap percentage. These commenters suggested that even wage-index declines within the 5 percent cap can erase most of the annual payment update in competitive markets like Pennsylvania, Northern California, and Michigan, leaving providers with net increases of only 0.4 to 0.5 percent. Therefore, a commenter recommended lowering the cap percentage to 2 percent, while another commenter requested a provider-level floor limiting total revenue loss to 1 percent. Another commenter suggested that CMS could limit a provider's wage-index-related payment loss relative to the overall annual payment update or adopt another methodology that provides a more gradual transition where updated geographic data produce substantial reductions.

Response: We appreciate commenters' recommendations for changes to the finalized 5 percent cap policy. However, we did not propose to make changes to this policy in the CY 2027 HH PPS proposed rule. Therefore, these comments are outside the scope of the proposed rule. Any changes to the finalized 5 percent cap policy would need to go through notice and comment

rulemaking. However, consistent with our finalized 5-percent cap policy outlined in the CY 2023 HH PPS final rule (66851 through 66853), we continue to believe that 5 percent is a reasonable level for the cap because it would more effectively mitigate any significant decreases in a geographic area's wage index for a calendar year, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, we believe that the 5 percent cap on wage index decreases provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face year to year.

Final Decision: We did not propose any changes to the finalized 5 percent cap policy in the proposed rule. Therefore, the CY 2027 HH PPS wage index will continue to include the 5 percent cap on wage index decreases. For CY 2027, the 5 percent cap on wage index decreases will also continue to be calculated at the county level. While some counties that required a transition code for CY 2025 and CY 2026 will continue to use the same transition code for CY 2027, other counties that previously required a transition code will no longer require a transition code in CY 2027. These counties will use the CBSA or rural county code of the area they were redesignated into based on OMB Bulletin No. 23–01. The complete list of counties and corresponding transition codes can be found as a separate tab in the calendar year's wage index file located on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.

c. Final CY 2027 HH PPS Wage Index

The appropriate wage index value is applied to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined in section 1861(m) of the Act as the beneficiary's place of residence). For CY 2027, we proposed to base the HH PPS wage index on the FY 2027 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023 (FY 2023 cost report data). The CY 2027 HH PPS wage index would not take into account any geographic reclassification

of hospitals, including those in accordance with sections 1886(d)(8)(B) or 1886(d)(10) of the Act but would include the 5 percent cap on wage index decreases as discussed previously.

There exist some geographic areas where there are no hospitals, and thus, no hospital wage data on which to base the calculation of the HH PPS wage index. 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 2027 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 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 2027, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). Using the average wage index of all urban areas in Georgia as a proxy, we proposed the CY 2027 wage index value for Hinesville, GA, would be 0.8797. With updated wage data, the final CY 2027 HH PPS wage index value for Hinesville, GA will be 0.8798.

For rural areas that do not have inpatient hospitals, we use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. The term "contiguous" means sharing a border (72 FR 49859). In the CY 2025 HH PPS final rule (89 FR 88422), we finalized a policy that rural North Dakota would become a rural area without a hospital from which hospital wage data can be derived. Therefore, in order to calculate the wage index for rural area 99935, North Dakota, we finalized using as a proxy, the average pre-floor, pre-reclassified hospital wage data from the contiguous CBSAs: CBSA 13900-Bismark, ND, CBSA 22020-Fargo, ND-MN, CBSA 24220-Grand Forks, ND-MN, and CBSA 33500, Minot, ND. Using this methodology, we proposed that the CY 2027 HH PPS wage index for rural North Dakota would be 0.8210. With updated wage data, the final CY 2027 HH PPS wage index for rural North Dakota is 0.8209.

Previously, the only rural area without a hospital from which hospital wage data could be derived was rural Puerto Rico. However, for rural Puerto Rico, we did not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the proximity of almost all of Puerto Rico's various urban and non-urban areas to one another, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we used the most recent wage index previously available for that area, which was 0.4047. Beginning in CY 2025, due to the adoption of the revised OMB delineations, there is now a hospital in rural Puerto Rico from which hospital wage data can be derived. Therefore, we finalized a policy that the wage index for rural Puerto Rico would now be based on the hospital wage data for the area instead of the previously available wage index of 0.4047.

The unadjusted CY 2027 proposed wage index for rural Puerto Rico is 0.2577. However, because 0.2577 is more than a 5 percent decline in the CY 2026 wage index, we proposed that the CY 2027 5 percent cap adjusted wage index for rural Puerto Rico be set equal to 95 percent of the CY 2026 wage index of 0.3653, which resulted in a proposed wage index value of 0.3470. With updated wage data, the unadjusted CY 2027 final wage index for rural Puerto Rico is 0.2576. However, because 0.2576 is more than a 5 percent decline in the CY 2026 wage index, the CY 2027 5 percent cap adjusted wage index for rural Puerto Rico will be set equal to 95 percent of the CY 2026 wage index of 0.3653, which results in a final wage index value of 0.3470.

Additionally, due to the adoption of the revised OMB delineations in the CY 2025 HH PPS final rule, Delaware, which was previously an all-urban state, now has one rural area with a hospital from which hospital wage data can be derived. As such, we proposed that the CY 2027 wage index for rural Delaware would be 0.9590. With updated wage data, the final CY 2027 wage index for rural Delaware is 0.9590.

Finally, the Northern Mariana Islands and American Samoa are rural areas with no hospital data from which a wage index can be calculated. In the CY 2026 HH PPS final rule (90

FR 55405), using our established methodology for rural areas with no hospitals, we finalized that for CY 2026 and subsequent years, HHAs that provide services in the Northern Mariana Islands and American Samoa would use CBSA 99965 (Guam) and receive the wage index assigned to CBSA 99965 (Guam) of 0.9611. While we appreciate that the islands of the Pacific Rim are not actually contiguous, we believe that same principle applies here, and that Guam is a reasonable proxy for American Samoa and the Northern Mariana Islands. We believe that CBSA 99965 (Guam) represents a reasonable proxy because the islands are located within the Pacific Rim and share a common status as United States Territories.

The final HH PPS wage index file applicable for CY 2027 (January 1, 2027, through December 31, 2027) is available on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.

We received public comments on the proposed HH PPS wage index. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for the proposed CY 2027 HH PPS wage index.

Response: We thank the commenters for their support.

Comment: Commenters broadly criticized the current methodology of using the inpatient hospital pre-floor, pre-reclassified wage index as an inaccurate proxy for home health labor costs. With respect to Maryland, several commenters stated that the current wage index methodology imports the effects of Maryland's hospital cost-containment incentives into Medicare payment for home health providers, which creates a policy spillover where hospital wage data affected by Maryland's Total Cost of Care Model is used to reduce payment to providers that are outside the hospital global budget system. These commenters recommended that CMS avoid exporting hospital-specific budget incentives into the payment methodology for independent home health and other post-acute providers.

Response: We continue to believe that in the absence of home health specific data, the pre-floor, pre-reclassified hospital wage index is appropriate for the geographic adjustment of home health claims. While we did not propose any changes to the CY 2027 HH PPS wage index methodology in the proposed rule, we did request information on changes to the home health wage index methodology and may consider these recommendations and the comments received on the RFI in future rulemaking as appropriate. A discussion of the comments received on the RFI for a new home health specific wage index can be found in section III.F. of this final rule.

Comment: Several commenters expressed concern that home health providers are unable to benefit from IPPS hospital wage index policies such as reclassification and the rural floor. A commenter recommended that CMS modify the agency's wage index policy to use the final FY 2027 hospital wage index, including geographic reclassifications and rural floor adjustments.

Response: While we appreciate the commenters' concerns that HHAs are unable to benefit from IPPS hospital wage index policies, we continue to believe that the regulations and statutes that govern the HH PPS differ from the hospital regulations and statutes, such that there would be differences between how these payment systems apply wage index policies including geographic reclassification, or the rural floor. Section 4410(a) of the Balanced Budget Act of 1997 provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that State. This rural floor provision is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Medicare Geographic Classification Review Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification for purposes of payment under the IPPS. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act. Therefore, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals.

Comment: Some commenters expressed concern that the current wage index methodology often fails to accurately capture the labor market realities experienced by rural HHAs. These commenters suggested that the current wage index ignores drive time, low population density, and travel expenses that increase rural care costs. One commenter noted that the wage index for Maine shows a 20 percent urban-rural wage gap when actual wages differ by less than 5 percent. Another commenter expressed concern that staff working for rural HHAs drive up to 600 miles a week without adequate mileage reimbursement. A commenter stated that due to the lower population density, more miles are driven between patients, increasing both direct costs and indirect costs through lower productivity.

Response: We appreciate commenters' concerns regarding the wage index values assigned to rural areas. As discussed in the CY 2022 HH PPS final rule (86 FR 62285), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the need for higher reimbursement due to the added cost of traveling from one patient to the next. However, urban HHAs cite the need for higher reimbursement due to 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. Regarding the commenter's concern with the wage index values assigned to rural Maine versus the wage index values assigned to Maine's urban CBSAs, we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. Therefore, as previously stated, in the absence of home health specific data we believe that the pre-floor, pre-reclassified hospital wage index is an appropriate proxy for the home health wage index.

Comment: A commenter stated that although the aggregate effect of wage index changes may be budget neutral nationally, the distributional impact can create substantial financial challenges for providers operating in markets where reimbursement does not align with the costs of attracting and retaining qualified staff.

Response: We appreciate the commenter's concern that despite the wage index being budget neural nationally there may be distributional impacts to individual providers that can create substantial financial challenges. However, we reiterate that we believe the 5 percent cap on wage index decreases should provide a degree of predictability in payment changes for individual providers and allows providers time to adjust to any significant decreases they may face year to year.

Final Decision: After consideration of public comments, we are finalizing our proposal to base the HH PPS wage index on the FY 2027 hospital pre-floor, pre- reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023 (FY 2023 cost report data). The final CY 2027 HH PPS wage index will include the 5 percent cap on wage index decreases. The final HH PPS wage index file applicable for CY 2027 (January 1, 2027, through December 31, 2027) is available on the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.

3. Final CY 2027 Home Health Payment Update

a. Background

The HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000, HH PPS 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 2024 HH PPS final rule (88 FR 77676), we finalized the rebasing of the home health market basket to reflect 2021 Medicare cost report data. We also finalized a policy that, for CY 2024 and subsequent years, the labor-related share is 74.9 percent, and the non-labor-related share is 25.1 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2027:

- 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 (74.9 percent) and a non-labor portion (25.1 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 percentage, minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will 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 would 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 partial payment adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

b. Final CY 2027 National, Standardized 30-Day Period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different HHAs in a budget-neutral manner. We stated in the proposed rule that to determine the CY 2027 national, standardized 30-day period payment rate, we would continue our practice of using the most recent, complete utilization data at the time of rulemaking; that is, we are using CY 2025 claims data for CY 2027 payment rate updates.

As discussed in section II.C.1. of the CY 2026 HH PPS final rule (90 FR 55406), we finalized the implementation of a temporary 3.0 percent reduction to the CY 2026 base payment rate that was equivalent to a final temporary adjustment factor of 0.97000. Per section 1895(b)(3)(D)(iii) of the Act, a temporary adjustment is to be applied for the applicable year and not included when computing a payment rate for a subsequent year. In other words, the temporary adjustment factor for CY 2026 will not be included in the starting payment rate for CY 2027. Therefore, we calculated the CY 2026 national, standardized 30-day period payment with and without the temporary adjustment factor.

To calculate the CY 2027 national, standardized 30-day period payment amount, we began with the actual CY 2026 national standardized 30-day period payment amount (with the temporary adjustment factor included) and applied an adjustment factor of 1.03093 (which is equal to 1 divided by the CY 2026 temporary adjustment factor of 0.97000) to remove the temporary adjustment factor as shown in table 12.

TABLE B12: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT (WITHOUT TEMPORARY ADJUSTMENT)

CY 2026 National Standardized 30-Day Period Payment (With Temporary Adjustment)	Removing CY 2026 Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)
$2,038.22	1.03093	$2,101.26

We applied a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, the home health payment update percentage, and a temporary adjustment factor to update the CY 2027 payment rate. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we applied a case-mix weight budget neutrality factor to the CY 2027 national, standardized 30-day period payment rate. The proposed case-mix weight budget neutrality factor for CY 2027 was 1.0045. Based on updated CY 2025 claims data as of July 14, 2026, the final case-mix weight budget neutrality factor for CY 2027 is 1.0047.

Additionally, we applied a wage index budget neutrality factor to ensure that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day periods using the CY 2027 wage index (with the 5 percent cap) so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2026 wage index (with the 5 percent cap) and the CY 2026 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 2027 wage index with the 5 percent cap on wage index decreases) by the payment rate for non-LUPA 30-day periods using the CY 2026 wage index (with the 5 percent cap on wage index decreases), we obtain a wage index budget neutrality factor of 1.0009. We then apply the wage index budget neutrality factor of 1.0009 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the proposed CY 2027 home health payment update percentage of 2.1 percent. As discussed in section II.C.1. of this final rule, we are finalizing our proposal to apply the temporary 3.0 percent reduction to the CY 2027 base payment rate. The proposed temporary adjustment factor is 0.97000. As discussed previously, per section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied for the applicable year and not included when computing a payment rate for a subsequent year. In other words, the temporary adjustment factor for CY 2027 should not be included in the starting payment rate for CY 2028. Therefore, we have calculated the CY 2027 national, standardized 30-day period payment with and without the temporary adjustment factor. The CY 2027 national standardized 30-day period payment rate without a temporary adjustment is only for illustrative purposes. The actual CY 2027 national standardized 30-day period payment rate includes the temporary adjustment and is calculated in table 13.

TABLE B13: FINAL CY 2027 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2026 National Standardized 30-Day Period Payment Without Temporary Adjustment	CY 2027 Case-Mix Weights Recalibration Neutrality Factor	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor	CY 2027 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2027 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
$2,101.26	1.0047	1.0009	1.0210	$2,157.41	0.9700	$2,092.69

The CY 2027 national standardized 30-day period payment rate for an HHA that does not submit the required quality data will be updated by 0.1 percent (the final CY 2027 home health payment update percentage of 2.1 percent minus 2 percentage points) and is shown in table 14.

TABLE B14: FINAL CY 2027 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2026 National Standardized 30-Day Period Payment Without Temporary Adjustment	CY 2027 Case-Mix Weights Recalibration Neutrality Factor	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor Minus 2 Percentage Points	CY 2027 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2027 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
$2,101.26	1.0047	1.0009	1.0010	$2,115.15	0.9700	$2,051.70

c. Final CY 2027 National Per-Visit Rates for 30-day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health 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 final CY 2027 national per-visit rates, we started with the CY 2026 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 2027 wage index with the 5 percent cap on wage index decreases and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2026 wage index with the 5 percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2027 wage index by the total payments for LUPA 30-day periods of care using the CY 2026 wage index, we obtain a wage index budget neutrality factor of 0.9999. As a reminder, the wage index budget neutrality factors for the national, standardized 30-day period amount and the national LUPA per-visit rates are not equal because they are calculated differently. The wage index budget neutrality factor for the LUPA per-visit payments is calculated by simulating total payments for LUPA 30-day periods while the 30-day period budget neutrality factor is calculated by simulating payments for non-LUPA 30-day periods.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Additionally, we are not applying the permanent adjustment or the temporary adjustment to the LUPA per-visit payment rates but only to the case-mix adjusted 30-day payment rate. Lastly, the per-visit rates for each discipline are updated by the CY 2027 home health payment update percentage of 2.1 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 periods that occur as the only period or initial period in a sequence of adjacent periods. The final CY 2027 national per-visit rates for HHAs that submit the required quality data are updated by the final CY 2027 home health payment update percentage of 2.1 percent and are shown in table 15.

TABLE 15: FINAL CY 2027 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2026 Per-Visit Payment Amount	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor	CY 2027 Per-Visit Payment Amount
Home Health Aide	$80.12	0.9999	1.0210	$81.79
Medical Social Services	$283.64	0.9999	1.0210	$289.57

Occupational Therapy	$194.74	0.9999	1.0210	$198.81
Physical Therapy	$193.42	0.9999	1.0210	$197.46
Skilled Nursing	$176.96	0.9999	1.0210	$180.66
Speech-Language Pathology	$210.25	0.9999	1.0210	$214.64

The CY 2027 per-visit payment rates for HHAs that do not submit the required quality data will be updated by 0.1 percent, which is the final CY 2027 home health payment update percentage of 2.1 percent minus 2 percentage points and are shown in table 16.

TABLE 16: FINAL CY 2027 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2026 Per-Visit Payment Amount	CY 2027 Wage Index Budget Neutrality Factor	CY 2027 HH Payment Update Factor Minus 2 Percentage Points	CY 2027 Per-Visit Payment Amount
Home Health Aide	$80.12	0.9999	1.0010	$80.19
Medical Social Services	$283.64	0.9999	1.0010	$283.90
Occupational Therapy	$194.74	0.9999	1.0010	$194.92
Physical Therapy	$193.42	0.9999	1.0010	$193.59
Skilled Nursing	$176.96	0.9999	1.0010	$177.12
Speech-Language Pathology	$210.25	0.9999	1.0010	$210.44

We solicited comments on the proposed CY 2027 30-day home health payment rates and the per-visit payment rates but did not receive comments on this proposal.

Final Decision: We are finalizing the updates to the CY 2027 national, standardized 30-day period payment rates and the CY 2027 national per-visit payment amounts as proposed, using the final CY 2027 market basket update.

d. 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 described 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, whereby we finalized the approach of multiplying the per-visit payment amount for the first skilled nursing (SN), physical therapy (PT), or speech language pathology (SLP) visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by 1 + the proportional increase in minutes for an initial visit over non-initial visits. Specifically, we updated the analysis using 100 percent of LUPA episodes and a 20 percent sample of non-LUPA first episodes from CY 2012 claims data. At that time, we finalized add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. 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 SN, PT, or SLP 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 (using the already established LUPA add-on factors of 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.

In the CY 2025 HH PPS final rule (89 FR 88426 through 88427), in an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, we finalized updates to the LUPA add-on factors for PT, SN, and SLP, which had not been revised since the CY 2014 HH PPS final rule (using CY 2012 claims data). We finalized using the same methodology to establish the LUPA add-on amount as used for CY 2014, using updated claims data.

Specifically, in CY 2025, we updated the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data (as of September 11, 2024). Our analysis found that the average excess of minutes for the first

visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods are 29.91 minutes for the first visit if SN, 28.08 minutes for the first visit if PT, and 31.57 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes are 41.54 minutes for SN, 45.11 minutes for PT, and 47.15 minutes for SLP. To determine the LUPA add-on factors for each discipline, we calculated the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to these ratios to obtain the final add on factors. Therefore, beginning in CY 2025 the final LUPA add on factors for SN, PT, and SLP are 1.7200 for SN; 1.6225 for PT; and 1.6696 for SLP.

Additionally, as outlined in the CY 2025 HH PPS proposed rule (89 FR 55378), in order to implement Division CC, section 115, of the Consolidation Appropriations Act (CAA), 2021, CMS finalized changes to the regulations at § 484.55(a)(2) and (b)(3) that allowed occupational therapists 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 included OT, as well as either PT or SLP (86 FR 62351). This change necessitated the establishment of a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT 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. However, at the time of the implementation, we stated in the CY 2022 HH PPS final rule (86 FR 62289), there was not sufficient data regarding the average excess minutes for the first visit in LUPA periods when the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we finalized a policy using the PT LUPA add-on factor as a proxy. We also stated in the CY 2022 final rule that we will use the PT LUPA add-on factor 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 (86 FR 62289). Ultimately, we refrained from using CY 2022 data (and instead utilized the PT LUPA add-on factor as a proxy for the OT LUPA add-on factor), as we marked the first year that

occupational therapists were permitted to conduct the initial assessment. We wanted to extend our analysis to ensure we had sufficient data to reflect OT time spent conducting initial assessments to establish a discrete OT LUPA add-on factor (86 FR 62240).

In the CY 2025 HH PPS final rule (89 FR 88427), we finalized discontinuing the use of the PT LUPA add-on factor as a proxy and established a definitive LUPA add-on factor for OT. We used the same methodology used to establish the LUPA add-on amount for CY 2014, as described previously for the SN, PT, and SLP add-on factors. Specifically, we updated the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. Using updated analysis (as of September 11, 2024), we found that the average excess of minutes for the first OT visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods is 33.28 minutes for the first visit. The average number of minutes for all non-first visits in non-LUPA periods is 45.98 minutes for OT. To determine the LUPA add-on factor for OT to account for the excess minutes during the first visit in a LUPA period, we finalized calculating the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to this ratio to obtain the final add on factor of 1.7238 for OT. Therefore, the OT LUPA factor of 1.7238 is used when occupational therapy is the first skilled visit in a LUPA period that occurs as the only period or an initial period in a sequence of adjacent periods.

TABLE B17: LUPA ADD-ON FACTORS

Discipline	LUPA Add-on Factors
SN	1.7200
PT	1.6225
SLP	1.6696
OT	1.7238

4. Payments for High-Cost Outliers under the HH PPS

a. 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 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 is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the 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 as a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by 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 through 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 would 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 stated that we would continue to monitor the visit length by discipline as more recent data becomes available and may propose updating 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 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.

In the CY 2021 HH PPS final rule (85 FR 70322), given that CY 2020 was the first year of the PDGM and the change to a 30-day unit of payment, we finalized maintaining the same FDL ratio of 0.56 for 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. In the CY 2022 HH PPS final rule with comment period (86 FR 62292), we estimated that outlier payments would be approximately 1.8 percent of total HH PPS payments in CY 2022 if we maintained an FDL of 0.56. Therefore, in order to pay up to, but no more than, 2.5 percent of total payments as outlier payments we finalized an FDL of 0.40 for CY 2022. In the CY 2023 HH PPS final rule (87 FR 66875), using CY 2021 claims utilization data, we finalized an FDL of 0.35 in order to pay up to, but no more than, 2.5 percent of the total payment as outlier payments in CY 2023. In the CY 2024 HH PPS final rule (88 FR 77749), using CY 2022 claims utilization data, we finalized an FDL of 0.27 for CY 2024. In the CY 2025 HH PPS final rule (89 FR 88354), using CY 2023 claims data (as of July 11, 2024) we finalized an FDL ratio of 0.35 for CY 2025. In the CY 2026

HH PPS final rule (90 FR 55411), using CY 2024 claims data (as of July 11, 2025) we finalized an FDL ratio of 0.37 for CY 2026.

b. Final FDL Ratio for CY 2027

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). We use a value of 0.80 for the loss-sharing ratio, which we believe preserves incentives for HHAs 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.

Using CY 2025 claims data (as of March 12, 2026) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we proposed an FDL ratio of 0.29 for CY 2027. We also proposed to update the FDL ratio in the final rule based on more complete CY 2025 claims data.

We solicited comments on the proposed CY 2027 FDL. The following is a summary of the comments we received and our responses:

Comment: Most commenters expressed support for CMS's proposal to lower the fixed-dollar loss ratio. These commenters stated that this proposed update to the FDL would appropriately expand access to outlier payments for high-cost, medically complex care.

Response: We thank the commenters for their support.

Comment: A few commenters opposed the proposed update to the CY 2027 FDL and requested more transparency with the data surrounding the FDL and home health outlier payments. A commenter suggested that successive FDL decreases correlate with declining visit volumes, suggesting HHAs may be reducing visits to avoid disqualifying themselves from outlier payments rather than accepting costly patients as intended. This commenter requested deeper analysis of the 10 percent agency-level outlier cap and its relationship to visit-intensity trends. Multiple commenters requested that CMS publish detailed year-by-year reconciliation data from CY 2011–2027 comparing the 5 percent outlier set-aside, the 2.5 percent statutory ceiling, and actual outlier payments made. These commenters stated that the persistent gap suggests systemic underfunding of the home health benefit and requested that CMS quantify this trade-off for Congress, with one commenter recommending Congress consider eliminating the outlier provision entirely. One commenter asked CMS to confirm that high-complexity, caregiver-intensive episodes with respect to ADRD (Alzheimer's disease and related dementia) retain meaningful outlier access as the FDL is recalibrated.

Response: We remind commenters that, as established in section 1895(b)(5) of the Act, both the 2.5 percent target of outlier payments to total home health payments and the 10- percent cap on outlier payments at the home health agency level are statutory requirements. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or the 2.5- percent target amount. We appreciate commenters' recommendation to provide a detailed analysis that compares the 2.5 percent statutory ceiling and the actual outlier payments made; however, we are not required by statute to reconcile the 2.5 percent target of outlier payments. Because the FDL is calculated prospectively such that outlier payments do not exceed 2.5 percent of total home health payments, there are some years we may reach the 2.5 percent target and some years we may not. However, we believe that our current methodology for calculating the FDL remains appropriate. A high FDL ratio reduces the number of episodes that can receive outlier payments but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier

payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower. 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 periods of care. We have used the most recent claims data to calculate the FDL ratio since that time. In the CY 2027 HH PPS proposed rule, we stated that we would use the most recent claims data available, which is CY 2025 claims data. Using CY 2025 claims data (as of July 14, 2026), we found that the FDL ratio would need to be lowered from the final CY 2026 FDL of 0.37 to 0.29.

We appreciate the commenters' concerns regarding the successive decreases in the FDL and the impact that it may have on visit patterns and the impact to high intensity periods of care and recommendations to provide more transparency regarding the data used to calculate the FDL. We believe that outlier payments are beneficial in helping to mitigate the incentive for HHAs to avoid patients that need higher levels of medical care. We will continue to evaluate changes to the FDL, analyze patterns in home health outlier payments, and monitor for any impacts, particularly for those beneficiaries with clinically complex conditions, and may include the results of such efforts in future rulemaking as appropriate.

Comment: Some commenters expressed concern that CMS is updating the FDL based on potentially fraudulent data, specifically in what they describe as high fraud areas such as Los Angeles County. These commenters stated that fraudulent, low-acuity, high-volume billing distorts the ratio's underlying math and disadvantages legitimate HHAs serving genuinely high-cost patients. Some commenters requested that CMS withhold finalizing the update to the FDL until this fraudulent data is removed.

Response: We appreciate the commenters' concerns regarding potential fraudulent billing and its potential impact on the proposed FDL. However, as discussed previously, outlier billing

patterns are not always indicative of fraudulent practice. Further evidence would be required to determine definitively whether their activities can be connected to fraudulent practices. Depending on the circumstance, anomalous patterns can prompt further review and initiate investigation for evidence of fraud, waste, and abuse. CMS currently includes the most recent and complete claims data when updating the FDL. If CMS excluded the claims the commenters view as outliers from the calculation of the FDL, CMS would need to make thresholds for determining what qualifies as an outlier to be excluded from the analytical sample; and the available aggregate data do not establish that these outlier claims are in fact improper and should be excluded. In addition, dropping providers with anomalous billing patterns can cause the sample to be much smaller relative to the most recent and complete claims for that given year. LA County is not the only area with unusual utilization patterns, and a blanket geographic exclusion for any geographic area showing varying utilization patterns would potentially remove a large number of legitimate claims with any potentially improper claims. CMS will continue to analyze utilization patterns due to commenter concern regarding fraudulent data; however, thus far these patterns do not establish fraud or the necessity to remove claims from rulemaking analysis.

We appreciate commenters sharing insight into how we can address concerns about potential fraud in the home health market. Cost report fraud and abusive billing behavior are concerns that need to be addressed through the appropriate channels with the authority to pursue enforcement action, such as the hotline for reporting fraud at the following website: https:// www.cms.gov/medicare/medicaid- coordination/center-program-integrity/ reporting-fraud.

Final Decision: With updated CY 2025 claims data (as of July 14, 2026) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are finalizing an FDL ratio of 0.29 for CY 2027.

F. Palliative Care Services as Home Health Services

In the proposed rule, CMS noted that it is seeking to advance its broader goal of promoting access to and utilization of palliative care services, with a particular focus on expanding opportunities for beneficiaries to receive these services under the Medicare home health benefit. As part of this effort, CMS included a Request for Information (RFI) in the FY 2027 Hospice Wage Index and Payment Rate Update proposed rule (91 FR 17359) to solicit public input on potential policy, operational, and payment approaches to strengthen and enhance the delivery of palliative care services outside of the hospice benefit. We were especially interested in hearing more about how Medicare practitioners and post-acute care providers furnish community-based palliative care, well as opportunities for improvement. We stated we believe that, as palliative care is a method of care delivery that is provided throughout the continuum of illness, it can be furnished under various Medicare benefits. We also stated that the home is an ideal environment for individuals to receive palliative care services, as remaining in the home during a serious illness may help alleviate psychological and mental distress and allow for more intimate caregiving to be provided by family members. As such, we believe the Medicare home health benefit can be an important step in the care continuum when a patient needs palliative care, either during episodes of serious illness or near end of life, before choosing hospice care.

In accordance with § 409.42(c), to qualify for Medicare coverage of home health services, a beneficiary must need skilled services as set out at § 409.32. Section 409.32(a) states that "[t]o be considered a skilled service, the service must be so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel." Under the home health benefit, a beneficiary's unique condition and individual needs should be considered in deciding whether skilled nursing care is reasonable and necessary, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time. There are no expectations that life-prolonging therapies will be avoided or that the patient must be considered terminally ill, and the restoration potential of a

patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current capabilities. Further, as discussed in chapter seven of the Medicare Benefit Policy Manual (BPM)[6], it is a physician or an allowed practitioner, as defined at § 484.2, who is familiar with the patient who determines whether a skilled service is reasonable and necessary based on the patient's individual care needs and goals, and accepted standards of medical and nursing practice. Therefore, if the beneficiary meets the qualifications for coverage of services as set out at § 409.42, he or she could receive palliative care services under the home health benefit, if ordered by a physician or an allowed practitioner.

Often skilled services are determined to be reasonable and necessary when a patient has multiple medications and comorbidities, with resultant functional impairments, that leave them homebound with a need for skilled observation of the patient's condition and medication management. A discussion on palliative care delivery in the home emphasizes the importance of home-based care for patients with multiple morbidities and limited mobility.[7] The structure of the PDGM allows, in general, for palliative care services to be most appropriately grouped into the medication, management, teaching, and assessment (MMTA) clinical group. As discussed in the CY 2019 HH PPS proposed rule (83 FR 32402), health teaching; guidance and counseling; case management, treatments and procedures; and surveillance are integral to the care of most home health patients. Palliative care is defined at § 418.3 to mean "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, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice." We noted that we believe this definition encompasses all the services provided under the

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

[7] National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Board on Health Care Services; Roundtable on Quality Care for People with Serious Illness. Models and Strategies to Integrate Palliative Care Principles into Care for People with Serious Illness: Proceedings of a Workshop. Washington (DC): National Academies Press (US); 2017 Oct 24. Proceedings of a Workshop. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538355/.

Medicare home health benefit. Additionally, these important interventions are often the primary reason for home health services. Section 1861(m) of the Act requires the 30-day period to include all covered home health services: skilled nursing; home health aide; physical therapy; speech-language pathology; occupational therapy; medical social services, and medical supplies. Skilled nursing services can address advanced symptom management, including specialized care to manage pain, nausea and vomiting, depression and anxiety, and respiratory distress. This may also include medication management to monitor therapeutic and adverse effects and review and adjust medications in coordination with allowed practitioners. Medical social services can help address advance care planning needs (including discussion on transition to hospice) as well as offer referrals for social and emotional support for families and caregivers. Physical therapists (PTs), occupational therapists (OTs), and speech language pathologists (SLPs) enhance patient quality of life, comfort, and dignity by maximizing functional independence and managing symptoms. PTs focus on mobility, pain management, and safe transfers, while OTs specialize in adapting activities of daily living (ADLs) and environments to maintain independence for as long as possible. SLPs support safe eating and drinking and help facilitate communication and decision making for those patients with deficits.

We reiterated that, like other skilled services, comprehensive home health clinical notes are expected to substantiate the need for palliative care necessitating medication management, teaching, and assessment through documentation of the patient's achievement of care needs and goals as outlined in the plan of care. Accordingly, we pointed to chapter seven of the BPM that includes an example of a patient with malignant melanoma who is terminally ill and requires skilled observation, assessment, teaching, and treatment, and who has not elected hospice care. This example explains that the documentation should describe the goal of the skilled nursing intervention, and at each visit the services provided should support that goal. The skilled nursing care that the patient requires would be covered, notwithstanding that the condition is terminal, because the documentation and description must support that the needed services required the

skills of a nurse. We stated that a palliative care plan for this type of patient would likely include medication and symptom management, including expected treatment responses for pain, anxiety, constipation, nausea, or dyspnea; education and caregiver training on managing symptoms at home; assessing social risk factors including caregiver burden and emotional and psychosocial distress; and skilled therapy for non-pharmacologic pain management strategies and interventions to maximize functional status and independence.

We noted in the proposed rule that we plan on adding additional palliative care examples of skilled care to the BPM following publication of this final rule to support our goal of encouraging community-based palliative care services, particularly under the Medicare home health benefit.

We solicited public comments on any concerns or suggestions reaching this goal. The following is a summary of the comments received and our responses:

Comment: The majority of commenters expressed support for CMS's goal of expanding community-based palliative care under the existing Medicare home health benefit, recognizing its potential to improve symptom management, caregiver support, and quality of life for seriously ill beneficiaries. Most of these commenters affirmed that skilled palliative services, including pain and symptom control, caregiver education, medication management, and care coordination are already authorized under chapter seven of the Medicare Benefit Policy Manual (BPM).[8]

However, many raised significant concerns regarding the disincentives created by current quality measurement and reimbursement frameworks that may penalize HHAs for serving patients who primarily require palliative care services. Specifically, commenters stated outcome measures tied to hospitalization and functional improvement in mobility and self-care may systematically disadvantage HHAs that appropriately prioritize comfort and quality of life over curative or rehabilitative goals. Commenters emphasized that for palliative care patients, a

[8] https://www.cms.gov/files/document/bp102c07pdf.

decline in these areas is often expected due to the natural progression of advanced disease and should not be interpreted as poor quality of care. Commenters expressed concern that as a result, HHAs that appropriately accept and manage these patients may receive lower performance scores and lower Star Ratings despite delivering high-quality, patient-centered care. Some commenters suggested CMS consider excluding palliative care patients from outcome measures that are based on functional improvement, discharge to community, and potentially preventable hospitalizations, or alternatively, implementing additional risk adjustment methodologies that account for the expected decline associated with serious progressive illness. Other commenters suggested a palliative track within the Home Health Quality Reporting Program, updating quality measures to distinguish between traditional home health patients and those receiving palliative care services.

Other commenters expressed concern regarding audit denials without specific, clinically realistic sub-regulatory guidance. Commenters consistently urged CMS to act quickly to update chapter seven of the BPM with concrete palliative care examples to avoid a scenario where policy encouragement exists in theory but is undermined in practice by audit risk, payment penalties, or lack of interdisciplinary infrastructure. Some commenters asked CMS to clarify how the homebound requirement applies to seriously ill patients who leave home for palliative-intent outpatient treatment (for example, palliative radiation or infusions), where leaving the home requires a considerable and taxing effort. These commenters also encouraged CMS to ensure Medicare Administrative Contractor (MAC) medical review aligns with new guidance.

Several commenters raised regulatory concerns that the homebound requirement is a barrier to earlier palliative intervention and suggested a potential non-homebound pathway to home-based palliative care; the need for nurse and nurse practitioner (NP) reimbursement integration within the home health interdisciplinary team; distinct Part B payment pathways for a community-based palliative care benefit, including the possibility of an add-on payment or development of specific CPT codes; and revising the regulations to explicitly include palliative

care among covered home health services. Additionally, we received some comments indicating confusion regarding whether this discussion on palliative care was indicative of a new benefit or distinct service model under Medicare. Other commenters emphasized that CMS should avoid establishing separate palliative care eligibility criteria, duplicative assessments, or additional documentation standards that could discourage providers from furnishing these services. Additionally, a commenter asked whether the clarification of the provision of palliative care services under the home health benefit would require other providers or suppliers to enroll or be certified as an HHA in order to furnish palliative care.

One commenter cautioned that expanding palliative care without competency standards risks diluting specialty palliative care and further delays appropriate hospice referrals. A commenter specifically noted that HHAs do not have the resources to furnish these services at scale to beneficiaries with such complex and serious illness; that these patients require much more comprehensive, longitudinal, and coordinated care than can be provided by HHAs. This commenter pointed to the Home-Based Primary Care (HBPC) model as the standard for which palliative care should be provided in the community and stated that CMS discussing palliative care provision under the home health benefit understates the complex nature of palliative care and the importance of home-based primary care clinicians as the primary coordinators of palliative care services in the home. Several commenters urged CMS to maintain a clear boundary between the home health and hospice benefits, recognizing that the home health benefit is not a substitute for hospice, but may be a bridge for those seriously ill beneficiaries who are not ready to elect hospice. These commenters stressed that home health does not support the same intensity of interdisciplinary care that the hospice benefit provides.

And finally, some commenters requested that CMS clarify that palliative care can be provided across all disciplines and all PDGM clinical groups and is not only limited to the MMTA clinical group, and that we study the resource use of palliative and maintenance periods of care and pay commensurately.

Response: CMS thanks all commenters for their thoughtful and detailed input on the provision of community-based palliative care under the Medicare home health benefit. The breadth and quality of these comments reflect the deep commitment of clinicians, advocates, caregivers, and health systems to improving care for seriously ill beneficiaries, and CMS acknowledges the broad commenter support for its goal of expanding access to community-based palliative care by acknowledging its provision under the existing home health benefit. We agree that seriously ill beneficiaries stand to benefit significantly from improved pain and symptom management, caregiver support, and enhanced quality of life when palliative care principles are integrated into home health services. CMS remains committed to advancing this goal in a manner that is clinically sound, operationally feasible, and equitable across the beneficiary population.

We recognize concerns regarding current quality measures including improvement standards, which are less likely to occur in palliative care patients. We agree this would not indicate poor quality of care but rather could be expected in this population as a result of the natural progression of serious illness. With current discussions about opportunities for potential alignment between the expanded Home Health Value-Based Purchasing (HHVBP) Model and the Home Health Quality Reporting Program (HH QRP), the home health measure sets used for both the HH QRP and the expanded HHVBP Model will emphasize measures that address expected functional outcomes instead of an emphasis on functional improvement. For example, the Discharge Function measure used in the HH QRP and the expanded HHVBP Model assesses each patient's expected functional status at discharge based on the patient's clinical profile and then evaluates management of functional status based on whether the patient is expected to improve, maintain or decline in function. Over time, the functional status measures used in the expanded HHVBP Model and HH QRP measure sets will focus more on a patient's expected outcome and not simply assess functional improvement.

CMS recognizes commenter concerns that palliative requires specialized clinical skills, including advanced symptom assessment, goals-of-care communication, and interdisciplinary coordination; however, we believe that HHAs are well-positioned to provide these services given their existing infrastructure for interdisciplinary care planning, skilled nursing and therapy, and coordination with physicians, as part of comprehensive, home-based care. CMS will explore the development of minimum competency expectations for HHA staff providing palliative care services, in consultation with relevant clinical and professional organizations. Any future guidance will seek to preserve the integrity of specialized clinical skills in palliative care while enabling broader access to these services at the community level. Further, CMS recognizes the critical role NPs play in expanding access to care, particularly in underserved communities, and we note that "allowed practitioners" include NPs, physician assistants (PAs), and clinical nurse specialists (CNSs). These types of providers are allowed to certify patients for Medicare home health services and establish the plan of care, affording them the ability to participate in and manage community-based palliative care delivery under the home health benefit. CMS disagrees, however, that supporting home-based primary care and strengthening HHAs palliative care capacity are competing strategies. The regulatory framework already governing Medicare-certified HHAs makes them a well-suited, and readily scalable, environment for furnishing palliative care, consistent with the goals underlying this rule. The Conditions of Participation (CoPs) at CFR 42 part 484 require HHAs to conduct a comprehensive patient assessment, develop an individualized plan of care, and deliver services through an interdisciplinary group encompassing skilled nursing, therapy, medical social services, and aide support. These same requirements, symptom management, psychosocial and caregiver support, and coordinated interdisciplinary planning are the operational building blocks of palliative care.

CMS is not proposing a new service delivery model or a new benefit in this rule; rather, this clarification is intended to confirm that HHAs may furnish palliative care as a component of a skilled service already covered under the home health benefit, such as skilled nursing visits for

pain and symptom management, patient and caregiver education, or care planning. It does not create a new, distinct benefit category or service type, and it does not modify the existing HH PPS payment methodology. Accordingly, CMS is not establishing a separate payment, add-on payment, or billing code specific to palliative care furnished under the home health benefit. HHAs should continue to bill for these services consistent with existing home health billing and coverage requirements, and any palliative care activities performed by home health staff must fit within the scope of a covered skilled service and be included in the individualized plan of care.

Additionally, this rule does not modify the eligibility requirements for the home health benefit or require any provider or supplier to enroll or be certified as an HHA in order to furnish palliative care. All home health eligibility requirements (homebound status, a qualifying skilled need, an allowed-practitioner order, a plan of care, and a face-to-face encounter) all still apply to palliative care patients. Regarding homebound status, the same criteria exist for determining whether a patient is confined to the home, meaning a patient can still be considered homebound if absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment. Additionally, nothing in this rule alters the requirement that home health services be furnished under a physician or allowed practitioner established plan of care. These clinicians, often the patient's primary care provider, retain full authority over diagnosis, treatment planning, and goals-of-care decisions. Enhancing HHAs' palliative care role would extend that plan of care into more frequent, hands-on interdisciplinary contact, complementing, not substituting for, the clinician relationship present in the HBPC model. Further, while we stated in the proposed rule that MMTA would likely be the most appropriate grouping for palliative care services, we recognize that these services can be applied across all home health disciplines and as outlined in the care plan.

Regarding concerns that CMS may be indicating these services are substitutes for hospice care, we agree that the home health and hospice benefits, while complementary, serve distinct purposes and beneficiary populations. We recognized in the proposed rule that the home health

benefit can be an important step in the care continuum when a patient needs palliative care, either during episodes of serious illness or near end of life, before choosing hospice care. However, we do not intend for this clarification to blur the distinction between home health and hospice care, and we will continue to monitor program data and beneficiary experience to ensure that beneficiaries are directed to the benefit that best matches their care needs.

And finally, CMS agrees that consistent review and implementation across MACs is essential to the success of any palliative care policy initiative. CMS will work with MACs to ensure that medical review criteria, documentation expectations, and coverage determinations reflect updated guidance. We will issue specific MAC instructions and education materials in conjunction with BPM updates to promote national consistency and reduce audit-related and claims denial deterrents to palliative care delivery. We also thank commenters for submitting suggested examples for the BPM and will update this sub-regulatory guidance promptly to represent the various palliative care services we believe HHAs can provide under the home health benefit.

G. Request for Information on the Construction of a Home Health Specific Wage Index

For CY 2027, we are finalizing our proposal to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the HH PPS wage index. We continue to believe that this is the best available Medicare data to estimate costs per day, in accordance with our longstanding wage index policy at § 412.424(a)(2). The purpose of this comment solicitation was to gain information from the public regarding the appropriateness of alternative data sources consistent with our statutory authority and regulatory requirements. We noted that other payment systems have explored and are exploring alternative wage index methodologies under their specific programmatic and statutory circumstances. For example, CMS finalized changes to the ESRD PPS wage index using Bureau of Labor Statistics (BLS) occupation-level wage data in the CY 2025 ESRD PPS final rule (89 FR 89116). We noted that while this approach was developed under the specific programmatic and statutory circumstances of the

ESRD PPS and may not be directly transferable to the HH PPS, CMS is interested in exploring whether similar methodologies using publicly available wage data could be used to better reflect the geographic variation in labor costs for HHAs. In addition, we noted that we are also considering the potential use of alternative data sources in other payment systems, including with respect to hospices (91 FR 17361 through 17363), the Inpatient Rehabilitation Facilities PPS (91 FR 17206 and 17207), and the Skilled Nursing Facilities PPS (91 FR 17692).

Furthermore, in its 2023 Report to the Congress[9], MedPAC discussed various conceptual approaches to Medicare wage indexes, including the use of county-level wage data from BLS with an occupational mix to construct wage indexes that are more specific to the payment setting. MedPAC has previously written about using all-employer, occupation-level wage data to establish different weights for setting-specific occupational labor mixes as one approach to geographic adjustments.

We solicited public comments on whether we should consider using alternative data sources to construct an HHA specific wage index for potential use in future years. CMS sought feedback to understand the potential advantages and limitations of using alternative data sources, such as BLS data and home health Medicare cost reports, as well as other methodologies that stakeholders believe could appropriately reflect the geographic variation in labor costs for HHAs. We also sought feedback on the unique considerations applicable to HHAs that should inform how CMS considers the potential use of alternative data sources.

The following is a summary of the comments we received and our responses.

Comment: Overall, commenters expressed support for an approach that would more closely represent the geographic variation of wages related to occupations used in home health. Commenters requested that CMS provide more information on the potential methodology to calculate a home health specific wage index using alternate data sources and home health specific occupational mix, and recommended CMS convene a Technical Expert Panel to seek

[9] https://www.medpac.gov/document/chapter-9-reforming-medicares-wage-index-systems-june-2023-report/.

broader input based on presented analysis. Many commenters stated that any occupational mix must extend beyond RNs and therapists to include home health aides, medical social workers, LPNs, and community health workers. Commenters were split on data sources: many favored BLS Occupational Employment and Wage Statistics as independent and more current, while others raised concerns that BLS data is not home-health-specific, excludes benefits, dilutes the labor pool with non-Medicare providers, and relies on unverifiable survey samples. Some commenters stated that home health cost reports have serious data-quality problems, such as inconsistent contract-labor reporting, lack of audits, and distortion from what they describe as high-fraud cohorts such as Los Angeles County. All commenters supported publishing a detailed prototype/RFI with methodology, occupational weights, and provider/county-level impact files before implementation; convening a Technical Expert Panel; multi-year phase-in with continuation of the 5 percent cap on decreases; and robust stakeholder/industry engagement.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future development of a home health specific wage index and for potential future rulemaking as appropriate.

III. Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each home health agency (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 pursuant to section 1895(b)(3)(B)(v)(I) of the Act. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, as further reduced by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP 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 HH PPS for a year being less than payment rates for the preceding year. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890 of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the HH QRP. The HH QRP regulations can be found at 42 CFR 484.245 and 484.250.

B. Summary of the Proposed Rule and Responses to Public Comments

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we proposed the following policies in the proposed rule:

First, we summarized potential initiatives to improve alignment between the HH QRP and expanded HHVBP Model. We also proposed to revise the HH QRP data submission deadlines beginning with the CY 2027 HH QRP. In addition, we proposed to revise the HH QRP

OASIS and HHCAHPs annual payment update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We proposed some revisions to regulatory text in support of rule proposals and to improve digital transfer of information during the reconsiderations process. Finally, we solicited public comments on one Request for Information (RFI) on future measure concepts for the HH QRP.

For a detailed discussion of the considerations that we historically have used for measure selection for the HH QRP quality, resource use, and other 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 finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2026 HH QRP

The HH QRP currently includes 18 measures for the CY 2027 program year. As finalized in the CY 2026 HH PPS final rule, the HH QRP currently uses thirteen OASIS-based measures, four claims-based measures, and a HHCAHPS Survey-based composite measure (see table 18).

D. Opportunities for Potential Alignment Between the HH QRP and the Expanded HHVBP Model

As discussed in the proposed rule, CMS has identified substantial opportunities to better align the HH QRP and the expanded HHVBP Model. While the HH QRP and expanded HHVBP Model share similar goals and measures, differences in measure sets, reporting periods, and performance assessment processes may create unnecessary complexity and administrative burden for HHAs. For example, misalignment between HH QRP APU reporting periods and the expanded HHVBP Model's annual performance period may contribute to confusion. Greater alignment would support more consistent evaluation of HHA quality performance and advance CMS quality priorities. Greater alignment is also consistent with CMS's priority of reducing provider burden and creating efficiencies across CMS programs. Opportunities for potential alignment between the HH QRP and expanded HHVBP Model include the following:

- Increasing alignment in expanded HHVBP Model and HH QRP Quality of Patient Care (QoPC) Star Ratings measure sets.
- Aligning HH QRP and expanded HHVBP Model measure reporting periods.
- Aligning HH QRP APU and expanded HHVBP Model annual payment reporting periods.
- Aligning expanded HHVBP Model Interim Performance and HH QRP QoPC Star Rating Reports.
- Aligning timeframe of appeals/suppression review processes for the expanded HHVBP Model and HH QRP.
- Updating scoring methodology to incorporate HH QRP APU penalties in expanded HHVBP Model payment adjustments and factoring HH QRP Quality Assessments Only (QAO) values into QoPC Star Ratings scoring.

We convened a Technical Expert Panel (TEP) meeting addressing HH QRP and expanded HHVBP Model alignment in December 2025. Please see the 2025 TEP Summary Report for more information (*www.cms.gov/priorities/innovation/files/hhvbp-tep-summary-report.pdf*).

Table 18 reflects current and expected usage of measures for both the expanded HHVBP Model and the HH QRP.

TABLE 18: QUALITY MEASURE USAGE IN HHVBP AND HH QRP COMPONENTS

Measures	Included in HHVBP Performance Measures	Used in HHQRP QoPC/ Patient Survey Star Ratings	Expected Inclusion in both HHVBP and HHQRP Star Ratings	HHQRP Non-QoPC Star Ratings QMs
OASIS-based Measures				
Discharge Function Score*^	Yes	No	Yes	Yes
Improvement in Bathing**	Yes	Yes	Yes	No
Improvement in Upper Body Dressing**	Yes	No	No	Yes
Improvement in Lower Body Dressing**	Yes	No	No	Yes
Improvement in Bed Transferring	No	Yes	No	No
Improvement in Ambulation/Locomotion	No	Yes	No	No
Improvement in Dyspnea	Yes	Yes	Yes	No
Improvement in Management of Oral Medications	Yes	Yes	Yes	No
Timely Initiation of Care	No	Yes	No	No

Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury - HH	No	No	No	Yes
Falls with Major Injury	No	No	No	Yes
Transfer of Health Information to Provider	No	No	No	Yes
Transfer of Health Information to Patient	No	No	No	Yes
Influenza Immunization Received	No	No	No	Yes
Drug Regimen Review	No	No	No	Yes
Claims-based Measures				
Potentially Preventable Hospitalizations (PPH)*	Yes	Yes	Yes	No
Discharge to Community – Post Acute Care (DTC-PAC)* ^	Yes	Yes	Yes	Yes
Medicare Spending per Beneficiary- Post Acute Care (MSPB-PAC) **	Yes	No	No	Yes
Potentially Preventable Readmission	No	No	No	Yes
HHCAHPS Survey-based Measures				
Care of Patients***	Yes	Yes	No	Yes
Communication Between Providers and Patients***	Yes	Yes	No	Yes
Talk About Home Safety******	No	No	No	Yes
Review Medicines******	No	No	No	Yes
Talk About Medicine Side Effects******	No	No	No	Yes
Overall Rating of Care Provided by the Home Health Agency	Yes	Yes	Yes	Yes
Willingness to Recommend the Home Health Agency	Yes	No	No	Yes

^ Measures expected to be added to QoPC Star Ratings in the near future.
* Measure added to the expanded HHVBP Model starting with the CY 2025 applicable measure set.
** Measure added to the expanded HHVBP Model starting with the CY 2026 applicable measure set.
*** Measure removed from the expanded HHVBP Model starting with the CY 2026 applicable measure set.
****Measure added to HH QRP Non-QoPC CY 2026 measure set to replace the Specific Care Issues measure.

Though we did not seek comments on the list of opportunities for potential alignment between the HH QRP and the expanded HHVBP Model, numerous commenters offered feedback. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly supported potential efforts to align the HH QRP with the expanded HHVBP Model, emphasizing the potential to reduce duplicative reporting, administrative complexity, and provider burden. Many commenters urged CMS to ensure that potential alignment efforts account for the unique needs of high-acuity and palliative-intent patients, recommending mechanisms such as palliative-status exclusions, refined risk adjustment, and the development of outcome measures appropriate for patients with declining trajectories to prevent HHAs from being unfairly penalized. Several commenters advocated for greater transparency, public engagement, and adequate lead time in implementing any potential future changes, as well as the inclusion of functional, caregiver-facing, and clinically relevant measures—particularly for populations with dementia, neurological diseases, or serious illness.

Response: We thank commenters for their input and will take this feedback into consideration as appropriate.

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

1. Revise HH QRP Data Submission Deadlines Beginning with the CY 2027 HH QRP

a. Background

Section 1899B(f)(1) of the Act also requires the Secretary to provide confidential feedback reports to PAC providers on the performance of such PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning 1 year after the applicable specified application date. Further, section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public for the PAC provider prior to such data being made public.

Although assessment data submission, quarterly performance reports, and public reporting are required by statute, timing of data submission under the HH QRP was not initially specified. Thus, in the CY 2017 HHS PPS final rule (81 FR 76784) we finalized our proposal to comply with the requirements of section 1899B(g) of the Act, that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures.

Public reporting of data collected under our quality reporting programs, such as the HH QRP, is designed to provide consumers and their families with the most current information to empower them to make quality-informed decisions about where to receive their care. We have identified that the time between when data on measures is submitted to us and when those data

are publicly reported (approximately nine months) may be too long to provide the most accurate and up to date information for the public. We have received feedback from the provider community and TEPs that the aged data used in publicly reported quality measures diminishes their value to consumers. Furthermore, we have heard from HHAs that the HH QRP measure results they receive prior to public reporting are less useful for their quality improvement efforts due to the aged data and the delay in when they receive these reports.

Currently, the largest contributing factor to the 9-month lag between the end of the data collection period and when measures are publicly reported is the 4.5-month timeframe for data submission. Reducing the data submission timeframe from 4.5 months to the 15th day of the second month after the end of the calendar quarter could reduce this lag by up to 3 months, resulting in more timely public reporting of data for consumers and increasing the value of publicly reported data. Additionally, this timeframe provides HHAs with more recent data in support of their quality improvement activities.

In the CY 2026 HH PPS proposed rule, we included a request for information (RFI) on reducing the OASIS assessment data submission deadline from 4.5 months to 45 days (90 FR 29182). We refer readers to the CY 2026 HH PPS final rule (90 FR 55429 and 55430) for a full summary of the public comments received.

b. Revise the HH QRP Assessment Data Submission Deadline

Beginning with the CY 2027 HH QRP, we proposed that HHAs be required to complete their data submissions and make corrections to their OASIS assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter. However, if the 15th day of the second month fell on a Friday, weekend, or Federal holiday, the date would be delayed until 11:59 p.m. EST on the next business day. We proposed that HHAs follow the deadlines presented in Table 19 for the CY 2027 HH QRP. We also proposed that similar calendar year data submission deadlines apply to future years' payment determinations.

TABLE 19: DATA COLLECTION TIMEFRAME AND DATA SUBMISSION DEADLINES FOR OASIS ASSESSMENT DATA AFFECTING THE CY 2029 PAYMENT DETERMINATION

Calendar Year (CY) Quarter	Data Collection Timeframe	Final Data Submission Deadlines for CY 2029 Payment Determination*
CY 2027 Quarter 1	January 1–March 31, 2027	May 17, 2027
CY 2027 Quarter 2	April 1–June 30, 2027	August 16, 2027
CY 2027 Quarter 3	July 1–September 30, 2027	November 15, 2027
CY 2027 Quarter 4	October 1–December 31, 2027	February 15, 2028

* Data submission deadlines will follow a similar quarterly schedule for subsequent CYs.

We believe that requiring HHAs to submit OASIS assessment data by the 15th day of the second month after the end of the calendar quarter is reasonable. We conducted an analysis on the potential impact of reducing the timeframe by determining how many assessments are currently being submitted by this deadline, which is approximately within 45 days of the end of the quarter. Using 2024 data, we determined that 99.27 percent of all OASIS assessments were submitted to CMS within a 45-day timeframe. Of the remaining 0.73 percent submitted beyond 45 days, 0.24 percent of the total (that is, about one third of the post-45 day timeframe) were submitted after the current 4.5-month data submission deadline and would not be further impacted by a change in the data submission deadline. Therefore, only 0.49 percent of OASIS assessments will be impacted by changing the data submission deadline from 4.5 months to require data submission by the 15th day of the second month after the end of the calendar quarter.

We received public comments on the proposal to require that HHAs complete their data submissions and make corrections to their OASIS assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter beginning with the CY 2027 HH QRP. The following is a summary of the comments we received and our responses.

Comment: A majority of commenters supported CMS' proposal to revise the OASIS data submission deadline, stating that more timely reporting of HHQRP data could help HHAs implement quality improvement initiatives and beneficiaries and their caregivers make better-informed decisions when selecting HHAs. Several commenters supported the proposal based on

data showing that most HHAs are already meeting the 45-day submission requirement. Many commenters who supported the proposal urged CMS to ensure clear guidance and training is in place to support the implementation of this proposal.

Response: We thank commenters for their support and agree that this proposal would give patients and consumers more timely access to quality data and give HHAs better data for quality improvement. Clear guidance around the new submission deadline will be available through the range of communication channels used to reach HHAs.

Comment: Some commenters supported the proposal and the goal of improving the timeliness of publicly reported data, but had concerns about operational and staffing challenges, administrative burden, and data validation, especially for small or rural HHAs that may struggle with staffing challenges and operational issues. A few commenters expressed concerns that providers continue to experience staffing shortages and turnover of HH staff. Some commenters that supported the proposal noted the current clinical and administrative burden around implementing OASIS all-payer submissions and changing payment requirements. Several commenters encouraged CMS to establish a phased implementation or grace period to meet submission requirements, to provide flexibility for the first several data submission cycles. A few other commenters cited recent implementation of the HOPE tool to stress the benefits of a phased implementation.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural HHAs. However, we do not believe that the proposal adds burden for HHA staff by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Since workflows are in place for the necessary processes, we do not believe a phased implementation approach is necessary. As previously stated in the CY 2027 HH PPS proposed rule, our internal analysis showed that 99.27 percent of all OASIS assessments are already being submitted within a 45-day timeframe, which

suggests that data submission within this timeframe is the current practice for most HHAs. Further, we believe a phased implementation approach would add operational complexity, as providers would have to update workflows and modify staffing numerous times over the implementation period. We will continue to monitor data submission compliance rates as part of already implemented program monitoring.

Comment: Some commenters were concerned that the proposed timeline may not provide adequate time for agencies to validate data to identify and correct errors, particularly for new admissions near the end of a reporting quarter. They raised concerns that review processes are critical to ensuring high-quality data but may no longer be feasible within a 45-day submission window.

Response: We believe that we are providing HHAs sufficient time to adjust staffing and workflow operations that will allow them to validate data and make any corrections needed by the new deadline. In general, we believe data validation and quality checks to be complete with the initial data submission, with better proximity to the patient. We would also like to note that this proposal will benefit HHAs by allowing them to have access to more timely data for quality improvement efforts.

Comment: A few commenters supported the proposal but recommended allowing HHAs to request an extension if there are circumstances out of the HHA's control impacted the HHA's ability to submit data in a timely manner.

Response: Currently, in the event they were unable to submit quality data due to extraordinary circumstances beyond their control, we provide HHAs with the opportunity to request an exception or extension from the program's reporting requirements. HHAs affected by a natural or man-made disaster or other extraordinary circumstances may request an exception or extension using instructions provided on the HH QRP website: *https://www.cms.gov/medicare/quality/home-health/home-health-quality-reporting-reconsideration-and-exception-extension*

Comment: Some commenters recommended that CMS provide enhanced technical assistance and support as part of the transition to the new reporting timeframe. Several commenters suggested updated training resources and outreach to HHAs to ensure providers have sufficient support to implement this proposal. A few commenters requested the ability for vendors to have a test period for submissions.

Response: We appreciate commenters' input and recommendations for implementation of this proposal. We would like to note that we currently conduct national outreach (such as email communications) about upcoming data submission deadlines. We also provide guidance and technical manuals, data submission deadline documents, and training resources. We intend to make updates to our outreach processes, manuals, data submission deadline documents and training resources related to this change. Regarding technical assistance and support, we list resources and on our website: *https://www.cms.gov/medicare/quality/home-health/home-health-quality-reporting-training.* We do not anticipate that the new submission timeframe will require data processing since the submission processes have not been changed with this proposal.

After consideration of public comments, we are finalizing as proposed to require that HHAs submit their OASIS assessments and make corrections to their OASIS assessment data where necessary no later than the 15th day of the second month after the end of the calendar quarter beginning with the CY 2027 HHQRP.

2. Revise the OASIS Annual Payment Update Reporting Timeframe

a. Background

HHAs are required to submit OASIS data in a timely manner as outlined under section 1895(b)(3)(B)(v) of the Act, as amended by the Deficit Reduction Act (Pub. L. 109-117). Failure to submit OASIS data in a timely manner with respect to a HH QRP year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. This annual payment update (APU) was initiated for the HH QRP on January 1, 2007. The HH QRP APU requirements were

finalized in the CY 2007 HH PPS Final Rule (71 FR 44087 through 44088) outlining data collection of 12 months of data beginning July 1, 2005 and running through July 1, 2026. This timeframe allowed a full 12 months of data and provided CMS the time necessary to analyze and make any necessary payment adjustments to the CY 2007 payment rates (71 FR 44087 through 44088). The timing for APU reporting has remained on this data calculation cadence since this update.

The current OASIS APU reporting timeframe differs from that used by other major CMS payment updates. Notably, the expanded HHVBP Model annual payment adjustment and the HH PPS updates are both based on a calendar year timeline. To improve alignment between HH payment policies and OASIS QRP reporting requirements, CMS proposed to revise the OASIS APU data reporting timeframe to reflect a January 1 through December 31 reporting timeframe, or the calendar year. We believe this update would provide clarity to HH payment updates and facilitate the alignment of the HH pay-for-reporting policies with other HH payment policies.

b. Revise the OASIS Annual Payment Update Reporting Timeframe

The revision of the OASIS APU data reporting to a calendar year timeframe would require a transition year in which the current reporting timeframe was moved to the new proposed reporting timeframe. We proposed the transition occur with the 2028 APU and further proposed that the 6 months data collected from July 1, 2026 through December 31, 2026 would serve as the OASIS APU data reporting timeframe to determine the HH QRP 2028 OASIS APU. We also proposed that the 2029 OASIS APU would be the first iteration in which the OASIS APU data reporting timeframe will be based on the calendar year, from January 1, 2027 through December 31, 2027. We would continue this new pattern for each subsequent OASIS APU with effective dates for data reporting of January 1 through December 31. OASIS assessments will be considered complete if they comply with the HH Conditions for Payment (COPs) that apply to the applicable year. Please see table 20 that outlines the current OASIS APU data reporting

timeframe, the proposed transition reporting timeframe, and the revised OASIS APU timeframe used for the CY 2029 APU and later.

TABLE 20: DATA REPORTING TIMEFRAMES ASSOCIATED WITH UPCOMING HHQRP OASIS APU

OASIS APU Issued	Data Reporting Timeframe
January 2027	July 1, 2025 – June 30, 2026
January 2028 transition	July 1, 2026 - December 31, 2026
January 2029	January 1, 2027 – December 31, 2027

In the CY 2024 HH PPS final rule, CMS finalized adding the following language to the regulatory text at § 484.245(b)(2)(ii)(A): "A home health agency must meet or exceed the data submission threshold for each submission year (July 1 – June 30) set at 90 percent of all required OASIS or successor instrument records and submitted through the CMS designated data submission systems" (88 FR 77676). With the proposed change to a calendar year reporting timeframe, CMS proposed to revise the language in § 484.245(b)(2)(ii)(A) that currently states "(July 1 – June 30)" to state "(January 1 through December 31)".

We received public comment on the proposal to revise the OASIS APU reporting timeframes to a calendar year period beginning with the CY 2027 HH QRP. The following is a summary of the comments we received and our responses.

Comment: Most commenters expressed strong support for CMS's proposal to align the OASIS Annual Payment Update (APU) reporting period with the calendar year, citing anticipated benefits such as improved administrative efficiency, consistency across payment and quality reporting programs, and reduced confusion for providers.

Response: We thank commenters for their support for our proposal to revise the OASIS APU reporting period to calendar year. We seek to align reporting periods, where possible, to provide clearer reporting processes across HH programs.

Comment: Several commenters who supported the CMS proposal also emphasized the importance of clear and timely guidance regarding the new reporting timeframe, standardized

reporting specifications, and transition support to ensure HHAs can comply with the new requirements and avoid unintended payment penalties. Some commenters highlighted concerns about a potential increase in operational burden, particularly regarding the inclusion of all-payer OASIS data and the risks associated with a shortened reporting period during the transition year. They recommended either an extended transition period or additional compliance resources. Several expressed concerns that there may be an increase in APU failure during the transition to the new calendar reporting timeframe.

Response: We thank commenters for their support of this proposal and for sharing criteria that would assist with implementation of revised calendar proposal. We will ensure that clear guidance around the implementation of revisions of the reporting timeframe for the OASIS APU will be shared via multiple means of communication, including the official HHQRP website. We will also work to ensure training materials related to the HHQRP APU addresses OASIS all-payer data submission. Our goal is to limit burden associated with a transition to calendar year reporting of the OASIS APU.

After consideration of public comments, we are finalizing as proposed to revise the OASIS APU reporting timeframe to a calendar year period effective January 1, 2027. We are also finalizing the transition period in which the six months of data collected from July 1, 2026 through December 31, 2026 would serve as the OASIS APU data reporting timeframe to determine the HHQRP 2028 APU. We are finalizing the 2029 OASIS APU data reporting timeframe would be the first iteration in which the OASIS APU data reporting timeframe would be for a calendar year, from January 1, 2027 through December 31, 2027.

3. Revise the HHCAHPS Annual Payment Update Reporting Timeframe

a. Background

HHAs are required to submit quality data in a timely manner as outlined under section 1895(b)(3)(B)(v) of the Act. Failure to submit HHCAHPS data in a timely manner with respect to a HH QRP year could result in the reduction of the annual home health market basket

percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. HHCAHPS data inclusion in the HH QRP was finalized with the CY 2010 HH PPS Final Rule (FR 74 58098 through 58104). Adding a HHCAHPS annual payment update (APU) to the current HH QRP requirements was also finalized with the CY 2010 HH PPS Final Rule where CMS finalized the policy that HHCAHPS will be included in the APU reporting for the CY 2012 APU based on 6 months of data from October 2010 to March 2011 (FR 74 58103). In the CY 2011 HH PPS final rule, CMS finalized a policy that HHCAHPS APU calculations would require four quarters of data collection from April 1, 2011 to March 31, 2012 for the CY 2013 HHCAHPS APU (FR 75 70406). The timing for HHCAHPS APU reporting has remained on this cadence since this update.

The current HHCAHPS APU reporting timeframe differs from that used by other annual HH CMS payment updates. The expanded HHVBP Model payment adjustment percentage and the HH PPS updates are both based on a calendar year timeline. The OASIS APU data reporting timeframe is also different from a calendar year timeline and we are also proposing an update to a calendar year timeframe in a previous proposal. To improve alignment between home health payment policies and HH QRP pay-for-reporting requirements, we proposed to revise the HHCAHPS APU data reporting timeframe to reflect a January 1 through December 31 reporting timeframe, or the calendar year. We believe this update would provide clarity related to HH payment updates and facilitate the alignment of CMS HH pay-for-reporting policies with other HH payment policies.

b. Revise the HHCAHPS Annual Payment Update Reporting Timeframe

The proposed revision of the HHCAHPS APU data reporting to a calendar year timeframe would require a transition year in which the current reporting timeframe was moved to the new proposed reporting timeframe. We proposed the transition occur with the 2028 HHCAHPS APU and further proposed that the nine months of data collected from April 1, 2026 through December 31, 2026 would serve as the HHCAHPS APU data reporting timeframe to

determine the HHQRP 2028 APU. We also proposed that the 2029 HHCAHPS APU data reporting timeframe would be the first iteration in which the HHCAHPS APU data reporting timeframe would be for a calendar year, from January 1, 2027 through December 31, 2027. We would continue this new pattern for each subsequent HHCAHPS APU with effective dates for data reporting of January 1 through December 31. HHA OASIS assessments would be considered complete if they complied with the HH CoPs and Conditions for Payment that apply to the applicable year. Please see Table 21 that outlines the HHCAHPS current APU data reporting timeframe, the proposed transition reporting timeframe, and the revised APU timeframe used for the CY 2029 APU and later.

TABLE 21: DATA REPORTING TIMEFRAMES ASSOCIATED WITH UPCOMING HHQRP HHCAHPS APU

HHCAHPS APU Issued	Data Reporting Timeframe
January 2027	April 1, 2025 – March 31, 2026
January 2028 transition	April 1, 2026 - December 31, 2026
January 2029	January 1, 2027 – December 31, 2027

We received public comment on the proposal to revise the HHCAHPS APU reporting timeframes to a calendar year period beginning with the CY 2027 HH QRP. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS's proposal to align the HHCAHPS APU reporting period with the calendar year. Commenters noted that this proposal could reduce confusion, improve compliance, and align the timing of HHQRP APU and the expanded HHVBP Model APR determinations. Commenters also shared the importance of clear implementation guidance and safeguards to ensure providers are not penalized for technical or vendor-related issues beyond their control during the transition from the current reporting schedule to a new reporting periods for the HHCAHPS APU.

Response: We thank commenters for their support for the proposal to revise the reporting timeframe for the HHCAHPS APU. We are working to improve alignment for HH program reporting requirements and simplifying program policies.

Comment: Some commenters who supported the HHCAHPS APU calendar update proposal raised the issue of burden associated moving to a new HHCAHPS calendar. They noted that to ensure an effective transition would require investments in quality assurance resources, data analytics, clinical education, software systems, and compliance oversight. One commenter supported the CMS proposal but requested that CMS clarify whether any scoring methodologies for HHQRP or the expanded HHVBP Model would change.

Response: We thank commenters for outlining potential burden issues related to this proposal. We will provide clear guidance around the implementation of this issue that we believe will limit undue costs associated with the transition and implementation of calendar year HHCAHPS APU reporting. Since no new processes are required and only a shift in the submission workflow, we do not anticipate the requirement for new investment of processing or validations systems. We also do not anticipate changes for the HH QRP or expanded HHVBP Model scoring methodologies associated with this transition to calendar year reporting of HHCAHPS APU calculations.

After consideration of public comments, we are finalizing as proposed to revise the HHCAHPS APU reporting timeframes to a calendar year period effective January 1, 2027. We are also finalizing the transition period in which the nine months of data collected from April 1, 2026 through December 31, 2026 would serve as the HHCAHPS APU data reporting timeframe to determine the HHQRP 2028 APU. We are finalizing the 2029 HHCAHPS APU data reporting timeframe would be the first iteration in which the HHCAHPS APU data reporting timeframe would be for a calendar year, from January 1, 2027 through December 31, 2027.

4. Updates to Regulation Text related to Reconsiderations

In the CY2026 HH PPS final rule, CMS updated regulation text language to codify how a provider may request an extension to file a request for reconsideration (90 FR 55342). We proposed to further clarify aspects of the reconsideration process to facilitate more timely, digital transmission of information. Specifically, § 484.245(d)(1)(i) currently states that HHAs that do

not meet the quality reporting requirements under this section for a program year will receive a letter of noncompliance via the United States Postal Service and the CMS-designated data submission system. We proposed to revise this language to specify that HHAs that do not meet the quality reporting requirements under this section for a program year would receive a notification of noncompliance via the CMS-designated data submission system. Section 484.245(d)(1)(ii) currently states that an HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance. We proposed to revise this language to state that an HHA may request reconsideration no later than 30 calendar days after the date identified on the notification of non-compliance. Section 484.245(d)(2)(v) currently states that CMS identified reason(s) for non-compliance as stated in the non-compliance letter. We proposed to revise this language to state, that CMS identified reason(s) for non-compliance as stated in the non-compliance notification.

Section 484.245(d)(4)(i) currently states that CMS notifies the HHA, in writing, of its final decision regarding any reconsideration request through at least one of the following methods:

- CMS designated data submission system.
- The United States Postal Service.
- Email from the CMS Medicare Administrative Contractor (MAC).

We proposed to revise this language to state that CMS would notify the HHA of its final decision regarding any reconsideration request through a CMS designated data submission system.

We received comments on the proposed updates to the regulations text related to the reconsideration process. The following is a summary of the comments we received and our responses.

Comment: Most commenters supported CMS modernization and digital communications efforts but expressed concern that relying on a single portal could cause providers to miss

important notices due to staff turnover, account-access issues, technical failures, emergencies, or system outages. They stressed that missing a notice could have significant financial consequences, including payment reductions.

Response: We thank commenters for their support of the proposed updates. Communication with providers via the CMS electronic systems has been in place for numerous years and has been effectively utilized across numerous CMS programs including the expanded HHVBP Model.

Comment: Several commenters recommended maintaining redundant notification methods. They proposed safeguards including sending email alerts to multiple designated contacts whenever a notice is posted, allowing optional text-message notifications, continuing mailed notices or allowing agencies to opt into them, maintaining auditable records of notice availability and retrieval, and ensuring appeal deadlines begin only after providers have been alerted that a notification is available. Commenters also urged CMS to account for outages or access failures that could prevent timely review of notices.

Response: The processes that will remain in place after this update has been implemented will continue to include multiple forms of outreach. These include electronic distribution to multiple designated contacts and through multiple distribution channels for HHA contacts.

Comment: Several commenters further emphasized the need for due-process protections and operational safeguards as the electronic system is implemented. They suggested allowing agencies to designate multiple authorized users, ensuring system accessibility and compliance with Section 508 standards, providing machine-readable notice formats, issuing receipts and timestamps for submissions, and retaining records throughout the appeal period.

Response: We appreciate these comments and agree that there is a need to have operational safeguards related to these important reconsideration processes. We believe that our current safeguards address the concerns raised by the commenters. HHAs can have confidence that their reconsideration requests will be processed effectively.

Comment: Commenters also raised concerns related to scenarios in which there was some CMS system failure. Commenters suggested extending deadlines during system downtime, offering alternative submission methods when technical issues occur, and providing a clear human point of contact for reconsideration-related questions. Overall, commenters support digital modernization but believe additional protections are necessary to ensure fairness and prevent avoidable payment penalties.

Response: We appreciate commenters addressing concerns when technical issues may occur during the reconsideration process. We have established policies and procedures to allow HHAs to receive timely communication about their compliance status and to expect consistent communication during reconsideration follow-up. Should technical issues arise, our policies in place to reach providers when contingencies are necessary.

After consideration of public comments, we are finalizing revising this language to state that we will notify the HHA of its final decision regarding any reconsideration request through a CMS designated data submission system.

F. HH QRP Measure Concepts Under Consideration for Future Years – Request for Information (RFI)

In the CY 2024 HH PPS proposed rule (88 FR 43738 through 43740), we included an RFI on a set of principles for selecting and prioritizing HH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. We refer readers to the CY 2024 HH PPS final rule (88 FR 77773 through 77774) for a summary of the public comments received in response to the RFI.

We sought input on the importance, relevance, appropriateness, and applicability of the quality measure concepts related to advance care planning (ACP). Advance care planning is a continuous process that supports people in understanding and communicating their goals, values, and preferences regarding future medical decisions.[10] The Patient Self Determination Act of

[10] McMahan, R. D., Tellez, I., & Sudore, R. L. (2021). Deconstructing the Complexities of Advance Care Planning

1990[11] supports this process by requiring healthcare facilities to inform patients of their rights regarding medical decisions, including advance directives and end of life care.[12] In post-acute care (PAC) settings, where patients recover from acute illness, injury, or major procedures, their needs and goals may evolve as their condition changes. Factors such as clinical stability, functional status, therapy tolerance, cognition function, prognosis, and personal preferences can all shift during recovery. Regular reassessment and transparent communication are essential to maintaining person-centered care, while advance care planning facilitates shared decision-making by documenting patient preferences and ensuring goal-concordant care throughout care transitions.[13]

As we review new measure concepts, we will prioritize evidence-based outcome measures that promote person-centered care practices. We sought input on the relevant aspects of advance care planning and measures appropriate for the HH setting. We received public comments on this request for information, and the following is a summary of the comments we received.

Comment: Many commenters expressed support for CMS's exploration of an ACP quality measure within the HH QRP while emphasizing the need for a patient-centered, practical, and clinically meaningful approach. Most commenters agreed that ACP is an important component of quality home health care, particularly for individuals with serious illness, chronic conditions, cognitive impairment, or complex care needs. Commenters who supported an ACP measure emphasized that home health clinicians are uniquely positioned to facilitate discussions about goals of care because they work directly with patients and families in the home environment and often develop trusted relationships that provide insight into patient preferences, caregiver capacity, safety concerns, and evolving care needs.

Outcomes: What Do We Know and Where Do We Go? A Scoping Review. Journal of the American Geriatrics Society, 69(1), 234–244. https://doi.org/10.1111/jgs.16801.

[11] Pub. L. No. 101-508, §§ 4206, 4751.

[12] https://www.congress.gov/bill/101st-congress/house-bill/4449https://www.congress.gov/bill/101st-congress/house-bill/5835.

[13] McMahan RD, Tellez I, Sudore RL. Deconstructing the Complexities of Advance Care Planning Outcomes: What Do We Know and Where Do We Go? A Scoping Review. J Am Geriatr Soc. 2021 Jan;69(1):234-244. doi: 10.1111/jgs.16801. Epub 2020 Sep 7. PMID: 32894787; PMCID: PMC7856112.

Some commenters who supported the ACP concept for HH shared that ACP should be understood as an ongoing process rather than a one-time documentation exercise. They cautioned CMS against creating a measure that simply rewards the presence of an advance directive or other legal document. Instead, commenters recommended focusing on meaningful conversations, shared decision-making, identification of patient goals and values, and documentation that reflects patient preferences over time. Several commenters stressed that success should be measured by whether care is aligned with patient wishes rather than whether a specific form has been completed. They also suggested that patients must retain the right to decline ACP discussions or defer decisions without providers being penalized.

Some commenters who support an ACP QM linked ACP closely with palliative care and serious illness management. Organizations representing patients, providers, and palliative care advocates noted that ACP plays a critical role in helping individuals understand treatment options, manage symptoms, plan for future care needs, and make informed decisions throughout the course of illness. Commenters highlighted that home health agencies increasingly serve older, frail, and medically complex beneficiaries whose primary goals may include symptom management, quality of life maintenance, caregiver support, avoiding hospitalizations, and remaining at home.

Several commenters argued that current home health quality measures primarily reward functional improvement, which may not accurately reflect quality care for patients with progressive or terminal illnesses. They encouraged CMS to develop measures that recognize goal-concordant care, symptom management, stabilization, caregiver preparedness, and successful transitions to hospice when appropriate.

Other commenters linked the palliative care RFI in a separate section of the proposed rule with the ACP RFI. These commenters generally supported CMS's efforts to expand awareness and accessibility of palliative care and appreciate clarification that beneficiaries do not need to be terminally ill or forgo curative treatment to receive these services. They suggested that increased

access to palliative care can improve symptom management, pain control, patient and caregiver support, care coordination, and overall quality of life. They also noted that earlier integration of palliative care may help patients better understand their treatment options and align care with individual goals and preferences.

Some commenters who expressed support for measuring ACP warned against creating additional documentation requirements that duplicate existing OASIS assessments, care planning processes, or regulatory obligations. Commenters recommended leveraging existing workflows and data whenever possible and ensuring that any new measure is operationally feasible for agencies of all sizes. Several organizations also noted that home health agencies currently lack reimbursement mechanisms akin to those available to physicians for conducting ACP conversations. They argued that meaningful ACP discussions require significant clinician time, training, and interdisciplinary collaboration and that CMS should consider payment pathways that support these activities in HH.

Several commenters emphasized that ACP information is most valuable when it can travel with patients across settings, including hospitals, rehabilitation facilities, home health agencies, palliative care programs, and hospice. Commenters urged CMS to align future ACP measures with national interoperability standards and structured electronic data exchange rather than relying solely on OASIS items or scanned documents. They argued that standardized, machine-readable ACP information would improve care transitions and increase the likelihood that patient preferences are known and honored across the continuum of care.

Despite this support, several commenters requested additional guidance regarding how palliative care should be operationalized within home health settings. Commenters sought clearer distinctions between palliative care and hospice services, more detailed eligibility criteria, clarification regarding documentation and reporting requirements, and practical examples illustrating when palliative care interventions would be appropriate. Concerns were also raised

about potential confusion among providers, patients, and caregivers if definitions and expectations are not clearly communicated.

Several commenters also highlighted the importance of health equity, communication access, and caregiver engagement. Recommendations included accommodating individuals with communication disorders, cognitive impairment, limited English proficiency, low health literacy, cultural differences, and varying levels of caregiver support. Commenters stressed that family caregivers often play an essential role in decision-making, care coordination, and implementation of patient preferences and should be included in future quality measurement efforts. Some commenters recommended risk adjustment, stratification, and appropriate exclusions to ensure providers caring for complex or vulnerable populations are not unfairly disadvantaged. Commenters also consistently encouraged comprehensive testing, technical expert review, and ongoing collaboration before implementing any ACP measure in the HH QRP.

Commenters that supported ACP measure concept for HH also shared concerns regarding accountability and quality measurement. Commenters caution against measures that hold home health agencies' responsibility for outcomes outside their control, such as whether a patient completes an advanced care directive or changes previously established preferences. Commenters recommend that CMS develop measures that assess whether agencies offered information, facilitated discussions, and appropriately documented patient choices. Such an approach would more accurately reflect the quality of care provided while protecting patient choice and reducing unnecessary administrative burden.

Commenters who did not support an ACP concept in HH contend that home health agencies (HHAs) are not the most appropriate setting or provider type to lead ACP discussions. They also argue that home health services are typically short-term and intermittent, agency staff often lack the long-term relationship, clinical authority, and comprehensive knowledge of a patient's medical history needed to guide complex decisions regarding prognosis, treatment

options, and end-of-life preferences. Commenters suggest that primary care physicians and other long-term care providers are better positioned to lead these conversations.

Commenters who do not support an ACP QM expressed concerns about proposed ACP measures that would require documentation of an advance care directive or a completed decision. They argued that such measures could create inappropriate pressure on vulnerable patients, raise privacy concerns, duplicate existing documentation requirements, and unfairly hold agencies accountable for outcomes beyond their control. Many recommend that CMS instead measure whether a goals-of-care discussion was offered, documented, and conducted, regardless of whether a formal directive or final decision resulted.

Several commenters emphasized the importance of correct reimbursement, training, and quality measurement infrastructure that does not exist in HH for an ACP QM. They note that meaningful ACP and palliative care require significant clinician time, expertise, and care coordination. They urge CMS to first develop appropriate payment and reporting mechanisms that appropriately recognize these activities before looking to develop a measure.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the HH QRP.

IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing (HHVBP) Model ("original Model") in nine states on January 1, 2016. The design of the original Model leveraged the successes and lessons learned from other CMS 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--

- Provide higher incentives for better quality care with greater efficiency;
- Study new potential quality and efficiency measures for appropriateness in the home health setting; and
- Enhance the current public reporting process.

On January 8, 2021, CMS announced the certification of the HHVBP Model for expansion nationwide, as well as the intent to expand the Model through notice and comment rulemaking.[14] In the CY 2022 HH PPS final rule (86 FR 62292 through 62336), we finalized the decision to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. Payment adjustments under the Model are calculated in the year after each performance year and applied 2 years following each performance year. Therefore, payment adjustments for the first performance year of CY 2023 were implemented in CY 2025. Our codified policies for the expanded HHVBP Model can be found in our regulations at 42 CFR part 484, subpart F, §§ 484.300 through 484.375. The following description of existing HHVBP performance feedback reports is included for background and to provide context for the

[14] https://www.cms.gov/newsroom/press-releases/cms-takes-action-improve-home-health-care-seniors-announces-intent-expand-home-health-value-based.

discussion of potential alignment between the HH QRP and the expanded HHVBP Model in section III. of this final rule.

CMS publishes two types of routine performance feedback reports that provide HHAs with information on their measure performance:

- The first report type is the Interim Performance Report (IPR), which is issued quarterly. The information in the IPR reflects calculation of the TPS based on rolling data periods that are updated each quarter. CMS issues two versions of the IPR – a preliminary version and a final version that reflects any changes made as a result of the recalculation request process. The IPRs provide interim performance scores, achievement and improvement points, and TPS.

- The second report is the Annual Performance Report (APR). The APR provides HHAs with information on their measure performance using data from the prior calendar year. Like the IPR, the APR provides feedback to HHAs about performance relative to quality measure achievement thresholds, benchmarks, and improvement thresholds. Additionally, the APR includes the HHA's payment adjustment percentage for the upcoming CY, an explanation of when the adjustment will apply, and how CMS determined the adjustment.

For more information on the policies we have adopted previously for the expanded HHVBP Model, we refer readers to the following:

- CY 2022 HH PPS final rule (86 FR 62240).
- CY 2023 HH PPS final rule (87 FR 66790).
- CY 2024 HH PPS final rule (88 FR 77676).
- CY 2025 HH PPS final rule (89 FR 88354).
- CY 2026 HH PPS final rule (90 FR 55342).

CY 2027 will be the fifth performance year for the expanded HHVBP Model. As finalized in the CY 2026 HH PPS final rule, the expanded HHVBP Model currently uses six OASIS-based measures, three claims-based measures, and two HHCAHPS Survey-based

measures (see Table 31 in section III. (HH QRP) of this final rule). We continue to address the number of measures needed to maximize the number of HHAs in each cohort eligible for a payment adjustment.

CMS has identified substantial opportunities to better align the HH QRP and the expanded HHVBP Model, including measure-set alignment. Table 31 in section III. of this final rule reflects current and expected usage of measures for both the expanded HHVBP Model and the HH QRP. For more details on the potential alignment between the HH QRP and expanded HHVBP Model, see section III.D. of this final rule.

Though we did not propose any changes specific to the expanded HHVBP Model in the proposed rule, we did receive several public comments. The following is a summary of the comments we received and our responses.

Comment: Some commenters noted their appreciation that the proposed rule did not include new proposals related to the expanded HHVBP Model outside of outlining potential efforts to align the HH QRP and the expanded HHVBP Model. Several commenters submitted comments regarding potential updates to the expanded HHVBP Model's applicable measure set, cohort assignment, and the impact that HH QRP proposals and concepts discussed in HH QRP RFIs could have on the expanded HHVBP Model. Several commenters raised concerns about how additional emphasis on patients receiving palliative care via home health care could reflect negatively on HHA performance on HHVBP scores. Some commenters suggested that these patients should not be included in the expanded HHVBP Model if CMS further emphasizes palliative care in home health. Some commenters also suggested specific changes to the expanded HHVBP Model applicable measure set such as stratifying results by a patient's dual eligibility status for Medicare and Medicaid coverage. Other commenters noted that the expanded HHVBP Model should consider measures that do not only focus on functional improvement. A few commenters suggested that CMS should consider additional cohorts to better account for the differences in HHA characteristics.

Response: We thank commenters for their input. Since we did not propose any changes specific to the expanded HHVBP Model in the proposed rule, we are not responding to specific comments received in this final rule and will take this feedback into consideration as appropriate.

V. Durable Medical Equipment and Provider Enrollment Provisions

A. Overview

In this section of the final rule, we proposed changes and sought comment on the following DME and provider enrollment provisions:

- In section V.B. of the final rule, we will clarify the application of the DMEPOS face-to-face encounter requirements and the related documentation necessary to support the replacement of DMEPOS items.
- In section V.C. of the final rule, we proposed a number of Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process.
- In section V.D. of the final rule, we proposed to make changes to the Medicare Part B definition of DME regulations in accordance with the statutory changes implemented via section 6222(a) of the CAA, 2026.
- In section V.E. of the final rule, we discussed requesting revisions to the information collection requirements that will require DMEPOS CBP contract suppliers to report the country of origin for the lead items furnished during the contract's period of performance.

B. DMEPOS Encounter Requirements for Identical Replacement Items

1. Background

Section 1834(a)(11)(B)(ii) of the Social Security Act, as amended by section 504 of MACRA and codified in the Code of Federal Regulation (CFR) at 42 CFR 410.38, outlines a condition of payment for certain items of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Specifically, it requires a physician, physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) (as these four terms are defined in section 1861 of the Act) to write an order that is communicated to the supplier prior to delivery and document that the physician, PA, practitioner, or specialist has had a face-to-face encounter

(including through use of telehealth under section 1834(m) of the Act) with the individual involved, during the 6-month period preceding such written order.

On November 8, 2019 (84 FR 60648), we published a process whereby items identified as potential vulnerabilities to the Trust Fund may be placed on the *Master List of DMEPOS Items Potentially Subject to Face-to-Face Encounter and Written Orders Prior to Delivery and/or Prior Authorization Requirements* ("Master List"). We analyze the Master List and select items from the Master List to be placed on the *Required Face-to-Face Encounter and Written Orders Prior to Delivery List* ("Required F2F/WOPD List") via **Federal Register** notice. The face-to-face encounter requirements outlined in 42 CFR 410.38 are only applicable to items that are selected and placed on the Required F2F/WOPD List via **Federal Register** notice.

For the identified items, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription. The regulation requires supporting documentation to include the subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

Separately, in our Medicare Benefit Policy Manual (100-02) (Chapter 15, Section 110.2 - Repairs, Maintenance, Replacement, and Delivery) we define replacement as the provision of an identical or nearly identical item. Replacements may occur as a result of loss, theft, or irreparable damage, which may be due to a specific incident or event, or irreparable wear, in consideration of the reasonable useful lifetime of the equipment.

Section 414.210(f) discusses payment for replacement of equipment. As specified at 42 CFR 414.210(f)(1), the reasonable useful lifetime of durable medical equipment is generally determined through program instructions, or in the absence of program instructions, may be determined by the Medicare Administrative Contractors and be no less than 5 years. If the item of equipment has been in continuous use by the beneficiary for the equipment's useful lifetime or

if the contractor determines that the item is lost, stolen, or irreparably damaged, the beneficiary may elect to obtain a new piece of equipment. Replacement may be paid when the practitioner reaffirms the medical necessity of the item through a new order.

2. Provisions of the Regulation and Responses to Public Comments

CMS proposed to clarify that while an order would continue to be required for replacement DMEPOS items, a new face-to-face encounter would not need to occur to support payment for these DMEPOS items. We further proposed to clarify that, for purposes of 42 CFR 410.38(d)(2)(iii), a "replacement" refers to the provision of an item that replaces an item falling under the same Healthcare Common Procedure Coding System (HCPCS) code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition. In other words, for paragraph(d) the replacement would be the same type of item (that is, the same HCPCS code as that originally ordered and rendered) with no change to the type of item ordered and rendered. When an order is written to replace an item falling under the same HCPCS code, requiring a new face-to-face examination to document subjective and objective beneficiary specific information regarding how the DMEPOS item will continue to be used in relation to the beneficiary's clinical condition seems burdensome and redundant. If the item is not a replacement item identified by the same HCPCS code, then a new face-to-face encounter would continue to be required, as described in existing 42 CFR 410.38. This clarification does not eliminate the need for a new order, nor does it supersede or eliminate any other coverage instruction –including those iterated in national or local coverage determinations. In addition, we note that such claims may nonetheless be subject to medical review to ensure the appropriateness of claims billed for payment; particularly when there is concern for aberrant billing behaviors or potential fraud.

We received public comments on these proposals. In addition to the comments outlined below, CMS received some comments outside the scope of this regulation which will not be addressed. The following is a summary of the comments we received and our responses.

Comment: Commenters supported and encouraged finalization of CMS' proposal that a new face-to-face encounter would not need to occur to support payment for replacement DMEPOS items. Commenters acknowledged that the updates would prevent potential delays in the provision of replacement items, avoid unnecessary burdens and protect beneficiary access.

Response: We thank the commenters for their review and support of the proposed clarification.

Comment: A commenter suggested that CMS should consider establishing a reasonable timeframe after which a new face-to-face encounter would again be required to support continued use of the item. For example, if a replacement occurs many years after the original order, they shared their belief that a new clinical assessment may be appropriate to confirm that the beneficiary's condition, functional needs, and prescribed equipment remain consistent with current medical necessity requirements.

Response: We thank the commenter for their suggestion. We note that this clarification does not remove the need for the practitioner order, nor the need for the initial assessment to be provided, upon request, to support compliance with coverage requirements. We believe that these program integrity protections, coupled with regular clinical practice, will help ensure ongoing practitioner oversight of our beneficiary population.

Comment: Commenters requested that CMS look outside of the face-to-face requirements for evidence to support the item was initially medically necessary when such documentation is unavailable due to the lapse in time or other third-party documentation constraints.

Response: We appreciate the commenter's suggestion. We are finalizing the clarification that a face-to-face encounter does not need to be repeated for the sole purpose of ordering replacement items. However, we note that the regulation at 42 CFR 410.38 requires a face-to-face encounter for certain DMEPOS items. As such, documentation to support that the face-to-face encounter occurred when the item was initially furnished continues to be required.

Comment: A commenter requested CMS provide claim examples that define 'identical replacement' by HCPCS code, explain what documentation suppliers and treating practitioners should retain, and confirm that payment will not be denied solely because no new encounter occurred when the original encounter documentation remains valid and available.

Response: We do not believe that providing claim examples is necessary. The definition of 'identical replacement' is defined in this regulation as the same HCPCS code. In this regulation we clarify that when an identical DMEPOS item is being replaced, such claim will not be denied because a new encounter did not occur. However, we also clarify that the provider is expected to retain documentation to support that the original encounter occurred, as appropriate, when the item is initially furnished and that such documentation demonstrates compliance with our coverage requirements.

Comment: Commenters asked CMS to clarify that updated technologies, successor products, and newer device generations remain eligible for the replacement-item framework when they fall within the same HCPCS code and serve the same medical purpose.

Response: We agree. As stated in our proposal, it is our intent that this clarification would apply to the provision of an item that replaces an item falling under the same HCPCS code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition.

Comment: Commenters asked that CMS expand our current definition of an identical item as being the same HCPCS code to include any transitions within the same clinical product family, such as a beneficiary moving from a standard intermittent catheter to a hydrophilic-coated intermittent catheter. Likewise, commenters asked us to expand the definition to allow the provision of new accessory items, rendered with the replacement item, without a new face-to-face encounter being required.

Response: We thank the commenters for their feedback but are electing to retain our original language. As previously stated, we think that it is most appropriate to conduct a new

face-to-face encounter when there is a change in or addition of HCPCS items, as such deviations may indicate a change in condition.

Comment: A commenter expressed their concern that this regulatory clarification created misalignment amongst DMEPOS items. Specifically, they shared their concern that certain replacement items would not require a face-to-face encounter, while continuous glucose monitors require ongoing practitioner oversight, as a condition of payment, for continued coverage. Likewise, another commenter asked for our clarification that this provision would not impact the item-specific coverage requirements for wheelchairs (such as specialty evaluations for wheelchairs). Relatedly, a commenter asked CMS to remind contractors that they have the flexibility to revise local coverage determination requirements that may necessitate additional provider visits when furnishing identical replacement items.

Response: We are emphasizing our prior statement that this clarification does not eliminate the need for a new order, nor does it supersede or eliminate any other coverage instruction –including those iterated in national or local coverage determinations. If the item specific coverage policies include practitioner oversight requirements, such requirements would continue to apply. This provision only clarifies the intent of the regulatory text at 42 CFR 410.38.

Comment: Commenters requested CMS confirmation that the regulatory clarification would specifically apply to speech generating devices.

Response: This clarification applies for all DMEPOS items that require a face-to-face encounter per 42 CFR 410.38. Commenters can review those items that are currently included on the Required Face-To-Face Encounter and Written Order Prior To Delivery List, available at: https://www.cms.gov/files/document/required-face-face-encounter-written-order-prior-delivery-list.pdf.

Final Decision: After consideration of the public comments, we are finalizing our regulation as proposed to clarify that a new face-to-face encounter would not need to occur to support payment for these DMEPOS replacement items.

C. Provider Enrollment

1. Background and Applicability

a. Enrollment Process

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers (hereafter collectively "providers" unless otherwise noted) seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a "gatekeeper" that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one such requirement is that the provider must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, 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, PECOS), collects important information about the provider. Such data include, but are not limited to, general identifying information (for example, legal business name), licensure and certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment – The provider is -- (1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.

- Change of ownership – The provider is reporting a change in its ownership.

- Revalidation – The provider is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.)

- Reactivation – The provider is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.

- Change of information – The provider is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider 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.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers: (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 we discuss in this section V.C. of this final rule, we proposed several changes to our existing Medicare provider enrollment regulations.

b. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers; and

● Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Applicable Provider and Supplier Types

The provisions in section V.C. of this final rule apply to all Medicare provider and supplier types except as specifically indicated otherwise. The most prominent proposed provisions that would apply only to certain types of providers or suppliers include the following:

● New § 424.530(a)(20), which would permit denial of a hospice's enrollment application for the reasons specified therein.

● New §§ 424.530(a)(22) and 424.535(a)(25), which would allow denial or revocation of a hospice's, home health agency's, or DMEPOS supplier's enrollment for failing to comply with the change in majority ownership provisions in §§ 424.550(b) or 424.551.

● Revised § 424.540(b)(3)(i), which would require reactivating hospices to undergo a State survey or accreditation prior to reactivation.

● Revisions to our DMEPOS accreditation requirements in § 424.58.

d. Comment Solicitation

We solicited and welcomed comments on all of the proposed provider enrollment provisions that follow. We received approximately 375 sets of comments from stakeholders. We thoroughly and carefully read, reviewed, and considered all of them in full. Most comments will be addressed within the subject-matter section to which the comment pertained. More general comments, as well as comments that seemingly pertained to multiple topics, will be addressed at the end of this section (V.C.) (For instance, sets of comments that expressed the same concerns across several provisions.) This will reduce repetition and facilitate both clarity and brevity.

We also note that in some cases, it was difficult to determine whether the stakeholder's comment referenced a particular enrollment proposal or our current enrollment process as a whole; for example, some commenters were unclear as to whether they were requesting changes

to: (1) a proposed enrollment revocation reason; (2) how providers are currently revoked; or (3) both. We interpreted these comments as best we could based on their plain language.

2. Revocations and Denials of Enrollment

Under § 424.535(a), CMS may revoke a Medicare provider's enrollment for any of the reasons specified in that paragraph. These reasons include, for example, the provider's: (1) failure to adhere to Medicare enrollment requirements; (2) exclusion by the HHS Office of Inspector General (OIG); (3) felony conviction within the previous 10 years; (4) pattern of improper or abusive billing; and (5) termination by another Federal health care program. A revocation helps safeguard the Medicare program, the Trust Funds, and beneficiaries by removing from (and preventing payment to) Medicare providers that have engaged in problematic or otherwise non-compliant behavior. When a provider is revoked, it is generally barred from reenrolling in Medicare for a period of 1 to 10 years.

CMS also has numerous reasons in § 424.530(a) for which it can deny a provider's enrollment application, some of which duplicate our revocation grounds in § 424.535(a) (for instance, OIG exclusion). The general rationale for a denial is akin to that for a revocation: to protect the Medicare program and its beneficiaries from potentially fraudulent or abusive activity.

We have previously finalized a number of regulations adding or revising revocation and denial reasons in subpart P to address particular program integrity vulnerabilities and types of provider conduct. We have also used rulemaking to refine other revocation and denial policies, such as the effective dates of revocations. With our continuing obligation to establish strong payment safeguards, we proposed several changes to our revocation and denial policies in subpart P.

a. Modifications of Current Revocation Provisions

(1) Abuse of Billing Privileges (§ 424.535(a)(8)(ii))

Section 424.535(a)(8) permits revocation based on the provider's abuse of billing privileges. Per § 424.535(a)(8)(ii), this includes situations where CMS determines that the provider has a pattern or practice of submitting claims that fail to meet Medicare requirements. In making this determination, CMS considers, as appropriate or applicable, the following factors (outlined in § 424.535(a)(8)(ii)(A) through (D)):

- The percentage of submitted claims that were denied during the period under consideration (paragraph (a)(8)(ii)(A)).
- Whether the provider or supplier has any history of final adverse actions and the nature of any such actions (paragraph (a)(8)(ii)(B)).
- The type of billing non-compliance and the specific facts surrounding said non-compliance (to the extent this can be determined) (paragraph (a)(8)(ii)(C)).
- Any other information regarding the provider or supplier's specific circumstances that CMS deems relevant to its determination (paragraph (a)(8)(ii)(D)).

As we stated in the December 5, 2014, final rule that promulgated § 424.535(a)(8)(ii), a provider "should be responsible for submitting valid claims at all times and that the provider or supplier's repeated failure to do so poses a risk to the Medicare Trust Funds."[15]

We proposed the following two revisions to § 424.535(a)(8)(ii):

- Removing all the factors in § 424.535(a)(8)(ii)(A) through (D).
- Removing the second sentence of § 424.535(a)(8)(ii) that reads "In making this determination, CMS considers, as appropriate or applicable, the following".

We have seen a wide variety of potential § 424.535(a)(8)(ii) cases over the years. However, our existing factors often constrain our ability to effectively address all these factual scenarios. We noted the following in the proposed rule:

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[15] "Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment" (79 FR 72500).

- Final Adverse Actions – Most aberrant billing we have seen is done by providers with no history of adverse actions (for example, Medicare revocations or OIG exclusions). Yet the adverse action factor in § 424.535(a)(8)(ii) essentially requires us to weigh against a finding of improper billing for such providers. That is, this factor assists non-compliant providers so long as the provider lacks an adverse history, which it often will; this hinders our efforts to invoke § 424.535(a)(8)(ii) against the provider.

- Percentage of Claims Denied – This factor, too, is problematic. Non-compliant billing often occurs notwithstanding a low percentage of denied claims, especially with providers that submit many claims. Similar to the adverse history factor, the claim denial criterion thus makes it more difficult to use § 424.535(a)(8)(ii) even if a pattern of abusive billing exists. Moreover, the factor is limited to claim denials and does not consider other types of non-compliant claims (such as rejected claims). In our view, it is the lack of compliance itself, rather than the type of claim involved, that is pertinent.

In sum -- and given our responsibility to protect the Trust Funds and taxpayers from improper billing -- we must have the ability to address all possible § 424.535(a)(8)(ii) scenarios without the rigid constraints of our existing factors. Even with the "as appropriate or applicable" qualifier in the opening paragraph of § 424.535(a)(8)(ii), there could still be an implication that we must consider all the factors in our determinations, which, as indicated, hampers the usefulness of § 424.535(a)(8)(ii).

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our removal of factors from § 424.535(a)(8)(ii). They stated that clear criteria and thresholds (such as a minimum number of claims needed to constitute a "pattern or practice") are needed to foster transparency and certainty for providers. Some commenters stated that CMS should not only retain the current factors but also include new ones such as (though not limited to): (1) the statistical validity and representativeness of any

claim sample that CMS reviews; (2) the dollar amount, frequency, nature, severity, and materiality of the alleged errors; (3) whether the provider knew or reasonably should have known of the noncompliance; (4) whether CMS or the MAC previously notified or educated the provider; (5) whether the provider promptly refunded overpayments and implemented corrective action; (6) the provider's compliance history and prompt rectification of errors; (7) the presence or absence of fraud, waste, abuse, or beneficiary harm; and (8) whether the pattern or practice involved final adjudicated claims rather than initial denials.

Response: We appreciate the commenters' concerns and suggestions. Yet as previously explained, specifically delineated and mandatory factors have inhibited our ability to effectively utilize § 424.535(a)(8)(ii). This said, we emphasize strongly that CMS will take into account the facts and circumstances of every evaluation under § 424.535(a)(8)(ii) and, as we currently do, will only revoke under this ground when genuinely warranted and not as a matter of course. Moreover, stakeholders should not assume that our removal of § 424.535(a)(8)(ii)'s factors means that we will never again consider matters such as the percentage of claims denied or the type of billing non-compliance in our § 424.535(a)(8)(ii) determinations. Our change to § 424.535(a)(8)(ii) simply reflects the program integrity need to move away from explicit factors and towards a broader, more flexible "facts and circumstances" approach. This is also partly why we have not established a fixed, regulatory definition of "pattern or practice" with numerical and time thresholds.

We stress that up through 2014, none of CMS' denial or revocation grounds contained enumerated, mandatory factors – and even today, a number of our grounds do not. Both then and now, a lack of factors does not mean providers will be treated unfairly. We have for decades reviewed every case with the utmost care and consideration, recognized the heavy consequences of a revocation, and only taken this measure when necessary.

Comment: Commenters expressed concern about our statement in the proposed rule that § 424.535(a)(8)(ii) could be invoked if "several of the provider's claims do not meet Medicare

requirements." They contended that this represents an expansion of § 424.535(a)(8)(ii). They stated that occasional claim submission errors do not establish abusive billing and are largely unavoidable given, for example: (1) the complexity of Medicare billing; (2) that some providers submit thousands of claims; and (3) that small, independent practices do not have the billing staff and resources of larger providers. Several commenters requested that the final rule expressly state that isolated, inadvertent, immaterial, clerical, or promptly corrected claim errors -- standing alone -- do not constitute a pattern or practice of abusive billing. Others sought a CMS statement that a finding based only on "several" non-compliant claims should not invoke § 424.535(a)(8)(ii) unless the provider engaged in material and repeated non-compliance.

Response: We respectfully disagree that the quoted "several" statement is an expansion of § 424.535(a)(8)(ii). To the contrary, it represents CMS' position since the provision's inception in 2014. We have always had the authority to invoke § 424.535(a)(8)(ii) in such circumstances. For both this reason and the need to address many different factual scenarios, the unequivocal statements the commenters request are overbroad. On the other hand, we recognize and understand the commenters' concerns and, as we always have, will only use § 424.535(a)(8)(ii) when the facts and circumstances warrant it. The previously quoted statement and the removal of factors will not change this.

Comment: Commenters stated that instead of revoking a provider under § 424.535(a)(8)(ii), CMS should first: (1) use provider education and corrective action programs, including "Targeted Probe and Educate"; and (2) allow providers to explain the erroneous claim submissions and to resubmit said claims.

Response: We again appreciate the commenters' concerns about § 424.535(a)(8)(ii)'s potential application. However, we have consistently maintained that providers are responsible for always submitting accurate and compliant claims. If we routinely allowed providers to simply resubmit non-compliant claims without any invocation of § 424.535(a)(8)(ii), we believe

providers would have less incentive to initially submit correct claims, knowing that CMS will not take action against them.

This concept is especially true regarding pre-revocation opportunities to be heard, which we believe these commenters were requesting. (As addressed later, other commenters requested such a process for several of our other proposals.) We discussed this issue in the CY 2026 HH PPS final rule, published in the December 2, 2025, **Federal Register** (90 FR 55342).[16] We stated therein: "We have always maintained that establishing an informal pre-revocation appeals process could encourage providers to disregard compliance with Medicare requirements until they are notified of the non-adherence, upon which they will remedy the issue and remain enrolled but then perhaps resume their prior behavior. In other words, allowing providers to always take corrective action and resume compliance before revocation gives them no incentive to remain adherent in the first place, which leaves the Medicare program at risk of billions of dollars in payments to non-compliant providers."[17] We hold this same position regarding § 424.535(a)(8)(ii).

Comment: A commenter suggested that if CMS views the § 424.535(a)(8)(ii) factors as constraining, it could make them optional by replacing the language "CMS considers" in § 424.535(a)(8)(ii)'s opening paragraph with "CMS may consider".

Response: While we appreciate this suggestion, we remain concerned that even the optional nature of public, regulatorily specified factors could convey the impression that CMS should still consider them. This would present largely the same previously discussed problem we have seen with mandatory criteria.

Comment: Several commenters requested that CMS clarify the following: (1) whether initial claim denials, technical denials, documentation deficiencies, or coding disagreements are

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[16] "Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies".
[17] Ibid.

considered claims that fail to meet Medicare requirements; (2) whether claims that are subsequently overturned on appeal remain part of the analysis; (3) whether CMS intends to establish numerical thresholds or materiality standards before revocation; and (4) how CMS will distinguish isolated operational errors from systemic abusive conduct.

Response: Concerning the first two requests, we did not propose to interpret or clarify either the phrase "fails to meet Medicare requirements" or the types of claims that fall within our analysis. Thus, we believe these requests are outside the scope of this final rule. The answer to the third question is no for reasons already indicated. Regarding the fourth, CMS, as it long has, will carefully evaluate the facts and circumstances of every § 424.535(a)(8)(ii) case and only taken revocation action when justified.

After considering the comments received, we are finalizing proposed revised § 424.535(a)(8)(ii) without modification.

(2) False or Misleading Information (§ 424.535(a)(4))

Section 424.535(a)(4) permits revocation if the provider or supplier certified as "true" misleading or false information on the enrollment application to be enrolled or maintain enrollment in the Medicare program. We proposed to revise § 424.535(a)(4) to allow revocation based on the submission of false or misleading information on or associated with any CMS or Medicare enrollment-related form. This would include but not be limited to: (1) enrollment-related forms created by and/or submitted to CMS contractors; (2) false or misleading documentation furnished as part of the completion or submission of the CMS or Medicare enrollment-related form; (3) the Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB Control Number 0938-0626), which must be submitted with the enrollment application; (4) documents required to demonstrate compliance with HHA capitalization requirements in § 489.28; (5) opt-out affidavits under 42 CFR part 405, subpart D; (6) letters from a provider demonstrating that a particular provider official qualifies as an authorized or

delegated official under § 424.502; and (7) any other required or requested enrollment-related documentation.

We stated that providers and suppliers must always submit truthful enrollment and enrollment-related information to CMS and its contractors regardless of the form or document involved. Any false or misleading information could lead to serious doubts about the provider's veracity, a non-compliant provider being inadvertently enrolled in Medicare, or improper payments based on inaccurately submitted data. With this in mind, we also stressed that under revised § 424.535(a)(4):

- The submission need not be intended to gain or maintain Medicare enrollment. For § 424.535(a)(4) purposes, the ultimate aim of the submission – be it to enroll, revalidate enrollment, reactivate enrollment, voluntarily terminate enrollment, report changed EFT data, etc. – is not as crucial as the truthfulness of the submission. If we continued to limit § 424.535(a)(4) to "gain or maintain enrollment" situations, providers might believe they can submit false information on other enrollment-related documents without concern about possible revocation.

- The information need not have been certified as "true" for § 424.535(a)(4) to apply. The correctness of the information is the salient point and not whether it was certified as "true."

We believe that our § 424.535(a)(4) expansion would help ensure that providers furnish truthful and accurate enrollment-related data to Medicare.

The following is a summary of the comments we received on this proposal and our responses. Note that some of these comments and responses also pertain to proposed revised § 424.530(a)(4), which would permit denial based on the same grounds identified in proposed § 424.535(a)(4). Our final decision regarding § 424.530(a)(4) will be addressed later.

Comment: Numerous commenters stated that our proposed expansion of §§ 424.530(a)(4) and 424.535(a)(4) could result in denials and revocations based on inadvertent or immaterial administrative errors. They stated that CMS should distinguish between intentional fraud and

technical or minor mistakes that are promptly corrected. They added that CMS should: (1) include a materiality-based standard -- like "knowing and material misrepresentation" -- and other factors in §§ 424.530(a)(4) and 424.535(a)(4) (for example, whether the information is relevant to program integrity); (2) permit providers to cure any unintentional or clerical errors before revocation (such as a 30-day correction timeframe); and (3) always consider mitigating circumstances in its paragraph (a)(4) determinations.

Response: We appreciate these comments and address them as follows.

First, our proposal was not intended to change the standard we always apply when reviewing potential §§ 424.530(a)(4) and 424.535(a)(4) situations. We will continue to carefully consider the facts and circumstances of each case and only deny or revoke when truly justified.

Second, we respectfully decline to establish knowledge, materiality, or other regulatorily specified criteria or thresholds. Sections 424.530(a)(4) and 424.535(a)(4) have never had a knowledge or intent standard or required the data to be material, and we did not propose in this rule to establish such requirements. If we required knowledge or intent, providers might submit false data believing they could later simply disavow awareness thereof to avoid denial or revocation. A materiality threshold, meanwhile, would enable providers to, knowingly or unknowingly, submit incorrect information without fear of consequences so long as it is not deemed material. As for establishing new factors, we reiterate our previously noted concerns about required criteria that constrain our ability to take denial or revocation action when necessary. We also stress that it has long been CMS policy that the enrolling or enrolled provider bears ultimate legal responsibility for the accuracy and thoroughness of all submitted data, a point we reiterated in the CY 2026 HH PPS final rule.

Third, and consistent with our aforementioned quoted statement from the CY 2026 HH PPS final rule, we believe that permitting a pre-revocation correction period and/or quasi-appeals process could disincentivize providers to submit correct and truthful information in their initial submission.

Comment: Some commenters were concerned that the increased number of documents and communications covered by § 424.535(a)(4) could concomitantly increase the chances of a revocation based on an innocent error. This could prove especially problematic for large providers that submit many such documents.

Response: While we appreciate these concerns, the central issue is the submission of the false or misleading information itself and not the number of potential documents on which it could be furnished. All enrollment-related data provided to CMS and the MACs – irrespective of the volume of documents involved -- must be truthful and accurate. To restate, though, CMS will evaluate the facts and circumstances of every situation and only deny or revoke when genuinely warranted.

Comment: Several commenters requested clarification on which types of forms and communications are "associated with" a provider's enrollment.

Response: We identify in revised § 424.535(a)(4) various types of forms and documents that fall within this category. We will, if needed, issue guidance to further elucidate this term.

Comment: Several commenters recommended that CMS define "false or misleading information."

Response: We respectfully believe this comment is outside the scope of this final rule because we did not propose to define this term, which already appears in the current versions of §§ 424.530(a)(4) and 424.535(a)(4). Nonetheless, we can state that the terms "false" and "misleading" in the context of §§ 424.530(a)(4) and 424.535(a)(4) have – and have always had -- their plain meanings.

Comment: A commenter requested that CMS ensure that any technical or automated mechanism used by CMS to detect false information be configured so as not to flag providers that use different acronyms, abbreviations, or spellings for addresses or other demographic information.

Response: We appreciate this comment and stress that CMS in its §§ 424.530(a)(4)

and 424.535(a)(4) determinations takes into account the facts and circumstances of the situation.

Comment: A commenter sought confirmation that claims corrected through routine adjustments, self-audits, or voluntary refunds will not independently be treated as evidence of providing false or misleading information.

Response: Sections 424.530(a)(4) and 424.535(a)(4) only apply to enrollment-related submissions.

After considering the comments received, we are finalizing proposed revised § 424.535(a)(4) without modification.

(3) Extension of Revocation (§ 424.535(i))

Section 424.535(i) states that if a provider's enrollment is revoked under § 424.535(a), CMS may revoke any and all of the provider's other enrollments. This provision is designed to ensure that, if circumstances warrant, individuals and entities revoked for inappropriate behavior do not remain enrolled in Medicare – and, hence, potentially able to continue their conduct via their other Medicare enrollments -- in any capacity. We proposed to expand § 424.535(i) such that we could also revoke a provider's other enrollments if the provider's triggering enrollment is denied under § 424.530(a).

Numerous commenters opposed our proposal. Their principal contention was that enrollment denials can sometimes be for purely innocuous reasons and should therefore not trigger revocations of the provider's other enrollments.

After reviewing the comments received, we are not finalizing our proposed revision to § 424.535(i).

(4) Expansion and Reorganization of Retroactive Revocation Grounds (§ 424.535(g))

Section 424.535(g) addresses revocation effective dates. Current paragraph (g)(1) states that except as described in paragraphs (g)(2) and (g)(3), a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider; the revocation

is thus prospective. Existing paragraphs (g)(2)(i) through (xv) list situations where the revocation effective date is retroactive. This generally means that the revocation's effective date is retroactive back to the date on which the provider's non-adherence to Medicare requirements commenced.

The purpose of paragraph (g)(2) is to prevent payments to a provider while it is out of compliance. Using an example we included in the proposed rule, assume a provider's medical license is revoked by the State on March 1. CMS learns of this and sends a revocation notice to the provider on March 15. If we applied the prospective "30 days after mailing" timeframe in paragraph (g)(1), the provider could bill and be paid for services furnished between March 1 and April 15 while unlicensed, resulting in potentially thousands of dollars in improper Medicare payments. Preventing improper payments is a cornerstone of provider enrollment, and retroactive revocation effective dates are vital mechanisms for ensuring that taxpayer monies are paid only to compliant providers. As § 424.500 makes clear: "Providers and suppliers must meet and maintain [part 424, subpart P's] enrollment requirements to bill either the Medicare program or its beneficiaries for Medicare-covered services or supplies." This means, by extension, that if said requirements are not met, the provider cannot bill – or, in turn, receive payment – for Medicare services or supplies.

Our concerns about paying non-adherent providers are why we have increased the number of retroactive revocation grounds over the years. In the CY 2026 HH PPS final rule, we finalized numerous revisions to § 424.535(g) such that many of our existing revocation reasons are now retroactive.[18] So critical is it to make payments only to qualified providers and to be consistent with §§ 424.500 and 424.505 that we proposed in the CY 2027 HH PPS final rule to make the remainder of current prospective revocation grounds retroactive. We also believe that the prospect of a retroactive revocation no matter the § 424.535(a) reason could help spur providers to ensure constant compliance with Medicare requirements.

[18] Ibid.

We proposed two sets of changes to § 424.535(g). First, we would add new retroactive revocation bases. Second, we proposed to restructure § 424.535(g) to remove current § 424.535(g)(1) (which addresses prospective revocations) and realign the existing retroactive grounds to correspond to the numerical order of our § 424.535(a) revocation reasons. The following summarizes our proposed provisions in revised § 424.535(g)(1).

(a) General Non-Compliance, Licensure, and Provider Agreements

CMS may revoke a provider under § 424.535(a)(1) if the provider is not in compliance with the enrollment requirements in Title 42 of the Act or in the enrollment application applicable to its provider type. We proposed in new § 424.535(g)(1)(i)(A) that said revocation would be effective on the date the non-compliance began (per CMS' or the CMS contractor's determination). This comports with several other current retroactive grounds for which the commencement of non-compliance is the effective date; for said current grounds – as well as proposed § 424.535(g)(1)(i)(A) -- the rationale is that payments should not be made to non-adherent providers.

State licensure revocations, suspensions, and surrenders (in lieu of further disciplinary action) are also grounds for revocation. As stated in existing § 424.535(g)(2)(iii) and (v), these revocation effective dates are the dates of the revocation, suspension, or surrender. We proposed to consolidate paragraphs (g)(2)(iii) and (v) within new § 424.535(g)(1)(i)(B), retaining their current effective dates.

Current § 424.535(g)(2)(vii) addresses effective dates for revocations based on a provider agreement termination under part 489. We proposed to retain these dates and incorporate them into new § 424.535(g)(1)(i)(C).

(b) Exclusions/Debarments, Felony Convictions, False Information, and Non-Operational Status

These revocation grounds are addressed in § 424.535(a)(2), (3), (4), and (5)(i), with their concomitant effective dates outlined in existing § 424.535(g)(2)(i), (ii), (ix), and (iv),

respectively. Per § 424.535(g)'s proposed reorganization, § 424.535(g)(2)(i), (ii), (ix), and (iv) would become new § 424.535(g)(1)(ii), (iii), (iv), and (v)(A), respectively.

(Due to our aforementioned expansion of § 424.535(a)(4), we proposed that new § 424.535(g)(1)(iv) would include an additional effective date for paragraph (a)(4) revocations based on the submission of false or misleading data not involving the signature of a provider enrollment application certification statement. For these other false/misleading communications, the revocation effective date would be the date the false/misleading information was submitted.)

(c) Failure to Satisfy Enrollment Requirements

Section 424.535(a)(5)(ii) permits revocation if the provider fails to satisfy any Medicare enrollment requirement. We proposed in new § 424.535(g)(1)(v)(B) that a § 424.535(a)(5)(ii) revocation becomes effective on the date the Medicare enrollment requirement was not satisfied.

(d) Application Fee Payment

CMS can revoke a provider's enrollment under § 424.535(a)(6) in various situations concerning the required payment of a provider application fee under § 424.514. We proposed in new § 424.535(g)(1)(vi) that a § 424.535(a)(6) revocation is effective on the date on which CMS or its contractor determines that the provider or supplier should be revoked under this paragraph.

(e) Misuse of Billing Number

CMS may revoke a provider's enrollment under § 424.535(a)(7) if the provider knowingly sells to or allows another individual or entity to use its billing number. (This excludes providers who enter into a valid reassignment of benefits under § 424.80 or a § 489.18 change of ownership.) Given the seriousness of this conduct – with its significant potential for fraud – we proposed in new § 424.535(g)(1)(vii) that the revocation effective date should be the date on which the conduct resulting in the revocation occurred.

(f) Abuse of Billing Privileges

The effective dates for revocations under § 424.535(a)(8)(i) and (ii) are addressed in § 424.535(a)(8)(iii). So that all revocation effective dates can be located in one paragraph, we

proposed to move and redesignate § 424.535(a)(8)(iii) as new § 424.535(g)(1)(viii). Paragraph (iii) would be deleted from § 424.535(a)(8).

(g) Reporting Enrollment Data Changes

Section 424.535(a)(9) permits revocation if the provider failed to comply with the change of information reporting requirements in §§ 424.516(d) or (e), 410.33(g)(2), or 424.57(c)(2). These four paragraphs collectively address all Medicare provider and supplier types (except Medicare Diabetes Prevention Programs (MDPPs), which are dealt with in § 424.205)) and all types of enrollment data changes. Current § 424.535(g)(2)(x) partially addresses the effective date of a § 424.535(a)(9) revocation. For revocations based on the provider's failure to timely report a change of ownership or adverse legal action (or a change, addition, or deletion of a practice location), the effective date under § 424.535(g)(2)(x) is the day following the date by which the provider was required to report the change, addition, or deletion. All other changes are prospective under current § 424.535(g)(1).

We proposed in new § 424.535(g)(1)(ix) to make all § 424.535(a)(9) revocations retroactive to the day following the due date for reporting the change. While ownership, adverse legal action, and practice location changes are important (hence their inclusion in existing § 424.535(g)(2)(x)), other data changes are as well. A failure to timely report a new managing employee or corporate officer, for example, could result in CMS unknowingly paying a provider with a high-level official who poses a program integrity risk based on past or current conduct. If we do not timely learn of a provider’s new bank, billing agency, or correspondence address, CMS risks sending funds or information to -- or receiving claims from – the wrong entity or individual; this could lead to incorrect payments or the inadvertent release of confidential data. As we emphasized in the proposed rule: (1) outdated or erroneous enrollment information of any type – not simply ownership, adverse action, or location data -- can threaten the Trust Funds; and (2) any failure to timely report such changes means the provider is non-compliant with enrollment requirements. For these reasons – and because the prospect of a retroactive revocation

could encourage providers to timely report all enrollment changes -- we believed that § 424.535(g)(1)(ix) is warranted.

Although the provider is ultimately responsible for ensuring that its enrollment data is timely updated and always accurate, we solicited stakeholder comment on any administrative difficulties in reporting changes in enrollment information and how they could be addressed.

(h) Failure to Document or Furnish Documentation

CMS can revoke a provider under § 424.535(a)(10) if the provider fails to comply with the documentation or CMS access requirements in § 424.516(f). In general, § 424.516(f) requires providers (including physicians and eligible professionals) to: (1) retain for 7 years all documents regarding written orders, certifications, referrals, prescriptions and requests for payments for Part A or B services, items, or drugs; and (2) furnish access to that documentation upon CMS or CMS contractor request.

We proposed in new § 424.535(g)(1)(x)(A) and (B) that a § 424.535(a)(10) effective date is as follows:

- For revocations based on a failure to retain documentation, the date on which CMS or the CMS contractor determines that the provider has not complied with this retention requirement.

- For revocations based on a failure to provide access to that documentation, the day after the date by which the provider was required to give access.

We believed that proposed § 424.535(g)(1)(x)(A) and (B) balance the need for retroactivity – due to, for instance, the provider's non-compliance and our inability to make payment to non-adherent providers – and the need for a clear effective date. To illustrate, suppose CMS discovered several years after a particular service was ordered or certified that the provider lacks documentation thereof. CMS would have no means of knowing whether the documentation was never kept, discarded after 2 years or 4 years, etc. Therefore, it is difficult to establish an effective date in this scenario, hence the need to use the proposed – and much more

precise -- § 424.535(g)(1)(x)(A) date. Regarding § 424.535(g)(1)(x)(B), the provider's failure to provide the documentation constitutes non-compliance, similar to a provider's failure to timely report changes of information. Thus, we believe that the day after the due date for furnishing access is an appropriate effective date.

(i) Initial Reserve Operating Funds (IROF)

Under 42 CFR 489.28, HHAs must demonstrate that they have sufficient available funds upon application submission and for the 3-month period following the conveyance of Medicare billing privileges to operate the HHA for this 3-month timeframe. CMS can revoke the HHA under § 424.535(a)(11) if, within 30 days of a CMS or Medicare contractor request, the HHA cannot furnish supporting documentation verifying that it meets the IROF requirement. For the same reasons behind proposed § 424.535(g)(1)(x)(B) – specifically, the provider's non-compliance with § 489.28 based on its failure to demonstrate adequate funds -- we proposed in new § 424.535(g)(1)(xi) that the § 424.535(a)(11) revocation effective date is the day after the date by which the HHA was required to submit the requested documentation.

(j) Other Program Termination

CMS under § 424.535(a)(12) may revoke a provider's Medicare enrollment if the provider is terminated, revoked, or otherwise barred from participation in a State Medicaid program or any other Federal health care program. The effective date of a § 424.535(a)(12) revocation is, consistent with existing § 424.535(g)(2)(vi), the date of the termination, revocation, or bar (from the other program). As part of our restructuring of § 424.535(g), we proposed to redesignate § 424.535(g)(2)(vi) as new § 424.535(g)(1)(xii); however, we would include the terms "revocation" and "bar" within the latter to correspond to § 424.535(a)(12). (Current § 424.535(g)(1)(vi) only references terminations.)

(k) Drug Enforcement Administration (DEA) Certificates

Section 424.535(a)(13)(i) and (ii) permit revocation if--

- A physician or other eligible professional's DEA Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to a show cause order; or

- The applicable licensing or administrative body for any State in which the physician or eligible professional practices suspends or revokes the individual's ability to prescribe one or more drugs.

Existing § 424.535(g)(2)(xi) permits retroactive revocation based on the surrender of the provider's DEA certificate of registration in response to a show cause order. (The revocation effective date is the date the certificate was surrendered.) We proposed to include DEA certificate revocations and suspensions within this paragraph, with the date of the revocation or suspension as the effective date. It is the permanent or temporary loss of the certificate itself -- rather than the form of loss (for example, revocation or surrender) – that is important for program integrity purposes; it would be illogical for certificate surrenders to be part of paragraph (g)(2)(xi) but not revocations or suspensions. As we stated in the CY 2026 HH PPS final rule that promulgated paragraph (g)(2)(xi), meeting all applicable Federal and State requirements is necessary for enrollment.[19] If a provider is prescribing or dispensing drugs while non-compliant, we believe the risk this presents to beneficiaries after the certificate loss warrants a revocation back to the date said loss occurred.

Per current § 424.535(g)(2)(xii), the effective date of a revocation based on a State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs is the date of the suspension or revocation. We proposed to redesignate this paragraph without change as new paragraph (g)(1)(xiii)(B), with existing (g)(2)(xi) redesignated as new paragraph (g)(1)(xiii)(A).

(l) Improper Prescribing Practices

[19] 90 FR 55342

Section 424.535(a)(14) permits revocation if the physician or practitioner has a pattern or practice of prescribing Medicare-covered drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. We proposed in new § 424.535(g)(1)(xiv) that the effective date of a § 424.535(a)(14) revocation would be the last date of the prescription(s) in question. (This approach mirrors that for § 424.535(a)(8)(ii)'s revocation effective date, which, as noted, is the last date of service on the claims in question.) Applying a prospective effective date to a § 424.535(a)(14) would essentially allow the individual to continue prescribing for at least another 30 days, during which time additional beneficiaries might be placed as risk.

(m) False Claims Act (FCA)

Revocation is permissible under § 424.535(a)(15) if the provider (or owner, managing employee or organization, officer, or director thereof) has had an FCA civil judgment against them within the previous 10 years. We proposed in new paragraph (g)(1)(xv) a retroactive revocation effective date back to the date of the judgment.

(Proposed new § 424.535(g)(1)(xvi) is addressed later in this section V.C. of this final rule.)

(n) Debts Referred to Treasury

Section 424.535(a)(17) permits revocation if the provider failed to repay a debt that CMS appropriately referred to the United States Department of Treasury. (Paragraph (a)(17) does not apply if: (1) the debt has been discharged by a bankruptcy court; or (2) the administrative appeals process regarding the debt has not been exhausted or the timeframe for filing the appeal (at the appropriate appeal level) has not expired.)

All providers are responsible for satisfying their financial obligations to Medicare. Consistent with our rationale for the original promulgation of § 424.535(a)(17), we believe that referral to the Department of Treasury may indicate the provider's unwillingness to repay a debt,

which raises doubts regarding whether the provider is a reliable participant in the Medicare program.

With the need to protect the Medicare program's financial integrity, we proposed in new § 424.535(g)(1)(xvii) that the effective date of a § 424.535(a)(17) revocation would be retroactive back to the date on which CMS referred the debt to Treasury. As we explained in the proposed rule, a prospective effective date would give the provider more time to incur additional debts that it also might not repay, placing the taxpayers at considerable financial risk. We also believe that the prospect of a retroactive revocation under § 424.535(g)(1)(xvii) could spur providers to ensure that they repay all debts before the latter are sent to Treasury.

(o) Revoked Under Different Name or Identity

CMS under § 424.535(a)(18) may revoke a provider that is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period under § 424.535(c) has not expired. The objective is to prevent situations where a revoked provider changes its identity in order to re-enter Medicare and thus circumvent its existing bar on reenrollment. In light of such improper conduct, we proposed in new § 424.535(g)(1)(xviii) that a § 424.535(a)(18) revocation effective date would be the same as the effective date of the provider's current enrollment.

(p) Undue Risk

Per § 424.535(a)(19), CMS may revoke a provider or supplier that has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program. Due to the many different scenarios that could fall within § 424.535(a)(19)'s purview, we proposed in new § 424.535(g)(1)(xix) that a revocation under § 424.535(a)(19) is effective on the date on which CMS or its contractor determines that the provider or supplier should be revoked under this paragraph.

(q) Billing from Non-Compliant Location

CMS may revoke enrollment under § 424.535(a)(20) if the provider billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements. Given the importance of maintaining constant compliance with enrollment requirements, we proposed that a § 424.535(a)(20) revocation's effective date would be the earliest date on the claims for the non-compliant location that are triggering the revocation.

(r) Abusive Ordering, Certifying, Referring, or Prescribing

Section 424.535(a)(21) permits revocation if the physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. As with proposed § 424.535(g)(1)(xiv) regarding § 424.535(a)(14), the seriousness of the conduct described in § 424.535(a)(21) and the threats it can present to Medicare patients and the Trust Funds (for instance, ordering unnecessary tests) warrants a retroactive effective date. This date under proposed § 424.535(g)(1)(xxi) would be the date of the last order, certification, referral, or prescription in the applicable pattern or practice, akin to the proposed § 424.535(a)(14) effective date.

(s) Patient Harm

Revocation under § 424.535(a)(22) is permissible if the physician or other eligible professional has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper conduct that led to patient harm. Considering the need to protect Medicare beneficiaries from potential harm, we proposed that this effective date per new § 424.535(g)(1)(xxii) would be the date of the prior action that resulted in the revocation.

(t) Supplier Standard and Condition Violation

Several provider and supplier types have certain standards and conditions they must meet in addition to all other enrollment requirements. These types – and their corresponding standard/condition regulatory sections – include independent diagnostic testing facilities (IDTFs) (§ 410.33(g)), DMEPOS suppliers (§ 424.57(b) and (c)), opioid treatment programs (OTP) (§ 424.67(b) and (e)), home infusion therapy suppliers (§ 424.68(c) and (e)), and MDPPs (§ 424.205(b) and (c)). Except for § 424.57(b) violations, CMS under § 424.535(a)(23) may revoke the provider or supplier for non-compliance with any of the standards or conditions applicable to their provider/supplier type. (Revocation is permissible for § 424.57(b) violations (as well as § 424.57(c) non-compliance) under § 424.57(e)(1).) The current § 424.535(a)(23) revocation effective dates (outlined in § 424.535(g)(2)(xv)(A) through (D), respectively) are as follows:

- For standard or condition violations involving the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's Federal or State license, certification, accreditation, or MDPP recognition, the date of the suspension, revocation, termination, or surrender.

- For standard or condition violations involving a non-operational practice location, the date the non-operational status began.

- For OTP standard violations involving a felony conviction of a party described in § 424.67(b)(6)(i), the date of the felony conviction.

- For all standard violations not addressed in existing paragraph (g)(2) (which, as discussed, would be incorporated within revised (g)(1)), the prospective effective date in current paragraph (g)(1) applies if the effective date in existing paragraph (g)(3) (discussed shortly) does not.

We proposed to retain the dates in § 424.535(g)(2)(xv)(A) through (C), though we would re-designate them as new § 424.535(g)(1)(xxiii)(A)(*1*) through (*3*). In new § 424.535(g)(1)(xxiii)(B) -- and consistent with the foregoing concerns about paying non-

compliant providers -- we proposed that the effective date of all other revocations based on a condition or standard violation would be the date of non-compliance with the condition or standard.

We proposed three other organizational changes. First, existing § 424.535(g)(2)(viii) states that the effective date of a revocation based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6) is the date the insurance lapsed. We did not propose to include a separate effective date for this revocation in revised § 424.535(g)(1) because we believe it would fall within new § 424.535(g)(1)(xxiii)(B), with the lapse date being the standard violation date. Second, existing § 424.535(g)(2)(xiv) states that the effective date of a revocation based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c) is the date on which the non-compliance began. This provision would not be included in revised § 424.535(g)(1), for new § 424.535(g)(1)(xxiii) would cover § 424.57(b) or (c) violations. Third, existing paragraph (g)(3) would be re-designated as revised § 424.535(g)(2).

(u) Extension of Revocation

As already noted, § 424.535(i) states that if a provider's Medicare enrollment is revoked, CMS may revoke any and all of the provider's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types. The effective date of the revocation(s) of the other enrollment(s) is – per existing § 424.535(g)(2)(xiii) -- the effective date of the revocation that triggered the other revocation(s). We proposed to retain this effective date provision but would redesignate it as new § 424.535(g)(2)(xxvi).

(Proposed new § 424.535(g)(1)(xxiv) and (xxv) will be addressed later.)

The following is a summary of the comments we received on our retroactive revocation proposals and our responses.

Comment: Many commenters opposed CMS' proposal to extend its retroactive revocation authority to all revocations and recommended that it not be finalized. They stated that

retroactive revocations can impose severe and disproportionate financial consequences on otherwise legitimate providers and suppliers.

Response: We appreciate and understand the concerns expressed. We respond as follows.

First, and as previously noted, in past years we have gradually expanded the reasons for which we may retroactively revoke providers. In last year's CY 2026 HH PPS final rule, we added roughly 10 new retroactive grounds. Accordingly, retroactive revocations are not a novel concept but have been used to a considerable degree for some time. Our retroactive revocation proposals in this year's rule are consistent with current practice.

Second, we explained to commenters in last year's CY 2026 HH PPS final rule that retroactive revocations are intended to recoup payments to which the provider is not entitled due to its non-compliance. Generally, once the provider is non-adherent to Medicare enrollment requirements, it cannot receive payment for services furnished beginning on or after the point the non-compliance began. We especially emphasized in that rule that: (1) our allowance of prospective dates for certain revocation grounds has resulted in hundreds of millions of dollars in payments to non-compliant providers; and (2) we have an obligation to the American taxpayers to halt this.[20] We maintain this position in the present final rule; taxpayer monies must be protected against improper payments.

Third, retroactive liability under § 424.535(g) does not occur without a revocation. This may seem obvious, but it is critical for stakeholders to understand that revocations are actually quite rare when weighed against the universe of well over 2 million Medicare providers and suppliers. In fact, only about 3 percent of providers are ever revoked. It is never a step we wish to take -- partly because, like the commenters, we fully recognize its consequences and the potential retroactive financial liability – and in many cases we instead apply more modest actions such as deactivations under § 424.540 and stays of enrollment under § 424.541; indeed, we

[20] Ibid.

promulgated the latter action in the CY 2024 Physician Fee Schedule final rule (88 FR 78818)[21] to give us greater flexibility to address certain instances of comparatively minor non-compliance without having to pursue revocation.

In sum, despite our recognition of the commenters' concerns, we are unable to make payment to providers that are not compliant with Medicare enrollment requirements. This is consistent with the requirements of §§ 424.500 and 424.505 and underlies the need for our proposed expansion of retroactive revocation grounds. Yet because we recognize the consequences of a retroactive revocation, we seek to assure providers that revocations are not only infrequent but also are only imposed when genuinely warranted. This will not change under revised § 424.535(g).

Comment: Several commenters stated that retroactive revocations can impair or interrupt beneficiary access to care.

Response: Our expansion of retroactive revocation grounds in past years has not, to our knowledge, resulted in the material prevention or disruption of beneficiary care. Thus, we have no reason to believe said hindrances will occur with our revisions to § 424.535(g); this is especially true given, again, the infrequency of revocations. Nonetheless, we will, as we always have, remain watchful for any access to care issues.

Comment: Numerous commenters expressed concern that CMS' proposal would, in essence, unfairly convert technical or minor provider errors into a finding that every covered service during the period in question is unpayable. They stated that such deficiencies should not trigger a retroactive revocation, the current prospective dates for these reasons should remain (for example, reporting a change of information), and retroactive revocations should be reserved for serious misconduct, such as, but not limited to: (1) criminal activity; (2) intentional or systemic provider fraud, waste, or abuse; (3) material non-compliance; or (4) patient harm.

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[21] "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program".

Response: While we appreciate these comments, they appear to presume that every minor error does or will automatically result in a revocation. This has never been the case. As explained earlier, we frequently use other actions (for example, stays) to address such situations. On the other hand, we reiterate that non-compliance with enrollment requirements – even if the provider believes it is a mere technical or inconsequential violation – should result in non-payment. The current prospective effective date in § 424.535(g) for certain revocations is directly antithetical to this, which is why: (1) a retroactive date is needed if we believe the non-compliance warrants a revocation; and (2) we cannot restrict retroactive revocations to matters such as criminal or fraudulent behavior or beneficiary harm. Non-compliance at any level and to any degree remains non-compliance.

Comment: A few commenters stated that CMS' retroactive revocation proposals lack clear, explicit congressional authorization and fail the independent statutory interpretation standard.

Response: We respectfully disagree. We previously stated that sections 1102 and 1871 of the Act give the Secretary discretion to promulgate regulations that are necessary for the efficient administration of the Medicare program; section 1866(j), meanwhile, states in paragraph (1) that the Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title. In our view, establishing revocation effective dates and ensuring that Medicare payments are made correctly and only to compliant providers and suppliers – which is the central purpose of retroactive revocations – clearly falls within the scopes of sections 1102, 1871, and 1866(j) of the Act. Hence, we believe – as we have with our prior regulatory expansions of retroactive revocations -- that sections 1102, 1871, and 1866(j) of the Act furnish sufficient authority for our § 424.535(g) proposal.

Comment: Several commenters stated that CMS' proposed expansion of § 424.535(g) is inconsistent with certain aspects of section 1866(b)(2) of the Act. Under section 1866(b)(2)(i) and (ii), CMS may refuse to enter into a provider agreement or -- upon such reasonable notice to

the provider and the public -- may refuse to renew or may terminate such an agreement if CMS determines that the provider fails to: (1) comply substantially with the provisions of the agreement, with the provisions of Title XVIII and regulations thereunder, or with a corrective action required under section 1886(f)(2)(B); or (2) substantially meet the applicable provisions of section 1861 of the Act. The commenters appeared to contend that a provider that is retroactively revoked has not been given "reasonable notice" of its non-compliance because, in effect, the provider: (1) might not have realized it is non-compliant; (2) had thus been furnishing legitimate services in good-faith; (3) only belatedly learned of its non-adherence; and (4) is now responsible for repaying Medicare. Accordingly, they concluded that the revocation's retroactive nature violates section 1866(b)(2) of the Act. Another contention seemingly was that so long as the provider "substantially" (as that term is used in section 1866(b)(2) of the Act) complies with enrollment requirements, a retroactive revocation is impermissible.

Other commenters stated that section 1866(b)(2) would be violated if CMS applied one of its proposed retroactive revocation grounds to a time period prior to January 1, 2027. This is because, the commenters contended, the section 1866(b)(2) of the Act requirement of "reasonable notice" to the provider will not have been met – particularly if the revocation effective date goes back several years.

Response: Provider enrollment and provider agreements are different concepts operating under different authorities and requirements. In general, Medicare provider enrollment is the process by which providers and suppliers seek to obtain and maintain Medicare billing privileges; it is largely governed by section 1866(j) of the Act and 42 CFR 424.500 through 424.575. A provider agreement, as defined in 42 CFR 489.3, is an agreement between CMS and a provider identified in § 489.2(b) to furnish services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act. Subparts A and B of part 489 address provider agreements. The provisions and parameters of section 1866(b)(2) of the Act, in short, do not apply to provider enrollment, and we emphasize that complete compliance with enrollment

provisions – rather than merely "substantial" compliance – is required to obtain and maintain billing privileges.

Comment: Several commenters stated that retroactive revocations under § 424.535(a)(8)(ii) and any associated recoupment could violate section 1879(a)(2) of the Act whereby, the commenters contended, a provider need not reimburse any overpayment if it "did not know, and could not reasonably have been expected to know, that payment would not be made."

Response: We respectfully disagree with this comment. Section 1879(a)(2) of the Act is only one of two requirements needed for section 1879(a) of the Act to apply. The other, section 1879(a)(1) of the Act, requires a CMS determination that – based on section 1862(a)(1) or (9) of the Act or by reason of a coverage denial described in section 1862(g) of the Act – Part A or Part B payment may not be made for any expenses incurred for items or services furnished by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(ii) of the Act. Section 1879(a)(1) of the Act does not apply to retroactive revocations because, among other things, the specific denial reasons listed in that section are not applicable to the overpayment determination.

Comment: A commenter stated that retroactive revocations could disincentivize providers from self-disclosure and prompt remediation of non-compliance out of concern that CMS will revoke the provider based on said non-adherence.

Response: We respectfully disagree. We saw no evidence of this following previous expansions of retroactive revocation grounds. In fact, we believe it will encourage providers to be more vigilant in their reporting responsibilities.

Comment: A few commenters maintained that our retroactive revocation provisions would violate section 1866(b)(3) of the Act. Section 1866(b)(3) of the Act states that the effective date of a termination or refusal to renew a provider agreement shall become effective on the same date and in the same manner as an exclusion from participation under section

1128(c) of the Act. Section 1128(c)(1) of the Act conditions such an exclusion on "reasonable notice," and section 1128(c)(2)(A) of the Act limits this exclusion to services furnished to an individual on or after the effective date. Moreover, section 1128(c)(2)(B)(ii) of the Act provides that -- absent a health and safety determination -- an exclusion does not apply to payment for home health services and hospice care furnished to an individual under a plan of care established before the date of the exclusion. It follows, the commenters concluded, that: (1) under these statutes, a provider must first receive adequate notice prior to the effective date of any such termination action, including revocation; and (2) proposed § 424.535(g) would violate this requirement because the termination effective date would precede notice and apply retroactively to services already provided.

Response: We respectfully disagree with these contentions for two reasons. First, section 1866(b)(3) of the Act, like section 1866(b)(2) of the Act, is inapplicable to provider enrollment. As discussed earlier, provider enrollment and provider agreements are different concepts operating under different authorities and requirements, and termination of a provider agreement is distinct from a denial or revocation of enrollment in Medicare. Second, section 1128(c) does not apply to Medicare denials and revocations but only to OIG exclusions. Consequently, these retroactive revocation provisions do not violate section 1866(b)(3) of the Act.

Comment: Commenters recommended that in its retroactive revocation determinations, CMS should consider whether: (1) the provider reasonably believed it was compliant with enrollment requirements when it provided the services; and (2) the services were medically necessary, documented, and otherwise covered (including whether CMS or its contractor possessed the relevant information while continuing to process claims).

Response: We appreciate these suggestions but decline to commit to them. As we stated in the CY 2026 HH PPS final rule and have noted in other provider enrollment rules, it is ultimately the provider's responsibility to ensure constant adherence to Medicare enrollment

requirements.[22] While we say this most respectfully, simply having a reasonable or good-faith belief that is it compliant with these requirements does not exempt the provider from the obligation to actually be compliant. Payments to a non-adherent provider are inappropriate irrespective of: (1) the provider's belief in its compliance; or (2) whether the furnished services were otherwise proper.

Comment: Several commenters stated that CMS should limit recoupment to claims causally related to the identified noncompliance. Another commenter requested that accredited Complex Rehabilitation Technology suppliers be exempt from retroactive revocation effective dates.

Response: We respectfully refer these commenters to our previous response. The issue is the submission of claims for services furnished while the provider is non-compliant, irrespective of whether the claim is related to the non-compliance or to the type of provider or supplier involved; it is partly for this latter reason that we cannot exempt certain provider or supplier types from retroactive revocation application.

Comment: A commenter supported our retroactive revocation proposals. The commenter stated that prospective revocations create a window during which noncompliant providers can continue billing Medicare after the basis for revocation has been identified; retroactive revocations close this gap. The commenter also recommended that CMS supplement this provision with standardized documentation requirements that establish what evidence must be collected and maintained before a retroactive revocation decision is made.

Response: We appreciate the commenter's support and entirely concur with the concerns expressed about prospective revocation effective dates. However, we respectfully decline the commenter's documentation recommendation because we must retain the operational flexibility

[22] "Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies".

to address all types of potential retroactive revocations; given the very different facts of each case, a fixed, required form of documentation might not fit all scenarios.

Comment: A few commenters stated that providers should not be retroactively revoked based on requirements that were ambiguous, newly articulated, or not reasonably understood at the time services were furnished. They stated that before enforcing any expanded retroactive revocation authority, CMS should, among other things: (1) issue detailed guidance and practical examples; and (2) furnish education to providers and the MACs.

Response: We are respectfully uncertain as to which specific requirements the commenters believe are unclear or the matters on which the commenters seek guidance. We note that CMS cannot automatically exempt providers from retroactive revocations simply because the provider states that it did not understand certain requirements. If we granted such exceptions in all cases, each potentially revoked provider might claim said misunderstanding to avoid revocation. It is also each provider's responsibility to ensure that it comprehends all requirements. That said, and as later discussed, we expect– to the extent needed – to issue additional guidance regarding our new provisions following the publication of this final rule.

Comment: Numerous commenters stated that CMS should: (1) furnish a reasonable opportunity to cure technical deficiencies before CMS retroactively revokes a provider and begins recoupment; and (2) ensure that the consequence is proportionate to the conduct.

Response: Regarding cure opportunities, we respectfully refer the commenters to our earlier statements – both in the CY 2026 HH PPS final rule and the present rule – about informal pre-revocation appeals processes and our inability to make payment for services furnished while the provider is non-compliant, even if the issue is later corrected. As for the second comment, we reiterate that we: (1) often apply more modest actions (for instance, deactivations and stays) to help ensure proportionality; and (2) only undertake revocation when genuinely justified.

Comment: Numerous commenters stated that CMS should not commence retroactive revocation recoupment until after provider has exhausted its appeal rights or otherwise has had

an opportunity for administrative review. Some commenters also questioned whether recouped payments would be returned to the provider if the revocation is reversed on appeal.

Response: We thank the commenters for their feedback and note that we addressed these same issues in the CY 2026 HH PPS final rule. In response to comments, we stated that we historically have not delayed implementing retroactive revocations or commencing collections while appeals are pending.[23] We explained that because the appeals process can take some time, delayed revocation and recoupment implementation could result in many millions of dollars in continued payments to non-compliant providers as well as postponed repayment of monies to which Medicare and the taxpayers are entitled.[24] We stressed, though, that if the revocation is reversed is appeal, repayment of any collected monies to the provider can be facilitated.[25] These remain our stances with respect to our § 424.535(g) proposal in the current final rule.

Comment: A commenter stated that CMS should not have a retroactive effective date for § 424.535(a)(17) until it clarifies: (1) the circumstances under which a provider is treated as having failed to repay a debt referred to the Department of the Treasury; (2) the period a provider has before that determination is made; and (3) the number of contacts CMS will attempt beforehand.

Response: We refer the commenter to CMS Publication 100-06 (Financial Management Manual), Chapter 4 for information on these three issues.[26]

Comment: Commenters stated that retroactive revocations should require an individualized CMS determination of the provider's relative risk or non-compliance.

Response: With each potential revocation, CMS carefully reviews the facts and circumstances of the case. We view this as an individualized finding regarding the provider's conduct.

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[23] Ibid.
[24] Ibid.
[25] Ibid.
[26] https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019018.

Comment: Several commenters recommended a maximum lookback period for retroactive recoupment, with a few commenters suggesting 3 years.

Response: We respectfully disagree. When a provider furnishes services while non-compliant, it is largely immaterial whether, for instance, the service was provided two weeks before the provider received the revocation letter, one year prior, or even three years prior. Payments cannot be made to non-adherent providers.

Comment: Commenters stated that all retroactive revocation notices to providers should explain: (1) the factual and legal basis for – and identify the evidence behind -- any retroactive effective date; (2) the available rebuttal, corrective-action, and appeal options; (3) why the provider was noncompliant as of that date; (4) why retroactivity, rather than prospective revocation or a corrective action, is warranted; and (5) the timeframe for (and details of) recoupment.

Response: We appreciate these comments. CMS does not make a separate, individualized determination as to whether a revocation should or should not be retroactive. Retroactivity or prospectivity is determined by the applicable regulatory provision. For example, existing § 424.535(g)(2)(xii) requires that a revocation based on a State's suspension of a physician's prescribing ability be retroactive to the date of the suspension; the date cannot be made prospective. However, each revocation letter always identifies: (1) the factual and legal basis for the revocation; (2) the effective date as specified in § 424.535(g); and (3) appeal rights and procedures. We also separately notify providers of the recoupment process and its timing. Such will remain so under revised § 424.535(g).

Comment: A commenter requested that CMS not apply retroactive revocation effective dates to: (1) reporting-only State deficiencies absent intentional concealment; or (2) condition- or standard-level findings that the provider corrects through an accepted plan of correction.

Response: We believe the commenter is referencing State survey findings and deficiencies. There is no existing ground in § 424.535(a) (nor did we propose one in this rule)

under which CMS takes revocation action based solely and exclusively on such findings or deficiencies.

Comment: Commenters recommended that CMS define and provide examples and objective standards of "non-compliance" in this rule for cases where the revocation effective date is the date of non-compliance; several commenters requested the same for retroactive effective dates such as, but not limited to, "the date a Medicare enrollment requirement was no longer met" and the last date of improper billing. Second, commenters requested that CMS document (and provide evidence for) the factual basis for any CMS conclusion that the provider was noncompliant as of a particular date.

Response: Given the very large number of factual scenarios that can involve non-compliance, no longer meeting Medicare requirements, etc., and our need to have the flexibility to address them all based on their individual circumstances, we are unable to accommodate the commenters' first request.

We note that we currently have various revocation grounds and effective dates in § 424.535 based on non-compliance. The concept is not new. When revoking on this basis (such as non-compliance with a DMEPOS supplier standard under § 424.57(c)), we explain the reason for the action and how we determined the effective date. This will continue under revised § 424.535(g).

Comment: Several commenters stated that a retroactive revocation effective date based on the date that CMS determines that the provider should be revoked is overly vague.

Response: We respectfully disagree. To the contrary, we believe that the date on which CMS decides that the provider should be revoked is the clearest, most definitive date we can utilize given, as explained, the challenge of establishing precisely when the event generating the revocation occurred.

Comment: A commenter expressed concern about retroactive effective dates for § 424.535(a)(22) revocations. Since a State's investigation of patient harm could take

considerable time, the commenter stated that the physician or practitioner – though furnishing legitimate services while licensed and reasonably believing that no adverse State finding would occur – may ultimately be responsible for substantial overpayments. The commenter added that the physician or practitioner, concerned about retroactive liability, might even cease treating patients pending the State's decision.

Response: We appreciate the commenter's concerns. However, patient harm is a serious matter that we believe warrants an effective date that coincides with the date of the prior action from the State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program.

While the issue of whether a physician or practitioner may continue treating patients pending a State investigation for patient harm is outside the scope of this final rule, we again do not anticipate an impact on access to care; this is based on what we have seen after previous establishments of new retroactive revocation grounds.

After reviewing the comments received, we are finalizing our proposed revisions to § 424.535(g) without modification.

(5) Claim Submissions After Revocation (§ 424.535(h))

Under § 424.535(h)(1)(i) (and excluding HHAs), a revoked provider must -- within 60 calendar days after the revocation's effective date -- submit all claims for items and services furnished before the date of the revocation letter. For revoked HHAs, § 424.535(h)(1)(ii) states that claims must be submitted within 60 days after the later of the following: (1) the revocation effective date; and (2) the date that the HHA's last payable episode ends.

Prior to 2009, the post-revocation claim submittal period was up to 27 months. It was changed to 60 days for certain provider and supplier types in the CY 2009 Physician Fee Schedule final rule (73 FR 69726).[27] It was later made applicable to all provider and supplier

[27] "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E-Prescribing Exemption for Computer-Generated Facsimile Transmissions; and Payment for Certain Durable

types in a December 5, 2014, final rule (79 FR 72500).[28] In both rules, we explained that the reduction to 60 days was necessary because the prior 27-month period posed significant risk to the Medicare program; it gave problematic providers over 2 years to potentially continue their conduct via the submission of inappropriate claims.

Although the current 60-day period is far less than the prior 27-month timeframe, we have long remained concerned about possible fraudulent, improper, or other non-compliant activity by revoked providers. If a provider engaged in such conduct before the revocation, it may continue it afterwards – and 2 months is still an extensive timeframe in which to do so. Indeed, a revoked provider could submit hundreds of improper claims for hundreds of thousands of dollars during this period. If other providers did the same after their revocations, many millions of Trust Fund dollars would be threatened. With the need to protect taxpayer monies from such parties, we believe that further reducing the submission timeframe could correspondingly lessen the program integrity risk, for providers would have less time to engage in inappropriate billing. For these reasons, we proposed to change the 60-day timeframe referenced in § 424.535(h) to 15 days. While we recognized in the proposed rule that this would be a substantial time reduction, we believed the risk warrants it.

We proposed an additional change to § 424.535(h). We previously explained our proposal to make the remainder of our prospective revocation reasons retrospective. Under existing § 424.535(h), though, if a provider had 60 days from the revocation effective date to submit its claims but the effective date was more than 60 days retroactive, the submission period might well have expired before the provider even received the revocation letter. To ensure that the provider actually has an opportunity to submit its claims, we proposed to change:

Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)", published in the Federal Register on November 19, 2008.

[28] "Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment".

- Section 424.535(h)(1)(i) to state that a revoked provider must -- within 15 calendar days of the date of the revocation letter -- submit all claims for items and services furnished before the revocation effective date.

- Section 424.535(h)(1)(ii) to state that a revoked HHA must - within 15 calendar days of the date of the revocation letter - submit all claims for items and services furnished before the later of the following:

(We did not propose to change §§ 424.535(h)(1)(i)(A) and (B) or (h)(2) (which references the timely filing requirements of § 424.44).)

The following is a summary of the comments we received on this proposal and our responses.

Comment: Numerous commenters opposed the reduction to 15 days, citing two principal concerns. First, larger and moderate-sized providers would need more than 15 days to submit all outstanding claims given the amount of time it would take to identify and prepare potentially many claims. Second, certain provider types are subject to monthly billing cycles, notices of admission, minimum data sets (MDS), and other provider-specific requirements that would make it very difficult (if not impossible) to submit within 15 days all claims for all the services they furnished before the revocation effective date. They stated that CMS should retain the 60-day period or at least give providers and suppliers 30 days or 45 days with extensions for good cause or other special circumstances. Examples of the latter could include (but not be limited to): (1) when billing data cannot be completed and accepted by CMS systems within the filing window; and (2) claims cannot be finalized for periods of care already in progress. A few commenters suggested that if CMS wants to use a 15-day period, it should be 15 business days instead of calendar days.

Response: While we appreciate and understand these concerns, we believe that the seriousness of a revocation – and the program integrity risks that revoked providers pose – require a submission period of much less than 60 days. The risk of continued inappropriate

conduct for a 2-month period and the potential loss of many thousands of taxpayer dollars is simply too great to permit a timeframe greater than 15 days, which is why we are also unable to grant the commenters' requested extensions and a change to business days.

Comment: Commenters stated that the 60-day period should be retained for: (1) certain provider types (such as SNFs and HHAs) based on their billing cycles; or (2) providers not revoked for fraud, beneficiary harm, intentional misrepresentation, billing for services not rendered, or similar conduct.

Response: Excluding § 424.535(h)'s longstanding provision regarding HHAs' last payable episodes (previously noted), we do not believe that certain providers --- either by type or based on the revocation reason – should be exempt from the "15-day after the revocation letter date" requirement. This is because any revocation of any provider presents a heightened program integrity risk[29] – and with it, the potential for improper post-revocation claims to be submitted, even if fraud, patient harm, etc., did not trigger the revocation.

Comment: Several commenters stated that CMS should toll any post-revocation claims submission deadline: (1) pending completion of the revocation appeals process; and (2) for system outages and disasters.

Response: We respectfully disagree. This could result in a delay of many months – far beyond 15 and even 60 days -- due to the stoppage of the submission period clock; it would give revoked providers much more opportunity to potentially submit inappropriate claims. This would be contrary to our need to protect the American taxpayers and the Medicare program at large against improper activity.

Comment: Several commenters stated that the 15-day period should begin when the revocation notice is received rather than on the date of the notice.

[29] To illustrate this risk, revoked providers – irrespective of their type or the conduct underlying the revocation -- are subject to: (1) a minimum 1-year minimum reenrollment bar; and (2) the strictest level of enrollment screening under § 424.518 should they seek to reenroll once their bar expires.

Response: We respectfully disagree. Using the date of the notice adds far more certainty to when the timeframe actually began than the receipt date; the latter can depend on a variety of factors and be subject to different interpretations. (For this same reason, the 15-day timeframe for submitting stay of enrollment and deactivation rebuttals under §§ 424.541 and 424.546, respectively, is based on the notification letter date, not the receipt date.)

Comment: Multiple commenters questioned whether a provider may resubmit pre-revocation claims without being impacted by the reduced filing period if the revocation is reversed on appeal.

Response: Although it was unclear to us, it appeared the commenters were asking whether any 15-day deadline applies for the resubmission of any pre-revocation claims after a reversal occurs. If so, the answer is no.

Comment: A commenter requested that CMS: (1) explain how rejected claims submitted within § 424.535(h)'s timeframe are treated and whether providers can resubmit those claims; and (2) establish a minimum claims submission period rather than permit retroactive revocations.

Response: Regarding the second comment, merely adjusting the claim submission period in lieu of retroactive revocation would fail to address the aforementioned need to recoup payments that were made to non-compliant providers. For the first, rejected claims would be handled in the same manner they are under existing § 424.535(h).

Comment: Several commenters requested that CMS explain how the 15-day period would apply to SNFs, HHAs, and other provider types with specific billing requirements such as minimum data sets and monthly billing.

Response: We will, as appropriate, issue guidance on this matter.

Comment: A few commenters expressed concern that the provider may not receive the revocation letter, in which case the 15-day period might expire before the provider learns of the revocation.

Response: While we appreciate this concern, CMS and the MACs strive to take appropriate steps for affected providers to receive revocation letters timely.

Comment: A commenter expressed support for our proposed change to § 424.535(h).

Response: We appreciate the commenter's support.

After considering the comments received, we are finalizing our revisions to § 424.535(h) without modification.

(6) New Revocation Reasons

We also proposed to add several new grounds for revocation in § 424.535(a).

(a) High-Risk Enrollments (§ 424.535(a)(24))

As explained in the proposed rule, we have seen an alarming increase in situations where an unusually and disproportionately large number of providers and suppliers – sometimes of the same type – are simultaneously operating within a very small geographic area (for instance, a multi-block sector), the same complex or building, or even the same suite. Examples include: (1) several dozen hospices within a four-block area of Los Angeles County; (2) 18 HHAs within the same building in Columbus, Ohio; (3) at least nine cases in Ohio where at least five HHAs have the same practice location address, with four of these nine situations involving at least nine HHAs in one location; and (4) similar situations with several certified providers of the same type operating out of one building in Michigan, Nevada, North Carolina, and Texas. Per CMS data, the number of HHAs in Los Angeles County between 2019 and 2023 rose over 45 percent, and at least 1,400 new HHAs have enrolled in the county since 2019. There was no medical need for such an enormous rise, which was entirely out of proportion with any increase in the county's beneficiary population and can be a strong indicator of widespread fraud. Others share our

concerns about this, including the Medicare Payment Advisory Commission[30], members of Congress [31], and even several national HHA and hospice organizations.[32]

We recognize that many medical facilities, complexes, and geographic areas have large numbers of providers and suppliers located therein. To illustrate, a medical building on a hospital campus may have seven physician practices with different specialties, two laboratories, etc. Also, some areas may have several types of providers and suppliers within a particular neighborhood. The vast preponderance of these situations do not, in and of themselves, necessarily mean that fraud, waste, and abuse exists or that program integrity risks are otherwise present. Yet we believe those cases mentioned in the previous paragraph – as well as other situations – can and do. Fraud schemes can indeed involve problematic (or potentially problematic) providers operating in same general vicinity, as shown in the Los Angeles County and Columbus situations. Although having, for example, four organizational providers/suppliers of the same type (such as ambulance companies) in a seven-block area does not automatically signify fraud, waste, and abuse, it does – based on our experience -- raise questions as to whether there is a patient need for all these providers or whether other considerations, such as fraud, are involved.

With tens of millions of Medicare dollars at risk in any fraud scheme, our role in safeguarding the Trust Funds requires the ability to take revocation action – if circumstances warrant -- to address such situations. This is especially important because we currently lack authority under § 424.535(a) to revoke providers/suppliers based on program integrity threats stemming from an excessive number of enrolled providers/suppliers within a particular area. We accordingly proposed in new § 424.535(a)(24) that CMS may revoke a provider's or supplier's

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[30] https://www.medpac.gov/wp-content/uploads/2025/12/Tab-H-HHA-update-Dec-2025.pdf.
[31] Letter from United States House Representatives Brett Guthrie, John Joyce, M.D., Morgan Griffith, Jason Smith, David Schweikert, and Vern Buchanan to T. March Bell, Inspector General, HHS-OIG, January 9, 2026, https://energycommerce.house.gov/posts/chairmen-guthrie-joyce-griffith-smith-schweikert-and-buchanan-ask-hhs-oig-about-ongoing-hha-and-hospice-fraud-in-los-angeles-county-1.
[32] Letter from LeadingAge and the National Alliance for Care at Home Letter to Dr. Mehmet Oz, CMS Administrator, December 22, 2025, https://allianceforcareathome.org/wp-content/uploads/Final-Alliance-and-LeadingAge-Home-Health-and-Hospice-Program-Integrity-Recommendations.pdf.

enrollment if it deems the enrollment as presenting a high risk of fraud, waste, or abuse due to the provider's or supplier's location within a limited geographic area that has an excessive number of providers and suppliers. We noted the following regarding § 424.535(a)(24) in the proposed rule.

First, the term "high risk" for purposes of § 424.535(a)(24) does not mean the provider must be in: (1) the "high" screening level under § 424.518(c); or (2) a region that has traditionally posed a high risk of fraud, waste, and abuse, such as south Florida. To be sure, § 424.518(c) providers – as well as providers in known program integrity hotspots -- pose elevated risks, a matter we may consider in § 424.535(a)(24) determinations. Yet other provider types in other areas can present threats as well. The risk that a particular provider poses based on its proximity to other providers – somewhat more so than the provider type and historic geographic risk -- is the main consideration under proposed § 424.535(a)(24).

Second, a potential fraud scheme can involve multiple provider and supplier types; for example, several HHAs, hospices, DMEPOS suppliers, physicians, etc., might be participating in a single operation. A § 424.535(a)(24) revocation therefore would not require the provider in question and the other providers/suppliers in the area to be of the same type.

Third, the terms "limited geographic area" or "excessive number" in the context of § 424.535(a)(24) will have their ordinary, plain-language meanings. This is due to the many factual situations that could arise and our need to address them -- something that thresholds such as minimum/maximum distance or numbers of providers would obstruct. Moreover, such thresholds would alert potentially problematic providers as to how to circumvent a § 424.535(a)(24) revocation. If, to illustrate, we stated that § 424.535(a)(24) only applies if there are at least X number of providers within a radius of Y miles, providers seeking to engage in fraud might enroll immediately outside said radius and/or within an area with fewer providers. This would defeat the purpose of § 424.535(a)(24). That said, our primary focus is on providers in smaller areas – common buildings and complexes, city and town blocks, neighborhoods, etc.

Although we reserve the right to apply § 424.535(a)(24) to providers in larger areas (especially if there is an abnormally high number of providers therein), § 424.535(a)(24)'s application would typically be relatively narrow in scope.

Fourth, an actual finding of fraud, waste, or abuse by the provider or another provider in the area would not be required for a § 424.535(a)(24) revocation. This is akin to section 1866(j)(5) of the Act (codified in § 424.519), which permits denial or revocation if (1) the provider has or has had a certain type of affiliation with another provider or supplier, and (2) the affiliation poses an undue risk of fraud, waste, or abuse; no determination of actual fraud, waste, or abuse is needed. Section 424.535(a)(24) revocations would be based on the assessed risk and not whether the provider or nearby providers have actually engaged in fraudulent conduct.

Fifth, while several existing revocation reasons in § 424.535(a) require CMS to consider specified factors in its revocation decisions, we are not proposing the same for § 424.535(a)(24). Consistent with our prior discussion regarding § 424.535(a)(8)(ii), we must be able to address all potential § 424.535(a)(24) scenarios without the rigid restrictions of required criteria and based solely on the unique facts and circumstances of each case.

Sixth, some interested parties may detect certain similarities between § 424.535(a)(24) and our authority under section 1866(j)(7) of the Act (codified in § 424.570) to impose a temporary enrollment moratorium. Although we address temporary moratoria in greater detail later in section V.C.1.f.(2).(b). of this final rule, we state here that a moratorium differs from § 424.535(a)(24) in many ways. The latter, for instance: (1) is a revocation reason rather a prohibition on new enrollments; and (2) takes into account the provider's proximity to other providers of all types, not simply the number of (or risk posed by) providers of the same type.

As much as anything else, though, we emphasized that proposed § 424.535(a)(24) was not principally designed to revoke good-faith providers who otherwise present no apparent risks even though they might, for example, be in an area with numerous other providers. Providers should not at all assume they would be revoked under § 424.535(a)(24) merely because they

operate near other providers. Indeed, the overwhelming preponderance would not be. Section 424.535(a)(24) would only be applied in exceptional instances where, based on the facts and circumstances, the risk genuinely justifies it.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our proposal. They noted that providers – urban and rural, large and small -- are frequently located near other providers for reasons such as: (1) administrative and financial efficiency (for example, sharing a building to reduce costs); and (2) the facilitation of patient care as part of multi-provider, comprehensive treatment. A provider's mere presence among other providers, they contended, does not by itself indicate program integrity risk. While, in certain instances, they stated that proximity might be a basis for closer CMS review or investigation, it should never be grounds for revocation. They urged CMS to withdraw proposed § 424.535(a)(24) and instead use other means of addressing geographic concentration, such as enhanced screening and oversight.

Response: We appreciate these comments and respond as follows.

First, and as we have stated, we acknowledge that hospitals, medical complexes, office buildings, densely populated communities, etc., frequently have numerous providers and provider types operating within and around them. Many of these situations by themselves do not involve fraud, waste, or abuse, or risks thereof, and we do not believe the proposed rule stated otherwise. Our principal focus is instead on isolated cases we have seen where, for instance, there are obvious, extremely heavy, and highly aberrant clusters of providers – frequently of the same provider type – operating within a very small area similar to that we saw in our aforementioned Los Angeles and Columbus examples. Established health care systems, hospital campuses, medical complexes, etc., are not the targets of § 424.535(a)(24). We fully understand the concerns that commenters expressed about § 424.535(a)(24). We wish to again reassure providers and suppliers that, by and large, we are not seeking to target legitimate, common, and

standard concentrations of providers in places such as hospital medical centers and health system complexes that would normally have a greater number of providers and suppliers therein. It is the unusual situations that we seek to address – and even in some of these cases, revocation might not occur.

Second, and on the other hand, we disagree that concentration must never be a reason for revocation. Such a position, in our view, disregards the crucial concept of risk. While, as stated, concentration does not automatically mean that a program integrity risk exists – it very frequently will not – this does not mean that said risk can never exist. Consider the Columbus situation, where, inexplicably, there were 18 HHAs operating within one building and the program integrity risk was accordingly very high. If we took the stance that no action could be taken because concentration never means risk, we effectively must wait until we learn that fraud has actually occurred before taking measures – by which point millions of dollars in taxpayer monies may have been lost. This would reflect the pay-and-chase formula that has proven far less effective in halting fraud, waste, and abuse than the approach of stopping fraud before it begins. We believe that our duty to the American people to protect the Trust Funds and beneficiaries requires us be preventive and proactive - not reactive – in response to program integrity risks, hence the need for § 424.535(a)(24). Hence we respectfully decline to withdraw our proposal and maintain that it would be the most effective way – more so than other potential program integrity mechanisms – to address this particular vulnerability.

Comment: Commenters requested that CMS establish regulatory factors or standards that CMS must consider in determining risk and, in turn, whether to revoke a provider under § 424.535(a)(24). Criteria and parameters that commenters suggested included (but were not limited to): (1) the provider's ownership, billing patterns, adverse legal history, compliance history, history of timely responses to CMS inquiries, operational status, physical capacity, and specific conduct; (2) whether the provider furnished services inconsistent with beneficiary diagnoses; (3) the provider's relationships (if any) with other providers within the concentrated

area; (4) beneficiary complaints against the provider; (5) beneficiary demand and market access needs; (6) whether the provider engaged in patient harm; (7) numerical thresholds for a revocation to occur – such as a certain number of providers of a particular type within a regulatorily specified geographic area (for instance, within X number of square miles or neighborhood blocks; X square feet of a building or medical center size; (8) defining "limited area" and "excessive number" (potentially after consulting with the applicable State agency regarding provider need and market saturation); (9) referral sources and beneficiary overlap; and (10) the degree of concentration, including sub-factors CMS should consider in determining this. The commenters stated that having required factors will ensure objectivity and transparency and, a commenter contended, facilitate a "totality of the circumstances" approach.

Response: We appreciate these recommendations and reiterate that we will consider the facts and circumstances of every potential § 424.535(a)(24) case. This could, if warranted, include some of the data the commenters recommended. Yet as previously explained, we must have flexibility in potential denial and revocation determinations under §§ 424.530 424.535 in light of the wide range of factual situations that can and do arise. Having explicit, inflexible factors and numerical thresholds that we must consider in every case significantly hinders this ability. It can also, as already noted, alert dishonest providers as to what CMS contemplates in its denial and revocation decisions, hence enabling them to adjust their behavior to circumvent these criteria and thresholds; to illustrate, if we defined "excessive number" as meaning the particular cluster must have at least X number of providers within less than X square miles for § 424.535(a)(24) to apply, providers in a fraud scheme could position their locations so as to avoid this threshold. For all these reasons, § 424.535(a)(24) will not contain regulatorily-specified factors, parameters, or definitions.

Comment: Several commenters requested that CMS clarify a number of operational considerations regarding § 424.535(a)(24). These included, but were not limited to: (1) the data CMS will use in its determination and whether the provider may review it; (2) whether CMS'

methodology and the criteria CMS used will be made public; (3) the frequency with which CMS will re-review and, if needed, update said determination; and (4) whether a provider that is revoked under § 424.535(a)(24) based strictly on saturation may enroll in a different but non-saturated area.

Response: We will explain the basis for each revocation in our revocation letter to the provider. However, consistent with our decades-long revocation processes, we do not plan to disclose to the public the specific facts, data, and methodology used in each case. Furthermore, except as specified in the appeal process described in 42 CFR part 498, CMS also will not re-review § 424.535(a)(24) revocations. As for the fourth issue, we respectfully cannot pre-determine a particular situation based on hypothetical facts.

Comment: Commenters stated that § 424.535(a)(24) raises due process concerns because an otherwise compliant and legitimate provider could be revoked simply because of its location. They stated that in any § 424.535(a)(24) case, CMS should: (1) require clear evidence and an individualized finding of the provider's specific conduct (rather than mere location within a certain area), with several commenters requesting a formal finding of fraud, waste, or abuse; and (2) allow the provider to challenge and submit evidence to rebut CMS' decision – and to cure any deficiencies -- before the revocation occurs.

We appreciate these comments, understand the concerns expressed, and state as follows.

First, we respectfully disagree with the apparent assertion that a § 424.535(a)(24) revocation is based entirely on the provider's location per se. The basis, rather, is the fraud, waste, and abuse risk the enrollment poses within the context of the area in question. Explained otherwise, risk, not location, is the central issue. This distinction is important. For purposes of § 424.535(a)(24), a provider and its physical location -- standing alone -- typically do not raise concerns. When viewed in conjunction with other providers' nearby locations, though, a program integrity risk can arise, and this risk is what triggers the revocation. As noted, this situation is not considerably different from that addressed in section 1866(j)(5) of the Act and

§ 424.519, whereby denial or revocation can occur if the provider has or has had a certain type of affiliation that poses an undue risk of fraud, waste, or abuse. In both cases, the provider in question need not have engaged in fraud, waste, abuse, or other misconduct. The focus instead is the risk that either the affiliation or, with § 424.535(a)(24), the enrollment (based on proximity and concentration) poses. Likewise, we disagree that an actual fraud, waste, or abuse finding should be required since this would involve reverting to a "pay-and-chase" formula. We must take measures when risk arises instead of only doing so after the improper conduct occurs.

Second, in considering the facts and circumstances in a § 424.535(a)(24) situation, the provider's conduct may, if CMS deems it warranted, be a consideration in its decision. Yet because the issue is risk and because we are not establishing mandatory factors, we respectfully decline to require an assessment or individualized finding of the provider's behavior. Our finding will involve determining the risk described in § 424.535(a)(24).

Third, we are unable to establish the requested pre-revocation appeals process or cure opportunity for reasons previously stated. We believe that our current appeals process under 42 CFR part 489 affords providers adequate due process for revocations and denials.

Comment: Several commenters maintained that in any § 424.535(a)(24) revocation, CMS should: (1) furnish specific written findings (including, for example, (i) methodology, (ii) the legal basis for the action, (iii) the reasons why CMS believes a high risk exists, and (iv) the time period, comparator group, provider density, claims, locations, individuals, ownership relationships, etc. on which CMS relies); (2) give the provider access to the supporting evidence; (3) grant expedited review if the action threatens beneficiary access; (4) ensure that any review is performed by a CMS official who did not make the original decision; (5) stay any revocation and recoupment during a timely administrative appeal; and (6) explain, if applicable, the recoupment and repayment period and schedule.

Response: CMS in every revocation sends a letter to the provider explaining, among other things, the basis for revocation (including the legal basis) and the provider's appeal rights;

the latter includes a statement that the appeals/reconsideration review is performed by a CMS official who did not make the original decision. We also separately inform providers of the process and timing of recoupment.

We previously explained why we do not postpone revocations or recoupment pending the completion of appeals. In addition, the appeals process in 42 CFR Part 498 does not provide for expedited provider enrollment appeals for certain types of providers or situations. To do so, we believe, would be unfair to those without expedited appeal rights. All providers and suppliers are, and should be, subject to the same appeals procedures and timeframes.

Comment: Commenters recommended that CMS establish a safe harbor or rebuttable presumption of "no high risk" under § 424.535(a)(24) for legitimate providers that, for example, maintain bona fide locations, appropriate personnel, no problematic ownership relationships, etc. Some commenters went further and stated that providers with a passed site visit, an active State license and accreditation, and no adverse history should be explicitly excluded from (a)(24)'s purview. Other commenters urged CMS to explicitly state in the rule (including in the regulatory text) that: (1) provider concentration can be an investigative factor but cannot alone be grounds for revocation; and (2) § 424.535(a)(24) requires documented and individualized evidence that the provider presents a material and specific risk of fraud, waste, abuse, or beneficiary harm.

Response: We thank the commenters for these recommendations but must respectfully decline them. Formally establishing the requested presumption in the rule would hamstring our efforts to address the Los Angeles and Columbus-type situations heretofore mentioned. We would be stating at the outset of any potential § 424.535(a)(24) situation that the provider very likely presents no risk if the criteria the commenters reference (for example, operational locations) are met. We cannot make such pre-judgments before the facts and circumstances are reviewed, and we again remind commenters that the central question is not the risk the individual provider actually presents but the risk posed by the scenario in § 424.535(a)(24). Merely because we earlier recognized that provider proximity often does not present material program

integrity concerns does not mean we must or should create an official presumption in this rule that this is so. Furthermore, we have seen instances where a licensed or accredited provider's location, ownership, management, services, background, etc., appeared legitimate, but the provider later engaged in fraud, waste, or abuse as part of a larger scheme. In brief, we are unable to establish formal carve-outs or suppositions with respect to § 424.535(a)(24) since every situation will be different and will require an objective analysis of the facts and circumstances without preexisting assumptions.

Concerning the last comment regarding individualized findings, we refer the commenters to our earlier statements on this topic.

Comment: Several commenters believed that CMS' reference in the proposed rule to section 1866(j)(5) of the Act when explaining proposed § 424.535(a)(24) is erroneous. They contended that: (1) under section 1866(j)(5) of the act, the provider has an affiliation with an entity that had previously been suspended or excluded, whereas § 424.535(a)(24) permits revocation absent an affiliation or a prior adverse finding; and (2) neither section 1866(j)(5) nor any other statute allows the action that § 424.535(a)(24) contemplates.

Response: We stated in the proposed rule that a § 424.535(a)(24) situation "is not considerably different from" that addressed in section 1866(j)(5) of the Act and § 424.519. This is correct, for in both cases, the provider in question need not have engaged in fraud, waste, abuse, or other misconduct. The focus instead is the risk that either the affiliation or, with § 424.535(a)(24), the enrollment (based on proximity and concentration) poses."[33] The quoted statement merely aimed to show that § 424.535(a)(24)'s concept of revocation based on risk is not new. Respectfully, it neither stated nor implied that we were relying upon section 1866(j)(5) as authority for § 424.535(a)(24); the relevant authorities for this provision are sections 1102, 1871, and 1866(j) of the Act.

[33] 91 FR 41216.

Comment: Several commenters stated that § 424.535(a)(24) could: (1) restrict beneficiaries' access to care and limit their choice of providers; (2) discourage providers from locating in certain areas or associating with other providers; and (3) make it more difficult for smaller, independent providers to compete with larger health care organizations that have greater resources, thus leading the former to be acquired by the latter.

Response: We respectfully disagree with these contentions. We reiterate that we always carefully examine the facts of the case before undertaking revocation action, and that § 424.535(a)(24) revocations would largely be limited to exceptional situations. Accordingly, we do not believe patient care or choice will be impacted. Second, we have over the years increased the number and scopes of our revocation reasons; this included expanding the types of provider relationships and affiliations that could result in revocations. To our knowledge, none of these regulatory revisions led to the second and third events the commenters cited, and there is no evidence to suggest they will with respect to § 424.535(a)(24).

Comment: A few commenters questioned how § 424.535(a)(24) would apply to fixed-site institutional providers, with other commenters requesting that they be formally exempted from § 424.535(a)(24).

Response: The provision will apply to all providers in the same manner irrespective of provider size and type, and for reasons already noted we cannot establish carve-outs or exceptions to § 424.535(a)(24).

Comment: Some commenters contended that § 424.535(a)(24) inappropriately amounts to: (1) a certificate of need program (whereby, within some States and territories, certain new or expanding providers must demonstrate a need for their services); (2) a § 424.570-type temporary moratorium on the enrollment of specific new provider types within a particular area; and (3) a CMS-enforced limit on the number of providers an area may have, with revocations of all providers that exceed that threshold.

Response: We respectfully disagree. Section 424.535(a)(24) does not prohibit enrollment, require a demonstration of need, or impose strict numerical limits. It is solely limited to the isolated and very individualized situations previously described involving a provider excess in a limited area leading to a high risk of fraud, waste, or abuse.

Comment: A few commenters stated that the scenario described in § 424.535(a)(24) is not among the grounds in section 1866(b)(2) of the Act for provider agreements terminations. Hence, § 424.535(a)(24) violates this statutory provision.

Response: We disagree because, as previously explained, section 1866(b)(2) of the Act pertains to provider agreements. It does not apply to provider enrollment.

After considering the comments received, we are finalizing § 424.535(a)(24) without modification.

(b) Certain Misdemeanor Convictions (§ 424.535(a)(16))

In the CY 2024 PFS proposed rule (88 FR 52262), we proposed in new §§ 424.530(a)(16) and 424.535(a)(16) to deny or revoke enrollment if the provider -- or any owner, managing employee or organization, officer, or director thereof – was convicted of a Federal or State misdemeanor within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. We stated that offenses would include (but not be limited in scope or severity) to the following:

- Fraud or other criminal misconduct involving the provider's participation in a Federal or State health care program or the delivery of services or items thereunder.
- Assault, battery, neglect, or abuse of a patient (including sexual offenses).
- Any other misdemeanor that places the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.[34]

[34] "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare

We outlined in that CY 2024 proposed rule our increasing concern about providers convicted of misdemeanors for conduct that could endanger the Trust Funds and beneficiaries. We stated that our oversight of the Medicare program requires that we be able to take protective action in such instances.

We also noted that while some States may designate a particular crime as a misdemeanor while others deem it a felony, this does not lessen the risk that the former can pose to Medicare and its beneficiaries.[35] It is the conduct itself, not its classification under State law, that concerns us. This is particularly true since restricting our revocation authority for criminal convictions to felonies could leave us unable to address situations where a felony charge results in a misdemeanor plea.

We did not finalize this proposal in the CY 2024 PFS final rule (88 FR 78818).[36] However, we emphasized in that final rule that: (1) we would continue to monitor cases of misdemeanor convictions involving significant misconduct; (2) we might pursue future rulemaking to address them; and (3) many misdemeanors -- especially those involving assault, battery, neglect, or abuse of a patient (including sexual offenses) -- can involve disturbing activity.[37]

As explained in the CY 2027 HH PPS proposed rule, two particularly disconcerting categories of misdemeanor convictions we have recently seen involve sexual assault and financial misconduct. The former can endanger Medicare beneficiaries while the latter can threaten the Trust Funds – both of which we must safeguard. In line with our aforementioned willingness to pursue future rulemaking if warranted, we proposed in § 424.535(a)(16) (currently designated as "Reserved") to revoke enrollment if the provider or supplier -- or any owner,

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Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program", published in the **Federal Register** on August 7, 2023.

[35] Ibid.

[36] "Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program", published in the **Federal Register** on November 16, 2023.

[37] Ibid.

managing employee or organization, officer, or director thereof – was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

While parts of this proposal duplicate those in the CY 2024 proposed rule (for example, the 10-year period, the applicability to owners, directors, etc.), there is one critical difference: it is much narrower in scope. Whereas the CY 2024 proposal was rather open-ended in terms of potential misdemeanors, the present one is limited to sexual assault and financial misconduct. We believe this would reduce stakeholders' possible concerns that proposed § 424.535(a)(16) is too broad. In addition, we stress that: (1) terms such as "financial misconduct" would be based on their plain meanings; and (2) the misdemeanor convictions described in this paragraph must be detrimental to Medicare's (and Medicare beneficiaries') best interests, meaning that not every such conviction would result in revocation.

The following is a summary of the comments we received on this proposal and our responses. Some of these comments and responses also reference proposed revised § 424.530(a)(16), which would permit denial based on the same grounds identified in proposed § 424.535(a)(16). Our final decision regarding § 424.530(a)(16) will be addressed later.

Comment: Commenters requested guidance on how CMS will determine whether a misdemeanor: (1) is detrimental to the best interests of the Medicare program; and (2) constitutes "financial misconduct." The commenters also requested that CMS define this latter term (as well as "sexual assault") and outline all offenses that could fall within either category.

Response: As we do with the same "detrimental to the best interests standard" in §§ 424.530(a) and 424.535(a) for felony convictions, CMS considers the facts and circumstances of the case. Also, and as previously indicated, "financial misconduct" and "sexual assault" will have their plain meanings. Considering that the scope of offenses that fit within these two categories can vary by state, we are unable to list all of them.

Comment: Commenters requested that CMS establish regulatory factors and criteria it must consider in every potential §§ 424.530(a)(16) and 424.535(a)(16) case. Among commenters' suggested standards were: (1) whether any evidence of rehabilitation exists; (2) whether there is a connection between the provider and the behavior leading to the revocation; (3) whether a nexus exists between the criminal conviction on the one hand and either the Trust Funds or the provider's health care operations on the other; (4) how long ago the conviction occurred; (5) the nature of the offense; (6) the convicted party's current role within the organization; and (7) whether the underlying conduct leading to the misdemeanor has already been reviewed by the applicable State licensing or regulatory authority.

Response: We appreciate this request but reiterate our previously explained concerns about the restraints that factors pose. These concerns apply to §§ 424.530(a)(16) and 424.535(a)(16), too. Thus, we respectfully decline to include specific criteria in these two regulatory provisions.

Comment: Several commenters supported this proposed revocation and denial reason.

Response: We appreciate the commenters' support.

Comment: A commenter recommended that CMS confirm that the actions of an unpaid board member would not invoke §§ 424.530(a)(16) or 424.535(a)(16).

Response: Although it is somewhat unclear, we believe the commenter is referencing "directors" as that term is defined in § 424.502. A person can qualify as a director regardless of whether they are paid or unpaid. Sexual assault and financial misconduct misdemeanors by unpaid board members consequently fall within the scope of §§ 424.530(a)(16) and 424.535(a)(16).

Comment: Some commenters stated that CMS should: (1) explain how providers are expected to identify potentially qualifying convictions; (2) identify the safeguards that would apply before an individual's conduct results in the organization's revocation; (3) establish reasonable due diligence expectations, provider notification procedures, and clear responsibilities

when a potentially qualifying conviction becomes known but CMS has not yet determined whether it is detrimental to Medicare; and (4) explain what a provider must do upon discovering a potentially disqualifying misdemeanor conviction.

Response: We were unclear as to certain aspects of these comments. Based on our best reading, we address them as follows. First, this provision (like §§ 424.530(a)(3) and 424.535(a)(3)) does not require providers to review their personnel for potential convictions as part of the provider enrollment process. Whether they choose to do so is the provider's internal, independent business decision. Second, the principal safeguard is that CMS will, as always, consider the facts and circumstances of the case before taking action. (We are uncertain as to which other "safeguards" the commenters were referencing or seeking.) Third, if, as we suspect, the commenters are asking how much research they must perform regarding their employees' backgrounds, we refer them to our response to the first comment. Fourth, providers are notified by letter of any denial or revocation (regardless of the specific denial or revocation reason). Fifth, we believe the commenters are asking whether the provider must take certain action if CMS is reviewing a potential §§ 424.530(a)(16) or 424.535(a)(16) situation. If so, the answer is no – assuming the question's context is limited to the mere fact that the case is under CMS review. Sixth, CMS cannot direct providers on a particular course of action in the scenario described in the fourth comment. That, too, is an internal provider decision. We can only state that CMS would have the ability to utilize §§ 424.530(a)(16) or 424.535(a)(16) as circumstances warrant.

We wish to expound upon our responses to the first and third comments because, as discussed later, additional commenters raised similar issues concerning other provider enrollment proposals. Although the provider is not required under subpart P of part 424 to conduct these personnel reviews, this does not absolve the provider of ultimate responsibility if one of its owners, managing employees, etc., engages in conduct that could generate a revocation or denial. In addition, CMS cannot establish a "due diligence" standard that prohibits CMS from

denying or revoking the provider so long as the provider conducted a certain degree of review and did not find any prior adverse history, but CMS later found that the owner, director, etc., has such history. This has for decades been CMS' position for every denial or revocation reason that involves conduct by an owning or managing party. Applying a due diligence standard would mean that a provider could always avoid denial or revocation by simply stating that it examined the owner's or manager's background but found nothing. This would leave the Medicare program, the Trust Funds, and beneficiaries at tremendous risk; under this scenario, program integrity would be based strictly on the provider's actual or purported review of its affiliated parties rather than actual or potential threats to the program and its patients. Put otherwise, while we understand commenters' concerns about unknown adverse actions, we cannot predicate our payment safeguard efforts on the extent of providers' internal investigative activities (should they wish to perform them).

Comment: Some commenters requested that the proposed 10-year lookback period be reduced to, for example, 5 years.

Response: We believe the proposed 10-year period is appropriate. It achieves consistency the 10-year period in §§ 424.530(a)(3) or 424.535(a)(3), and convictions from as long as 10 years ago can still raise program integrity concerns.

Comment: A few commenters stated that "financial misconduct" misdemeanors should be limited to those involving the delivery of a health care item or service as described in section 1128 of the Act.

Response: We respectfully disagree. Considering our need to protect the Trust Funds against fraud, waste, and abuse, it is the conviction itself -- and the financial misconduct behind it -- that must take precedence over the precise forum in which the behavior occurred.

Comment: Several commenters questioned whether §§ 424.530(a)(16) and 424.535(a)(16) will be applied prospectively or retroactively in terms of when the conviction occurred.

Response: The interpretation of the terms "within the preceding 10 years" will generally be similar to the identical language appearing in §§ 424.530(a)(3) and 424.535(a)(3)(i). CMS, as appropriate, may issue public guidance on this issue.

Comment: A few commenters stated that CMS in proposed §§ 424.530(a)(16) and 424.535(a)(16) is effectively requiring providers to research their organizations for parties with financial misconduct and sexual assault misdemeanor convictions without providing a mechanism for providers to obtain this data.

Response: Consistent with our earlier statements -- as well as with prior rulemaking efforts where we expanded the scope of various denial and revocation reasons to include additional parties -- §§ 424.530(a)(16) and 424.535(a)(16) do not require providers to perform the research the commenters indicate.

Comment: Several commenters supported proposed §§ 424.530(a)(16) and 424.535(a)(16).

Response: We appreciate the commenters' support.

After considering the comments received, we are finalizing §§ 424.5355(a)(16) without modification.

(c) Effective Dates of New Revocation Reasons

Consistent with our proposed retroactive effective dates for all revocation reasons, we proposed the following effective dates for proposed § 424.535(a)(16) and (24). The § 424.535(a)(16) effective date would be the date of the conviction; this date would be referenced in new § 424.535(g)(1)(xvi). For § 424.535(a)(24), we proposed in new § 424.535(g)(1)(xxiv) an effective date that is the date on which CMS or its contractor determines that the provider should be revoked under § 424.535(a)(24); this is due to the difficulty in establishing a concrete date as to when the risk addressed in § 424.535(g)(1)(xxiv) commenced.

The following is a summary of the comments we received on this proposal and our

responses.

Comment: Numerous commenters opposed these proposed retroactive effective dates. They maintained that a misdemeanor conviction occurring some time ago should not require the provider to repay potentially years of Medicare payments. Regarding § 424.535(a)(24), they believed it would be unfair to recoup payments simply because the provider's location is near other providers. The commenters, in short, believed these retroactive dates could financially harm providers and cause beneficiary access issues.

Response: We appreciate this feedback. Concerning § 424.535(a)(16), the proposed effective date is the same as that for felony convictions § 424.535(a)(3). In both cases, the conviction presents a risk regardless of when it occurred. Hence, we believe it is appropriate to use the date it occurred as the revocation effective date. With respect to § 424.535(a)(24), we reiterate that: (1) as with § 424.535(a)(19), the issue is the risk presented and not the provider's location per se; and (2) § 424.535(a)(24) will only be used in exceptional situations. We add that even if the risk under § 424.535(a)(24) began years ago, the revocation effective date only goes back to the date on which CMS determines that the provider should be revoked. Given that the provider in most cases would receive the revocation letter comparatively soon after this determination is made, the recoupment period could be rather short.

Our prior responses to comments on revised § 424.535(g) also apply to those regarding §424.535(a)(16) and (a)(24).

After considering the comments received, we are finalizing §§ 424.535(g)(xvi) and (xxiv) without modification.

(7) Revised and New Denial Reasons (§ 424.530(a))

We also proposed a number of revised and new denial reasons in § 424.530(a).

(a) Changes to Existing Denial Reasons

Some of the following proposed denial reasons would be expanded to include actions by managing employees and managing organizations. We received comments from stakeholders:

(1) regarding the meaning of "managing employee" in the context of these denial reasons; and (2) expressing concern that a broad interpretation of "managing employee" could result in an increased number of denials. These comments will be addressed in our later discussion of our proposed revision to § 424.502's "managing employee" definition.

(i) Debt (§ 424.530(a)(6))

Current § 424.530(a)(6)(i) and (ii) permit denial if the enrolling provider or owner (as defined in § 424.502) thereof--

- Has an existing Medicare debt; or
- Was previously the owner of a provider that had a Medicare debt when the latter provider's enrollment was voluntarily terminated, involuntarily terminated, or revoked (and additional criteria in § 424.530(a)(6)(ii)(A) through (C) are met).

We proposed to include within the scope of § 424.530(a)(6) the provider's managing employees, managing organizations, and individuals and entities with any other form of business or financial relationship with the provider.

As noted in prior rulemaking efforts, managing employees and managing organizations (as defined in § 424.502) often have as much or more influence over a provider's day-to-day operations as an owner. Yet § 424.530(a)(6) only references the provider itself and its owners. Section 424.530(a)(6) thus cannot prevent enrollment if, for instance, a managing employee or organization of the prior provider ran its daily operations, was responsible for its accumulation of large debts, and now seeks to re-enter Medicare through their ownership of the new provider. Too, we have seen instances where parties other than owners and managing employees and organizations were involved with the former provider in some capacity. Therefore, the central issue is not the precise form or label of the relationship with the former provider – that is, whether it was ownership, financial, etc. It is instead the relationship itself and the party's effort to enroll new locations or reenter Medicare through the new provider.

We received a number of comments on our proposal.

Comment: Some commenters stated that before denying a provider under § 424.530(a)(6)(i) or (ii) based on the debt of another party (for instance, managing employee), CMS should add required factors to both paragraphs. Other commenters maintained that CMS's proposed § 424.530(a)(6) expansion could deny enrollment to providers based on financial obligations of parties that might only be minimally involved with the provider.

Response: After reviewing the comments received, we are not finalizing our proposed revisions to § 424.530(a)(6).

(ii) Payment Suspension (§ 424.530(a)(7))

Denial is permitted under § 424.530(a)(7) if the provider, or any owning or managing employee or organization of the provider, is currently under a Medicare or Medicaid payment suspension (as defined in §§ 405.370 through 405.372 or in § 455.23). We proposed to expand § 424.530(a)(7) to include individuals and entities with any other form of business or financial relationship with the provider. We explained that because a payment suspension is a serious matter, relationships other than those involving ownership and management should be considered under § 424.530(a)(7).

As with proposed § 424.530(a)(6), commenters expressed concern that the "any other form of business or financial relationship" category is unclear and potentially very wide in applicability. After reviewing these and other comments, we have decided not to finalize our proposed revisions to § 424.530(a)(7).

(iii) Program Terminations/Suspensions (§ 424.530(a)(14))

CMS may deny enrollment under current § 424.530(a)(14)(i) if--

- The provider is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other Federal health care program; or
- The provider's license is currently revoked or suspended in a State other than that in which the provider is enrolling.

We proposed two changes to § 424.530(a)(14)(i). One would include the provider's owners, managing employees, and managing organizations within its scope. This aligns with several other denial reasons – such as existing § 424.530(a)(3) and, as noted, (a)(7) – that include actions against owners and managing employees/organizations. Similar to these other denial grounds, revised § 424.530(a)(14)(i) would help prevent situations where the owning/managing party's conduct that led to the licensure action or the other program termination/suspension could be repeated with the prospective Medicare provider, especially considering the influence such parties typically have over a provider's operations. Furthermore, it could keep such parties from entering Medicare via a new provider, hoping to shield themselves from § 424.530(a)(14)(i)'s application due to the provision's current limitation to providers.

The other change would expand licenses to include those voluntarily surrendered in lieu of further disciplinary action. We have provisions in §§ 424.530 and 424.535 whose purview includes voluntary surrenders, and we believe the same approach for § 424.530(a)(14)(i) is needed because our overriding concern is the loss of the license rather than the type of loss. Voluntary surrenders in lieu of further disciplinary action, in our view, are as much a threat to the Trust Funds and beneficiaries as revocations and suspensions, since they all involve problematic conduct.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters questioned how CMS would apply § 424.530(a)(14)(i) in light of our proposed expansion of § 424.502's "managing employee" definition. They believed that a § 424.530(a)(14)(i) denial could stem from situations where: (1) the managing employee with the termination or suspension does not have close involvement with the provider's operations; and (2) there is little nexus between the managing employee's action and the provider. They stated that CMS should require a substantial connection between the provider, the managing employee,

and the employee's action. Others stated that the proposed expansion of § 424.530(a)(14)(i) is too broad and should not be finalized.

Response: As already stated, we consider the facts and circumstances of the case before denying a provider's enrollment. We note that there is no requirement that the managing employee's action be substantially connected to the provider's operations. This has long been our position for all denial and revocation grounds that can be based on an owner's or managing employee's conduct. For § 424.530(a)(14)(i) situations, the managing employee's program or license termination, suspension, or voluntary surrender alone poses considerable risk regardless of: (1) the relative degree of the person's involvement with the provider; or (2) the termination's, suspension's, or surrender's potential impact on the provider.

We also disagree that revised § 424.530(a)(14)(i) would be too broad. The addition of managing employee and organizations to its scope is consistent with other denial and revocation grounds pertaining to such parties.

Comment: Several commenters stated that providers should be able to remove a managing employee from their organization prior to any § 424.530(a)(14)(i) denial.

Response: Section 424.530(c) addresses the situation the commenters describe.

Comment: A commenter stated that because voluntary surrenders are not necessarily indicative of fraud, waste, or abuse, CMS should evaluate the circumstances and risk involving the surrender in § 424.530(a)(14)(i) determinations.

Response: CMS evaluates the facts and circumstances of the case in every potential denial or revocation situation.

Comment: A few commenters stated that if CMS revokes a provider under § 424.530(a)(14)(i) and the State reverses or overturns the Medicaid revocation, termination, or bar, CMS should reverse its § 424.530(a)(14)(i) revocation.

Response: As this comment appears to concern the general application of § 424.530(a)(14)(i) in the Medicaid context as opposed to the specifics of our proposed change, we respectfully believe it is outside the scope of this final rule.

After reviewing the comments received, we are finalizing our proposed revision to § 424.530(a)(14)(i) without modification.

(iv) False or Misleading Data (§ 424.530(a)(4))

Section 424.530(a)(4) allows denial based on the provider's/supplier's submission of false or misleading information on the enrollment application to gain enrollment in the Medicare program. We proposed to expand § 424.530(a)(4) in the same manner as with proposed § 424.535(a)(4) and for the same reasons. (The parenthetical concerning OIG referral would be retained in revised § 424.530(a)(4).)

The comments we received on this proposal were generally the same as those regarding § 424.535(a)(4), discussed previously. Our responses are likewise the same. We are accordingly finalizing proposed § 424.530(a)(4) without modification.

(b) New Denial Reasons

(i) Misdemeanor Convictions (§ 424.530(a)(16))

(A) New § 424.530(a)(16)

As previously noted, w proposed to duplicate proposed § 424.535(a)(16) in § 424.530(a)(16) (also presently designated as "Reserved") as a new denial ground. The same rationale is involved: the need to protect beneficiaries and the Trust Funds against parties convicted of sexual assault or financial misconduct misdemeanors.

The comments we received on this proposal mirrored those concerning § 424.535(a)(16), discussed earlier. Our responses are also the same. Thus, we are finalizing proposed § 424.530(a)(16) without modification.

(B) "Final Adverse Action" Definition

Section 424.502 defines "final adverse action" as any of the following: (1) Medicare revocation; (2) State health care license suspension or revocation; (3) revocation or suspension by an accreditation organization; (4) felony conviction; or (5) exclusion or debarment. Given our proposed denial and revocation reasons based on a misdemeanor conviction for sexual assault or financial misconduct, we proposed to add such misdemeanors as new paragraph (6) in the "final adverse action" definition. (As with felony convictions in paragraph (4), the 10-year period would be that preceding enrollment, revalidation, or reenrollment.)

The following is a summary of the comments we received on this proposal and our responses.

Comment: A commenter stated that CMS should delay this change (suggesting 2 years of non-enforcement) to enable providers to evaluate applicable individuals, obtain updated disclosures, and take corrective action where necessary.

Response: We respectfully are unable to delay the implementation or enforcement of this or any of our finalized provisions considering the important program safeguard issues they address.

Comment: A commenter requested that CMS explain the practical implications of our revision to the "final adverse action" definition.

Response: The principal implication is that under § 424.518(c)(3)(ii)(E), providers with a final adverse action within the past 10 years are screened at the "high" level. We believe providers with the misdemeanors in question would warrant this elevated screening.

After reviewing the comments received, we are finalizing our proposed revision to the "final adverse action" definition without modification.

(ii) Same Suite (§ 424.530(a)(19))

We proposed a new denial ground in § 424.530(a)(19) based on the provider having its practice location in the same suite or office as another provider whose Medicare enrollment has been revoked or denied. Sharing a suite or office with a provider who has been deemed non-

compliant with Medicare requirements could spur concerns about the newly enrolling provider's own willingness to retain compliance if enrolled. This is particularly true when – in situations we have seen -- several providers in the same suite engage (or seek to engage) in a fraud scheme, have their Medicare enrollments revoked or denied, and another provider aims to enroll in that same office. Considering the risks posed by the revoked or denied provider, we believe we must be able to prevent the new enrollment if circumstances justify it.

We explained in the proposed rule that § 424.530(a)(19) would differ from proposed § 424.535(a)(24). The latter is a revocation reason and not a denial ground; it is also partly based on the number of nearby providers, whereas § 424.530(a)(19) is based on shared suites and offices. Sections 424.530(a)(19) and 424.535(a)(24) therefore complement but do not duplicate each other.

We recognize that, for example, physicians that are part of a group frequently share the same suite. If 10 physicians are in the group and one (Dr. X) has their enrollment revoked, this does not automatically mean that a prospective (and Medicare enrolling) 11th group member will be denied enrollment based on Dr X's revocation. Every situation is different, and CMS will only invoke § 424.530(a)(19) when proper.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Numerous commenters opposed our proposal. They stated that space and office sharing is extremely common – especially for purposes of cost-savings and strengthening of patient care -- and not indicative of fraud, waste, or abuse. It would be improper, they added, to deny a provider on this ground, especially when the provider may have no knowledge of, connection to, or control over a neighboring provider's enrollment status.

Response: We appreciate and understand this feedback. As stated, we acknowledge that space-sharing (particularly involving physician practices) is very common and does not by itself raise serious program integrity concerns. Yet we reiterate that there have been situations where

providers in a shared office or suite have engaged – or, based on the facts and circumstances of the case, may engage in -- improper activity. The need to protect Medicare beneficiaries and the Trust Funds requires that we have the ability to address these situations. We believe that § 424.530(a)(19) could assist in this by enabling denial of an enrollment that might exacerbate the problem.

Comment: Commenters stated that CMS should establish regulatory factors, criteria, standards, and thresholds for potential § 424.530(a)(19) cases. These should include, for example, requiring: (1) a clear connection between the enrolling provider and the other provider's denied or revoked enrollment (and the conduct behind (or basis for) that other denial or revocation); (2) the enrolling provider's knowledge of the other denial or revocation; (3) common ownership, control, or coordination between the two providers; and (4) a lookback period, whereby § 424.530(a)(19) would not apply if the other provider's revocation or denial occurred more than a certain number of years ago.

Response: For reasons mentioned previously, we respectfully decline to add said criteria and thresholds to § 424.530(a)(19). As mentioned, though, CMS will only invoke § 424.530(a)(19) when warranted by the facts and circumstances of the case.

Comment: Commenters stated that instead of § 424.530(a)(19), CMS should concentrate on the individual behavior of each provider rather than tie the latter to a co-tenant's improper conduct. Additional commenters recommended that any § 424.530(a)(19) denial require a documented, individualized finding connecting the enrolling provider to fraud, waste, or abuse.

Response: While we appreciate the commenters' feedback, we have explained in this rule, the proposed rule, and prior rules that certain relationships and affiliations - whether organizational, managerial, business-based, geographic, etc. -- can present significant risks to Medicare. This by no stretch means that all (or even most) of them do, but some can in certain circumstances. If we simply disregarded all potentially problematic relationships and arrangements and only took action after an individual provider engaged in fraud or misconduct,

this would – as previously noted with respect to § 424.535(a)(24) – revert to a "pay-and-chase" model. In other words, we must: (1) proactively prevent improper activity before it happens; (2) treat the risk of misconduct as seriously as we do actual misconduct; and (3) deter possible wrongdoing involving relationships, multiple providers, and multiples parties as much as that involving a single provider. This is the basic reason for § 424.530(a)(19), § 424.535(a)(24), and certain other provisions promulgated in this and past rules. Even if the enrolling provider was not directly involved in its co-tenant's activities, we must have to ability to take action as needed to protect the Medicare program against potential threats.

Comment: Commenters stated that CMS should establish a safe harbor for providers that can demonstrate a legitimate, documented clinical or business rationale for co-location.

Response: While we appreciate this recommendation, the issue is not the need or rationale for the co-location; many such arrangements are for entirely legitimate purposes. Rather, it is the risk associated with the co-location due to the other provider's denial or revocation, which is why we must respectfully decline the commenters' safe-harbor request.

Comment: A commenter stated that because existing § 424.57(c)(29) prohibits DMEPOS suppliers from co-locating with another provider or supplier, § 424.530(a)(19) is unnecessary and duplicative.

Response: We respectfully disagree because the two provisions address different situations. Section 424.57(c)(29) is restricted to DMEPOS suppliers and prohibits co-location. Proposed § 424.530(a)(19) is not provider-type specific, does not itself bar space-sharing, and involves sharing an office or suite with a denied or revoked provider.

Comment: A few commenters contended that § 424.530(a)(19) should not apply if the enrolling provider has no ownership, management, financial, or operational relationship with the revoked or denied provider.

Response: We respectfully disagree. As stated elsewhere in this final rule section V.C., we cannot regulatorily exclude potential scenarios from our proposed denial and revocation

provisions, for the facts of each case will vary. Indeed, such exemptions could impair program integrity if, to illustrate, the circumstances of a particular exempted situation warranted denial or revocation but the exception prohibited action on our part.

Comment: Some commenters stated that § 424.530(a)(19) could discourage physicians and practitioners from joining and co-locating with group practices out of concern that their enrollments may be denied if the group has a denied or revoked provider.

Response: We respectfully disagree for two reasons. First, denials on this ground will be the exception, not the norm. They will only occur when genuinely justified. Second, we have added and expanded numerous denial and revocation grounds over the past two decades to include certain relationships and affiliations. We are unaware of large numbers of providers and other parties avoiding such arrangements as a result. We believe this will hold true with § 424.530(a)(19), too.

Comment: A few commenters urged CMS to state in the regulatory text that § 424.530(a)(19) would not apply to situations where a physician is: (1) joining an established group practice; or (2) otherwise enrolling at a location where the revoked or denied provider is no longer present.

Response: For reasons already stated, we cannot exempt certain arrangements from § 424.530(a)(19)'s scope. Regarding the second comment, CMS will issue guidance on this matter.

Comment: Several commenters recommended that CMS define what constitutes the "same suite or office".

Response: We respectfully believe that this phrase's meaning is plain on its face.

Comment: Noting our earlier scenario of a 10-physician group, a commenter -- seemingly believing this constituted an exception to § 424.530(a)(19) – requested that it be included in the regulatory text.

Response: While we appreciate this request, our scenario was not an exemption. It merely stated that § 424.530(a)(19) "does not automatically mean that a prospective (and Medicare enrolling) 11th group member will be denied enrollment" based on another group member's revocation. The purpose was to make clear that every case is different and will be evaluated on its own facts and circumstances.

After reviewing the comments received, we are finalizing proposed § 424.530(a)(19) without modification.

(iii) Hospice Medical Directors and Administrators (§ 424.530(a)(20))

We explained at length in the proposed rule the serious program integrity issues involving hospices. CMS in recent years has taken numerous steps to address them, including, for example:

- Under § 424.518(c), requiring persons who directly or indirectly own 5 percent or more of a newly enrolling hospice (or a hospice undergoing any ownership change) to submit fingerprints for a criminal background check.

- Requiring hospice medical directors who certify a patient's terminal illness under § 418.22(c) to be enrolled in or opted out of Medicare, which enables CMS to screen the medical director.

- Clarifying that hospice medical directors and administrators are "managing employees" (as that term is defined in § 424.502) and thus must be reported on the hospice's Form CMS-855A enrollment application (OMB Control No. 0938-0685). This helps ensure that CMS knows the identities of these parties and can vet them for potential issues.

In light of medical directors' and administrators' managing control over hospices, we believed that closer oversight of these individuals was necessary – particularly considering: (1) the criminal and False Claims Act cases we have seen involving hospice operators;[38] and (2)

[38] See, for example, the proposed rule titled, "Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice

reports of physicians falsely certifying patients' terminal statuses.[39] Despite the aforementioned steps, we continue to have program integrity concerns about hospice operators. We still see instances of false physician certifications, kickbacks to certifying physicians, criminal cases involving administrators, hospices billing Medicare while non-compliant with enrollment requirements, etc. On a more specific level, we outlined in the proposed rule three particularly problematic issues.

First, there are individuals who serve as medical director or administrator of numerous hospices. Ensuring-- (1) quality care to hospice patients; (2) the efficiency of the hospice's operations; (3) compliance with Medicare requirements; and (4) hospice program integrity requires the full attention and oversight of the medical director and administrator. We believe that having these roles at numerous facilities limits the time the individual can spend on each facility's operations and raises questions about the person's commitment to oversight. This places hospice beneficiaries and program integrity at risk.

Second, we have seen cases where the medical director or administrator is very far from the physical hospice facility; several instances, in fact, involved the hospice and medical director being on opposite sides of the country (for instance, the medical director is in New York, and the hospice is in California). This, too, generates significant concerns about the individual's oversight of the hospice.

Third, certain hospices have been using medical directors with inactive licenses. Section 418.22(c), as noted, requires the medical director who initially certifies the beneficiary's terminal status to be enrolled in or opted-out of Medicare. However, if the medical director is not certifying Medicare beneficiaries' terminal status -- and said physician is neither billing

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Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements" (88 FR 43654), published in the **Federal Register** on July, 10, 2023.

[39] See, for example, the proposed rule titled, "Medicare Program; FY 2024 Hospice Wage Index and Payment Rate Update, Hospice Conditions of Participation Updates, Hospice Quality Reporting Program Requirements, and Hospice Certifying Physician Provider Enrollment Requirements" (88 FR 20022), published in the **Federal Register** on April 4, 2023.

Medicare nor ordering/certifying the services/items outlined in § 424.507 -- enrollment is not required. Therefore, CMS might not know whether the medical director's license is active and only learn of the inactive status later. Since the medical director Conditions of Participation (CoPs) at § 418.102 and personnel requirements for physicians at § 418.114(b)(1) require hospice medical directors to be physicians (and thus licensed), hospices that have medical directors with inactive licenses are not compliant with the CoP Medicare requirements.

To further address hospice medial director and administrator program integrity issues and to protect beneficiaries, we proposed new § 424.530(a)(20). This would permit denial of a hospice's enrollment application if any of the following apply:

- The enrolling hospice's medical director is--

++ The medical director of multiple other hospices, or

++ Practices at such a distance (for example, in a different state) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR part 418.

- The enrolling hospice's administrator is--

++ The administrator of multiple other hospices; or

++ Located at such a distance from the enrolling hospice that the administrator cannot realistically perform all administrator functions required under 42 CFR part 418.

- The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

Section 424.530(a)(20) would not: (1) formally prohibit medical directors and administrators from serving at more than one hospice; or (2) change hospice CoPs or other hospice policies in 42 CFR part 418. It would simply help us address situations where the hospice's prospective enrollment raises the program integrity concerns outlined in this section V.C. of this final rule.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters opposed the multiple hospice and distance provisions in § 424.530(a)(20). Some stated that rural and small hospices – as well as larger health systems -- occasionally hire medical directors and administrators to provide consistent leadership and continuity of care across their service areas, partly because qualified candidates can be scarce. They believed our proposal could harm the ability of these hospices (particularly rural ones) to attract such officials. A commenter requested a specific exemption from § 424.530(a)(20) for hospices in a designated Health Professional Shortage Area (HPSA) by the Health Resources and Services Administration (HRSA).

Response: We thank the commenters for this feedback. As earlier stated, this provision establishes no actual or implied limits on the number of hospices a medical director or administrator can oversee. It also does not create mileage or other distance thresholds. We recognize the existence of the situations the commenters' raised, and our proposal is not intended to halt all arrangements involving either the direction of multiple hospices or direction from a considerable distance. It is instead aimed at isolated but highly disconcerting situations we have seen that involve, for instance, potential program integrity or beneficiary safety issues. We seek to assure hospices that -- as with other denial and revocation grounds -- we would only apply § 424.530(a)(20) in limited instances and after a careful review of the facts and circumstances involved. This said, we are respectfully unable to establish § 424.530(a)(20) carve-outs for certain hospices in this final rule (such as hospices in HPSAs), for we must be able to address a broad range of situations.

Comment: Commenters expressed concern that CMS did not define or establish thresholds for "multiple other hospices."

Response: As indicated in our previous response, we did not define "multiple other hospices" so we could retain the ability to address a wide range of factual scenarios. We also

believed that requiring numerical thresholds would effectively place limits on how many hospices a medical director or administrator could oversee, something we were not seeking to do in this rule.

Comment: Commenters stated that CMS should evaluate whether required functions are actually being performed rather than presume inadequacy based principally on mileage or the number of hospices served. They urged CMS: (1) to define objective, evidence-based criteria for determining whether a medical director or administrator can fulfill required responsibilities; (2) not to use oversight of multiple hospices or geographic distance alone as a basis for denial; (3) to provide a reasonable cure period for a temporary or administrative licensure lapse when appropriate; (4) to phase in any new requirements and consider protections for existing, disclosed arrangements that comply with 42 CFR part 418; (5) to identify the process CMS will use and the data and factors it will consider -- such as (but not limited to) the individual's regular availability, the scope of their role within the hospice, and the approximate number of patients the hospices in question have -- in determining whether a § 424.530(a)(20) denial is warranted; and (6) allow hospices to demonstrate how their operations ensure compliance.

Response: We appreciate these suggestions. Regarding the first, second, and fifth, we reiterate that while we decline to include specific criteria within § 424.530(a)(20), we will thoroughly examine the facts and circumstances of every case and will not automatically assume either inadequacy or sufficiency. For the third, we refer commenters to our earlier statements regarding cure periods and the need for constant compliance with Medicare enrollment regulations; allowing the former could disincentivize hospice physicians from maintaining the latter. We respectfully decline the commenters' fourth request regarding staged implementation. Arrangements of significant concern to us might warrant a possible § 424.530(a)(20) denial of an enrolling hospice soon after the January 1, 2027, effective date. (We note that § 424.530(a)(20) only applies to denials and not revocations, which we believe addresses the comments regarding existing, disclosed arrangements.) We view the sixth recommendation as a request that CMS's

§ 424.530(a)(20) investigation include discussions with the hospice about its medical director and administrator operations. While we appreciate the suggestion, CMS cannot pre-commit to an official, mandatory means of investigation in a particular enrollment case.

Comment: Several commenters stated that physical distance is an imperfect proxy for effective oversight.

Response: Again, we recognize that distance does not necessarily equate to a lack of oversight. Yet we have seen cases where it has. These include instances where the medical director or administrator is part of a wider scheme where the person only superficially monitors the hospice – or, in some situations, has no involvement at all but is listed as the medical director or administrator merely for appearances' sake. Such cases require us to take steps to protect the Medicare program and beneficiaries and, if the facts warrant it, deny enrollment.

Comment: Several commenters appeared to question the need for § 424.530(a)(20) because the CoPs already establish responsibilities for hospice medical directors and administrators. Another commenter stated that proposed § 424.530(a)(20) should be withdrawn from this rule and addressed in the hospice CoPs after CMS meets with stakeholders to better understand: (1) the needs of rural hospices; and (2) how to develop CoPs that address key personnel working at multiple providers.

Response: We appreciate this feedback but note that CoPs are separate from the question of risk in the context of provider enrollment. Even if a CoP is met, this does not mean that the facility, medical director, or administrator can never present a program integrity or enrollment risk – especially considering the situations we have seen. We accordingly believe our provision is necessary.

Comment: A few commenters questioned whether CMS whether § 424.530(a)(20)'s licensure provision pertains to the State in which the medical director practices or the State in which the hospice is located.

Response: It pertains to the former.

Comment: A commenter stated that CMS should publish de-identified implementation data as well as the grounds for denials and their disposition.

Response: Although we respectfully are unclear as to the type of "implementation data" the commenter suggests, CMS does not publish the specific facts, evidence, and reasons behind individual denial cases.

Comment: A commenter questioned how § 424.530(a)(20) would apply to system-level chief medical officers, regional medical directors, alternate administrators, and other leadership models used by multi-site hospice organizations.

Response: We believe the commenter is requesting clarity on whether § 424.530(a)(20) would apply not only to medical directors and administrators but also to the other officials the commenter cited. Assuming so, the provision only pertains to the activities of medical directors and administrators.

After reviewing the comments received, we are finalizing proposed § 424.530(a)(20) without modification.

(iv) Misuse of Identity (§ 424.530(a)(21))

We noted previously that § 424.535(a)(7) permits revocation if the provider knowingly sells to or allows another individual or entity to use its billing number. (This does not include providers or suppliers who enter into a valid § 424.80 reassignment of benefits or a § 489.18 change of ownership.) Yet there is no denial reason that specifically addresses misuse of identifiers. This is troubling given situations that have occurred where a party (X) steals the identity of another party (Y) (for example, another physician or practitioner) and enrolls Y without Y's knowledge and using Y's credentials and identifiers; X then bills and receives payment from Medicare under Y's name. To address this and other situations involving prospective enrollees using compromised identities, we proposed in new § 424.530(a)(21) that CMS can deny enrollment if the prospective provider or supplier is attempting to enroll under another party's identity.

The comments we received on this proposal were supportive. No opposition was expressed. Thus, we are finalizing § 424.530(a)(21) without modification.

(8) Reapplication Bar (§ 424.530(f))

Under § 424.530(f), CMS may prohibit a prospective provider from enrolling in Medicare for up to 10 years if its enrollment application is denied because the provider submitted false or misleading information on or with (or omitted information from) its application to gain enrollment in Medicare. The goal is to prevent dishonest providers from submitting false information on their initial application and, after being denied enrollment on this ground under § 424.530(a)(4), simply submitting a new application with correct data.

We believe that restricting § 424.530(f) to instances involving false information limits its potential effectiveness, for there are other § 424.530(a) denial reasons that could involve similarly inappropriate provider behavior. Assume a prospective provider's enrollment is denied because the provider is: (1) unlicensed; (2) OIG excluded or has a recent felony conviction; (3) using a false storefront as its practice location; (4) under a current Medicare and Medicaid payment suspension based on a credible allegation of fraud; (5) terminated from another Federal health care program; or (6) revoked from Medicare and attempting to enroll under a different identity. This casts serious doubt as to the provider's honesty and trustworthiness, since the provider likely knows it cannot enroll but is nonetheless hoping to somehow "sneak into" the program; indeed, without a reapplication bar in these and similar situations, the provider might routinely submit more such applications with this nefarious objective in mind.

Accordingly, and to safeguard the Medicare program, we proposed to revise the introductory text of § 424.530(f) to allow CMS to impose a reapplication bar for up to 10 years based on any § 424.530(a) denial reason (not merely § 424.530(a)(4)). We also proposed to delete factors at § 424.530(f)(2) that CMS currently must consider in determining whether to impose a reapplication bar (and the length thereof) for a § 424.530(a)(4) denial. There are two related reasons for this latter proposal. First, the current § 424.530(a)(4) factors pertain strictly

to false or misleading data situations and would thus be inapplicable to other denial grounds. Second, proposing different § 424.530(a)(4) criteria would essentially present the same problem mentioned in the previous sentence – specifically, a single set of § 424.530(f) factors could not possibly apply to all § 424.530(a) denial reasons considering the varying facts of each.

Unlike reenrollment bars under § 424.535(c), reapplication bars are discretionary. CMS need not impose them, and we are not proposing to change this. We recognize that less serious denial situations ---such as, but not limited to, failure to pay an application fee---might not warrant a reapplication bar. Our focus is mostly on providers whose conduct raises significant program integrity concerns.

We would retain current § 424.530(f)(1) and (f)(3), which address, respectively, the bar's: (1) applicability to the provider's other names, identities, etc.; and (2) impact on the ordering, referral, certification, or prescription of services, items, or drugs. Paragraph (f)(3), though, would be re-designated as revised paragraph (f)(2).

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our expansion of § 424.530(f) to include all denial grounds. They stated that 10 years is much too long a bar for what may be a comparatively modest reason for the denial and could effectively force the provider to cease operations.

Response: While we appreciate these concerns, we reiterate that a reapplication bar is completely discretionary; a bar may not be imposed in every case. Moreover, the 10-year period is a maximum, not a mandatory timeframe. It is not as though any bar we impose must be for 10 years. In fact, many bars will not be anywhere near this length. Only if a 10-year bar is truly necessary will it be imposed, and we will carefully consider the facts and circumstances in every reapplication bar case.

Comment: Commenters stated that when considering a reapplication bar and its length, CMS should distinguish between denials: (1) involving fraud, abuse, intentional

misrepresentation, or patient safety concerns; and (2) arising from technical, administrative, or similar issues. They maintained that this would allow CMS to concentrate on more serious conduct without harming providers whose enrollments were denied for less significant reasons. They believed longer bars should be reserved for more serious conduct.

Response: We thank commenters for this recommendation. We recognize that not all denials are the same and that the facts and circumstances of each situation will differ. We seek to assure providers that every reapplication bar case will be carefully evaluated, and we will only impose longer bars when warranted.

Comment: Commenters recommended that CMS retain and add mandatory reapplication bar factors (including data that CMS must review in every case) in § 424.530(f) so that stakeholders understand the bases for CMS' determinations. Suggested additional factors included, but were not limited to, the severity of the conduct and whether there was any beneficiary harm.

Response: As previously explained, regulatorily specified criteria has at times inhibited our ability to take necessary program integrity measures. Therefore, we believe that our proposed removal of factors from § 424.530(f) – and our declination to add new ones – is necessary.

Comment: A commenter requested that CMS: (1) identify denials that are considered less serious than others; and (2) not apply a reapplication bar to providers that are denied enrollment under § 424.530(a)(1) based on a failure to respond timely to a revalidation request or other request for information.

Response: We respectfully decline these requests because they both effectively require CMS to make certain reapplication bar decisions before we have reviewed the facts of a particular case. For instance, if we stated in this final rule that Denial Reason X generally might not involve the misconduct that Denial Reason Y does, this could – as with having factors within our denial and revocation reasons – obstruct our efforts to apply a reapplication bar (and an

extended one if needed) in Denial X cases. Likewise, we cannot formally exclude the § 424.530(a)(1) situation the commenter references because there could indeed be instances where a bar is warranted.

Comment: A commenter requested that CMS confirm that it will not issue a reapplication bar for a denial that has been reversed on appeal.

Response: No reapplication bar will be applied in this instance.

Comment: A commenter stated that: (1) providers must be able to challenge the imposition and length of a reapplication bar; and (2) the denial notice must explain why the selected duration is proportionate to the underlying conduct.

Response: The imposition of a reapplication bar and its length are not appealable matters because neither is an initial determination under 42 CFR 498.3. The denial letter describes the basis for the bar's length.

After reviewing the comments received, we are finalizing our proposed changes to § 424.530(f) without modification.

(9) Changes in Majority Ownership (CIMOs)

We previously mentioned § 424.550(b) and § 424.551, the former pertaining to HHAs and hospices and the latter to DMEPOS suppliers (hereafter collectively "providers"). Under these provisions, if the provider undergoes a CIMO within 36 months of its initial enrollment -- or within 36 months of its most recent CIMO -- and no exception applies, the provider's enrollment is terminated. (For HHAs and hospices, the provider agreement is also terminated and does not transfer to the new owner.) The provider under its new majority ownership must enroll as a new provider and undergo a State survey or accreditation. (DMEPOS suppliers must obtain a new accreditation.)

There are two main purposes of this "36-month rule". First, it enables CMS to perform a complete screening and vetting of the provider under its new ownership. This is vital for ensuring that the provider is compliant with all Medicare enrollment requirements. Second, it

helps prevent “flipping”. This involves a party enrolling a provider for the sole purpose of quickly selling it to another party without the latter having to newly enroll or undergo a survey/accreditation. The seller’s exclusive objective is profit and not patient care, which places beneficiaries and the Trust Funds at risk.

While the 36-month rule has helped to stem flipping and facilitate closer scrutiny of new owners, we have seen provider efforts to circumvent or ignore it. These include, but are not limited to:

- Failing to notify CMS of the ownership change -- meaning the sale occurs and the buyer assumes ownership under the existing enrollment without enrolling the entity as a new provider with a new survey/accreditation. Only later does CMS learn of the sale.

- Using a management (or similar) agreement in lieu of a formal sales agreement. Here, the management agreement states that: (1) managerial (and effectively all other) authority over the provider is transferred to Party X; and (2) X intends to later purchase the provider. Once the 36-month period expires, the sale occurs. In essence, Party X is purchasing the provider within the 36-month period but under the guise of a “management agreement”.

Such inappropriate attempts to avoid the 36-month rule undercut the rule’s overriding objective of protecting beneficiaries and the Trust Funds from unvetted and potentially problematic entities. To deter these efforts, we proposed in new §§ 424.530(a)(22) and 424.535(a)(25) that we may deny or revoke enrollment if CMS determines that the HHA, hospice, or DMEPOS supplier failed to comply with the provisions and requirements of, as applicable, §§ 424.550(b) or 424.551. The § 424.535(a)(25) revocation effective date under new § 424.535(g)(1)(xxv) would be the date on which CMS or its contractor determined that the provider should be revoked.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters supported proposed §§ 424.530(a)(22) and 424.535(a)(25). A commenter stated that the strengthening of oversight of ownership changes via these provisions is well targeted, adding that ownership changes are a documented vehicle for fraud scheme expansion in home health and other high-risk provider categories.

Response: We appreciate the commenters' support.

Comment: Commenters recommended that CMS add factors and criteria (including, potentially, a materiality standard) for §§ 424.530(a)(22) and 424.535(a)(25) determinations. They believed this would retain the provision's focus on inappropriate behaviors without chilling legitimate transactions.

Response: We thank commenters for this suggestion but restate our earlier position on required factors and the need to be able to address a multitude of situations. Thus, we respectfully decline the commenters' recommendation.

Comment: Commenters stated that CMS should implement §§ 424.530(a)(22) and 424.535(a)(25) with safeguards for bona fide transactions.

Response: Our proposed grounds are not designed to deter or discourage CIMOs, and we do not believe providers will be disincentivized from engaging in them. We recognize that many such transactions are legitimate. Yet this does not mean we should ignore instances where compliance is not maintained, circumvention has been attempted, etc., for we must ensure that parties comply with our provider enrollment requirements. All this said, and as with our other denial and revocation grounds, we will take action under §§ 424.530(a)(22) and 424.535(a)(25) only when justified and after a thorough review of the case's facts and circumstances; this, in itself, is an important safeguard for providers.

Comment: Commenters stated that provider confusion about whether a transaction constitutes a CIMO should not result in revocation where the entity acted in good faith and promptly corrects a reporting or procedural deficiency.

Response: We repeat our prior response regarding our careful review of the facts and circumstances of every case. We note, though, that: (1) providers are ultimately responsible for understanding and adhering to the CIMO requirements; and (2) a provider's claimed misinterpretation of §§ 424.550(b) and 424.551 is not, by itself, sufficient basis for avoiding a denial or revocation under §§ 424.530(a)(22) and 424.535(a)(25).

Comment: Commenters stated that CMS should not apply §§ 424.530(a)(22) and 424.535(a)(25) except in cases of fraud, misconduct, deliberate circumvention, or other serious activity. Technical or minor errors – or when there was no purposeful circumvention -- should be excluded, with a few commenters requesting a specific intent requirement for §§ 424.530(a)(22) and 424.535(a)(25) to be applicable. A commenter stated that no reapplication or reenrollment bar should be applied in §§ 424.530(a)(22) and 424.535(a)(25) situations if the CIMO was conducted in good faith but later found to be non-compliant.

Response: We respectfully disagree with these comments. Even if a provider believes its non-compliance is immaterial or was unintentional, it remains non-compliance. While we will, again, review every case on its own facts and circumstances, we are unable to promulgate a blanket exemption for situations not involving fraud, serious misbehavior, intentional circumvention, etc. This also applies to reenrollment bars, which are mandatory under § 424.535(c) (though the length of the bar is a matter of CMS discretion). Reapplication bars are discretionary, but CMS cannot exclude certain situations from § 424.530(f) given the need to address various types of factual situations.

Comment: Several commenters expressed concern that our proposals appear to prohibit management agreements in CIMO situations. They stated that such arrangements are common and legitimate.

Response: Sections 424.530(a)(22) and 424.535(a)(25) do not prohibit such agreements *per se.* However, and depending on the situation's circumstances, they can involve improper

efforts to sidestep the 36-month rule and its important protections – hence our citing it as an example of §§ 424.530(a)(22) and 424.535(a)(25)'s potential applicability.

Comment: A commenter requested that CMS identify which types of ownership arrangements it deems "abusive" under the 36-month rule.

Response: We respectfully decline the commenter's request because: (1) neither §§ 424.530(a)(22) nor 424.535(a)(25) use the term "abusive", nor did we do so in the proposed rule's preamble discussion of these two provisions; and (2) we cannot deem certain transactions as abusive or not abusive without assessing the case's specific and unique facts.

Comment: A commenter urged CMS to: (1) remove the reference to § 424.550(b) in § 424.535(a)(25); and (2) state that revocation is permissible if an HHA or hospice failed to report material ownership-related information within 30 days as required in § 424.516(e)(1). While it was somewhat unclear, the commenter appeared to contend that so long as the provider reported material data about the CIMO within 30 days, this should satisfy CMS' concerns about CIMO compliance.

Response: We respectfully disagree for two reasons. First, neither § 424.516(e)(1) nor § 424.550(b) contains a materiality standard. Required data must be reported regardless of its materiality. Second, and as explained in the proposed rule, our concerns go beyond the mere timely reporting of the change to include, for instance, non-compliance with other requirements as well as circumvention.

Comment: A few commenters stated that CMS should: (1) furnish additional guidance on what constitutes a CIMO and outline the facts that demonstrate a compliant CIMO; and (2) allow providers to obtain formal, pre-sale determinations directly from CMS or the MAC regarding whether their transaction (or potential transaction) triggers the 36-month rule's requirements.

Response: We appreciate the comments but believe they are outside the scope of this final rule.

Comment: A commenter recommended that CMS establish a risk-based "Trusted

Provider" CIMO voluntary registration and recognition mechanism. Under this approach, vetted, good-faith HHAs and hospices --- such as, the commenter believed, those with no adverse history or that are currently accredited – may complete a CIMO via expedited screening, with the provider agreement and billing privileges remaining intact; no new enrollment and survey would be required. The commenter maintained that this would be consistent with CMS' existing risk-based screening process under § 424.518.

Response: We appreciate this suggestion but believe it is outside the scope of this final rule.

Comment: A commenter opposed proposed § 424.535(g)(1)(xxv)'s revocation effective date of "the date on which CMS or its contractor determined that the provider should be revoked." The commenter believed this: (1) is inconsistent with the more fixed effective dates in § 424.535(g); and (2) would give CMS complete discretion to make the effective date retroactive to the provider's initial enrollment date. The commenter stated that the effective date should instead be that of the management agreement or other event that triggered the § 424.550(b) violation.

Response: Most respectfully, we believe the commenter may be misinterpreting this effective date. The § 424.535(g)(1)(xxv) date is the date of CMS's decision to revoke, not any random date back to which CMS believes the revocation should be made retroactive. The decision date is, in fact, a fixed date -- and as previously explained, it is necessary due to (1) the variety of situations that can arise under § 424.535(a)(25); and(2) the consequent difficulty of assigning a single effective date to cover all of them.

Comment: A commenter stated that a DMEPOS supplier should not be required to enroll as a new supplier and obtain a new accreditation after a CIMO.

Response: While we appreciate this comment, it appeared to relate to the CY 2026 HH PPS final rule wherein we finalized §§ 424.551. Hence, we believe it is outside the scope of the present final rule.

Comment: A few commenters stated that the following parties and situations should be exempt from §§ 424.530(a)(22) and 424.535(a)(25): (1) management or operating arrangements in connection with a bona fide joint venture – regardless of which joint venture participant holds the provider agreement or State license during the transition; (2) within-window providers as part of a bona fide package transaction not involving circumvention of § 424.550(b); and (3) management arrangements used to bridge CHOW processing for such packages.

Response: While we appreciate these requests, we are unable to formally exempt these and other transactions from the purview of §§ 424.530(a)(22) and 424.535(a)(25) because: (1) such situations can still involve §§ 424.550(b) and 424.551 non-compliance; and (2) doing so would involve CMS making determinations before reviewing the facts of a particular case.

After reviewing the comments received, we are finalizing proposed §§ 424.530(a)(22) and 424.535(a)(25) without modification.

3. Preclusion List (42 CFR 422.2 and 423.100)

Addressed primarily in 42 CFR 422.222 and 423.120, the preclusion list is a compilation of providers and prescribers who are prohibited from receiving payment for furnished, ordered, or prescribed MA items/services and Part D drugs. The list's objective is to effectively bar from the MA and Part D programs various entities and persons that pose program integrity risks. Per the definition of "preclusion list" in §§ 422.2 and 423.100, a party may be placed on said list if they fall into any of the following three categories:

- Currently revoked under Medicare for a reason other than that in § 424.535(a)(3) (which addresses felony convictions), the reenrollment bar has not expired, and CMS determines that the underlying conduct that led to the revocation is detrimental to the Medicare program's best interests.

- Engaged in behavior, other than that described in § 424.535(a)(3): (1) for which CMS could have revoked the provider/prescriber to the extent applicable had they been enrolled in Medicare; and (2) that CMS determines is detrimental to the Medicare program's best interests.

- Regardless of whether the provider/prescriber is or was enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the Medicare program's best interests.

We proposed to expand this third category to include felony convictions against the provider/prescriber's owner, managing employee, managing organization, corporate director, or corporate officer. As already stated, these parties typically exercise considerable influence over a provider/prescriber's operations, and a felony conviction against said party greatly concerns us; indeed, this is precisely why §§ 424.530(a)(3) and 424.535(a)(3) permit denial or revocation based on felony convictions against owners, managing employees/organizations, and corporate officers/directors. Our proposed change would not only ensure greater consistency with §§ 424.530(a)(3) and 424.535(a)(3) but also help protect the MA and Part D programs from program integrity risks.

The specific regulatory revisions would be to paragraph (3) of the "preclusion list" definitions in §§ 422.2 and 423.100. The language therein stating that the prescriber/provider, "regardless of whether they are or were enrolled in Medicare, has been convicted of a felony. . . " would be changed to the prescriber/provider, "regardless of whether they are or were enrolled in Medicare -- or an owner, managing employee, managing organization, director, or officer (as those terms are defined in § 424.502) thereof -- has been convicted of a felony . . .".

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters disagreed with our proposed preclusion list expansion. They stated that providers could have difficulty identifying and verifying information regarding individuals associated with the provider. They requested that CMS: (1) establish reasonable due diligence expectations; and (2) ensure that providers are not penalized for information they could not reasonably have known or verified. Commenters further recommended that CMS promulgate factors for determining whether the provider should be added to the preclusion list.

Recommended criteria included (but were not limited to) a nexus between the provider and the owning or managing party's action, the nature of the conviction, the risk posed to Medicare, when the conviction occurred, and the convicted party's role within the provider organization.

Response: Consistent with §§ 424.530(a)(3) and 424.535(a)(3)'s application to felony convictions of parties other than the provider, the primary consideration must always be the party's felony conviction itself and not: (1) the provider's efforts in screening personnel or associated parties; or (2) whether the provider knew of (or was involved in) the conduct. Similar to our earlier statements, we cannot base preclusion decisions under revised paragraph (3) on a knowledge or due diligence standard. If we did, providers could consistently avoid denial or revocation by simply asserting that they knew nothing of the conduct; this obviously would hamper our program integrity efforts, harm the Trust Funds, and potentially endanger beneficiaries. Hence, we respectfully decline to establish the requested knowledge or diligence standard.

Insofar as promulgating factors, we maintain our position that regulatorily-specified criteria hamstring our efforts to take required action against problematic providers. Therefore, we must decline to establish them with respect to revised paragraph (3) of the "preclusion list" definition.

Comment: Several commenters stated that it would be unfair to place a provider on the preclusion list based on a felony conviction of a party who may not have close, constant involvement with the provider's operations. They believed that CMS should not finalize its proposed expansion or, at a minimum, remove managing employees and organizations from the proposal.

Response: We disagree. Felony convictions are very serious matters, and the parties we propose to include within the preclusion list definition are sufficiently linked to the provider to – if warranted under the facts and circumstances – trigger the preclusion list's application.

Comment: A few commenters questioned whether a provider whose managing employee has a felony conviction would be added to or removed (as applicable) from the preclusion list if the provider terminated the person's employment. They requested that CMS allow providers to avoid the preclusion list by severing such relationships upon CMS notice of the issue.

Response: Section 424.535(e), in certain instances, affords a revoked provider a 15-day opportunity to remove from their organization the entity or individual whose action (for example, a managing employee's felony conviction) generated the provider's revocation. While there is no concomitant provision in our preclusion list regulations, we will consider this issue for future rulemaking.

Comment: A commenter requested that CMS explain why: (1) this preclusion list expansion is necessary; and (2) the problem cannot be addressed via existing means such as screening, denial, or revocation. The commenter added that a provider should only be included on the preclusion list per our proposal if a clear and ongoing program integrity risk exists.

Response: As we explained in the proposed rule, in this final rule, and when we promulgated (and later expanded) §§ 424.530(a)(3) and 424.535(a)(3), providers with owners and managing employees that have felony convictions have always generated serious and justifiable program integrity concerns. This is partly, but by no means exclusively, due to the possibility that the person's conduct may be replicated in the provider setting. Since there are no other statutory or regulatory means of addressing this vulnerability with respect to Medicare programs other than Parts A and B, our proposal is necessary

Regarding the commenter's last statement, CMS: (1) reviews the facts and circumstances of every potential preclusion list case under current paragraph (3) of the "preclusion list" definition; (2) will do the same with our proposed change; and (3) takes action only when justified.

Comment: A comment stated that in light of the "preclusion list" definition expansion, CMS should—

● Explain how qualifying convictions will be identified and verified;

● Clarify how and when providers, prescribers, and MA and Part D plans will be notified;

● Identify when preclusion list updates and associated payment consequences will take effect;

● Identify w responsibilities plans will have before payment is affected;

● Ensure that affected providers receive timely notice and a meaningful opportunity to—

++ Correct erroneous information;

++ Demonstrate that the provision does not apply; or

++ Otherwise challenge the proposed placement on the preclusion; and

● Clarify how MA and Part D plans should proceed while a determination is disputed or under review so that payment is not improperly disrupted based on unresolved information.

Response: Our proposed expansion does not change any procedures regarding the six issues the commenter raised, though we note there is no pre-preclusion quasi-appeals system. Should the commenter have questions regarding the preclusion list process, we respectfully recommend visiting CMS' preclusion list website at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/preclusion-list.

After reviewing the comments received, we are finalizing our proposed changes to the preclusion list definitions in §§ 422.2 and 423.100 without modification.

4. Temporary Moratoria (§ 424.570)

Pursuant to section 1866(j)(7) of the Act and § 424.570, we imposed several temporary enrollment moratoria between 2013 and 2019, and – as of May 13, 2026 -- there are national moratoria on the enrollment of new HHAs and hospices.[40] All moratoria (including a

[40] We also implemented a nationwide moratorium on DMEPOS medical supply companies in a notice placed on display at the Federal Register on February 25, 2026, and published in the Federal Register notice on February 27, 2026. ("Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratoria on Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medical Supply Companies" (91 FR 9855)). It expired on August 27, 2026, and was not extended.

moratorium extension) are announced via a notice published in the **Federal Register**. Under § 424.570(a)(1)(iii)(A) through (C), a temporary moratorium does not apply to any of the following:

- Changes in practice location (except if the location is changing from a location outside the moratorium area to a location inside the moratorium area).
- Changes in provider or supplier information, such as phone numbers.
- Changes in ownership (except changes in ownership of HHAs that would require an initial enrollment).

Since restarting the moratorium process in 2026 after more than 6 years, we have seen several issues that we believe must be addressed in regulation.

a. Effective Date

Per § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application received by the Medicare contractor prior to the date the moratorium is imposed. We proposed to revise § 424.570(a)(1)(iv) as follows:

- Existing § 424.570(a)(1)(iv) would be redesignated as new § 424.570(a)(1)(iv)(A).
- New § 424.570(a)(1)(iv)(B) would state that the date the moratorium is imposed is the moratorium's effective date, which is the date on which the moratorium notice was filed for public inspection at the Office of the **Federal Register** (OFR).

There are often gaps between when a document (such as a proposed rule) is filed for OFR public inspection and when it is published in the **Federal Register**. If we used the latter as the moratorium's imposition/effective date, the affected providers/suppliers might have several days to submit their initial applications in order to "beat the deadline." This would partly obstruct the moratorium's goal of halting all new enrollments and could lead to a rush of new applicants during this gap, some of whom may present program integrity threats. Using the OFR filing date would prevent this scenario, for the moratorium's imposition would be immediate.

b. Ownership Changes

We proposed to change the aforementioned parenthetical in § 424.570(a)(1)(iii)(C) from "(except changes in ownership of home health agencies that would require an initial enrollment)" to "(except changes in ownership that require an initial enrollment, such as, but not limited to, an HHA, hospice, or DMEPOS supplier change in majority ownership under §§ 424.550(b) or 424.551)". This update would codify existing CMS policy that -- like HHAs -- hospices and DMEPOS suppliers that undergo a non-exempt CIMO under §§ 424.550(b) or 424.551 must enroll as a new provider/supplier and are thus subject to the moratorium.

c. Other Applicability

Section 424.570(a)(1)(i) states that CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. To clarify what qualifies as a "new" provider/supplier or practice location under the moratorium, we proposed to outline in new § 424.570(a)(1)(i)(A) through (E) the application types that -- solely for purposes of § 424.570(a) -- are considered "new" and to which a moratorium applies:

- Initial enrollment applications.
- Change of ownership applications that require an initial enrollment per § 424.570(a)(1)(iii)(C).
- Enrollment applications from revoked providers/suppliers whose reenrollment bars under § 424.535(c) have expired and are seeking to enroll again in the Medicare program.
- Reactivation applications.
- Enrollment applications from voluntarily terminated providers/suppliers seeking to enroll again in the Medicare program.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Commenters opposed making the moratorium effective date the date of filing at the OFR instead of the publication date. They stated that providers may not receive adequate

notice of the moratorium when the notice is placed on display. They also disagreed with our statement that providers could quickly submit applications between the display and publication dates to get ahead of an effective date based on publication. They believed that using the latter date would be fairer and would give providers more time to prepare.

Response: We thank the commenters for their thoughts. Commenters can access the Federal Register website for newly displayed documents no less than for newly published ones; in both cases, the information is public and retrievable. Regarding application submission, providers can indeed attempt to send in applications before the notice is published - even if the application might be incomplete due to the abbreviated timeframe to prepare and submit it. Given the important program integrity aspects of a moratorium and the consequent need for immediate implementation, we cannot afford to assume that no providers will be able to submit applications during this period. We believe the OFR filing date is appropriate notwithstanding commenters' concerns about reasonable advance notice.

Comment: Commenters disagreed with including reactivations within § 424.570's purview. They maintained that deactivations can sometimes occur for what commenters stated were minor reasons -- such as a failure to timely report certain information or 6 consecutive months of Medicare non-billing – or on grounds unrelated to fraud, waste, abuse, or other misconduct. They believed it would be unfair to prevent these providers from reactivating their enrollment based on the moratorium. In addition, they contended that reactivations do not involve the enrollment of a "new" provider because: (1) the provider remains enrolled during the deactivation period; and (2) the reactivation process is less onerous than initial enrollment. Another commenter stated that including reactivations within § 424.570 violates section 1866(j)(7) of the Act.

Response: We thank stakeholders for these comments. We addressed the reactivation matter in the proposed rule and restate our position here.

Deactivation means the provider's billing privileges are stopped but can be restored (or "reactivated") upon the submission of information required under § 424.540. While a deactivated provider is not revoked from Medicare, the provider's: (1) ability to bill Medicare is halted pending its reactivation; (2) enrollment is effectively shut down; and (3) participation in Medicare is blocked in a manner akin to a revocation. The only material differences between a revoked and a deactivated provider are that the former: (1) is subject to a reenrollment bar and a potentially more exhaustive reentry process (for instance, undergoing a State survey or accreditation); and (2) involves appeal rights under 42 CFR part 498 whereas the latter triggers rebuttal rights. Also, the bases for both revocations and deactivations typically involve concerning provider behavior, such as non-compliance with enrollment requirements or a non-operational practice location. Even if the deactivation was based on non-billing with no nefarious conduct, said conduct could have ensued if, for example, an unscrupulous party attempted to access the provider's billing number during the non-billing period. We continue to believe that the significant similarities between deactivations and revocations warrant including reactivations within § 424.570(a)(1)(i).

We further maintain that: (1) we indeed have the legal authority to define in regulation the scope of the term "new" as used in section 1866(j)(7); and (2) we do not foresee beneficiary access issues arising from revised § 424.570 based on our past experience with moratoria.

Comment: Several commenters stated that CIMOs that (1) adhere to §§ 424.550(b) or 424.551, (2) involve compliant providers, or (3) pose no program integrity risk should be exempt from a moratorium.

Response: We respectfully disagree because non-exempt CIMOs under §§ 424.550(b) and 424.551 are – and have always been – considered new enrollments. This is because the provider must initially enroll and undergo a State survey or accreditation to bill Medicare under its new ownership. In addition, exempting certain CIMOs based on risk would require a CMS

examination of said risk for each CIMO scenario and potentially result in case-by-case moratorium exceptions, which section 1866(j)(7) does not permit.

Comment: Several commenters stated that CMS' moratorium authority is too broad because a moratorium can impact bona fide providers as much as problematic ones. They recommended that CMS use more targeted means of addressing fraud, waste, and abuse that would not negatively impact honest providers and their patients.

Response: While we appreciate these comments, we believe they focused on our use of moratoria as a whole rather than our specific proposed revisions. Accordingly, we believe they are outside the scope of this final rule.

As an aside, we emphasize to stakeholders that moratoria under § 424.570(a)(1)(i) are actually very infrequent and typically limited. While our present hospice and HHA moratoria – as well as our 6-month long and now expired DMEPOS medical supply company moratorium – are nationwide – these three are the only national enrollment moratoria we have ever implemented going all the way back to 2011. Our moratoria from 2013 to 2019 were restricted to only a few provider and supplier types in certain regions. All this means that the overwhelming majority of providers and provider types – even newly enrolling ones – have not been impacted by § 424.570 to the extent it might appear to some.

Comment: Several commenters stated that including reactivating providers within § 424.570 could lead to access to care issues without improving program integrity.

Response: We respectfully disagree. Again, moratoria are, generally speaking, quite limited, meaning that comparatively few reactivating providers would be impacted and, consequently, patient care should not be affected. We also restate our position regarding the program integrity need for adding reactivations to § 424.570.

Comment: Several commenters stated that CMS should exempt from § 424.570: (1) service-line and other provider expansions involving legitimate providers; and (2) reenrollments.

Response: We are respectfully unclear as to the specific exemptions the commenter seeks. If, by "service-line expansions", the commenter is referencing practice location additions, these have previously been included in our moratoria because – depending in part on the provider or supplier type involved -- they involve the establishment of a new site. Insofar as reenrollments, we believe the commenter is referencing situations where a provider has either voluntarily or involuntary departed the Medicare program and seeks to enroll in Medicare again. These have always been treated as initial enrollments and thus subject to our moratoria.

Comment: A commenter supported our proposed changes to § 424.570.

Response: We appreciate the commenter's support.

Comment: A commenter stated that CMS should complement any imposed temporary moratorium with the following: (1) issuing sub-regulatory guidance clarifying appropriate billing requirements for G0390 (a HCPCS code used to report trauma response team activation), including activation criteria and documentation expectations; (2) conducting targeted program integrity reviews focused on outlier billing patterns, rather than applying broad-based restrictions that may affect compliant providers; (3) increasing transparency regarding how CMS identifies and monitors high-risk utilization patterns; and (4) considering a revised reimbursement model for trauma services aligned with developing a national military and civilian system. The commenter also stated that CMS should impose a temporary moratorium on the enrollment of new trauma centers in geographic areas experiencing oversaturation.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: A commenter requested that CMS establish a process by which reactivating providers can request an exemption from a moratorium's applicability based on administrative deactivation, contractor error, or deactivations under appeal.

Response: While we appreciate this request, we reiterate that section 1866(j)(7) of the Act does not permit individual, case-by-case exceptions to a moratorium.

After reviewing the comments received, we are finalizing our proposed changes to § 424.570 without modification.

5. Hospice Reactivations (§ 424.540(b)(3))

We mentioned earlier that hospices (like HHAs) that undergo a non-exempt CIMO within 36 months of their initial enrollment (or within 36 months of their previous CIMO) must initially enroll as a new hospice and have a State survey or accreditation. A new enrollment and survey/accreditation help confirm that the hospice under its new ownership is properly vetted, is committed to furnishing quality care, meets all enrollment requirements and CoPs, and does not pose program integrity risks. The program integrity and quality of care benefits of a State survey/accreditation are why in 2009 we promulgated § 424.540(b)(3)(i), which requires a deactivated HHA to obtain an initial survey/accreditation before it can be reactivated.

We believe the payment safeguard and patient care protections afforded by § 424.540(b)(3) should be extended to hospices. The previously noted hospice problems we have seen require, in our view, much closer scrutiny of reactivating hospices -- particularly since, deactivated hospices are essentially blocked from Medicare. We must ensure that the reentering hospice is compliant with all Medicare requirements. Thus, we proposed to revise § 424.540(b)(3)(i) to include hospices.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters supported our proposed change.

Response: We appreciate the commenters' support.

Comment: A commenter stated regarding our proposal that CMS has not demonstrated that: (1) current reactivation processes are inadequate; or (2) providers deactivated for administrative reasons pose a heightened quality or program integrity risk warranting additional survey requirements. Several other commenters contended that the hospice reactivation survey

requirement should exclude hospices that were deactivated for reasons other than fraud, abuse, or patient harm.

Response: We respectfully disagree with these comments. In our view, the existing reactivation process for hospices is not entirely adequate because it lacks the protection that surveys provide. While we are uncertain as to which "administrative" reasons the commenter had in mind, all deactivated providers present a degree of risk based on the deactivation itself. This is especially the case with deactivated hospices in light of – as explained in the proposed rule – the high risk that hospices as a provider category present. Given all this, we must ensure that a reactivating hospice (that, as explained, is effectively seeking to reenter Medicare) meets the hospice CoPs via a new survey or accreditation. This protects both beneficiaries and the Trust Funds.

After reviewing the comments received, we are finalizing our proposed change to § 424.540(b)(3)(i) without modification.

6. Opt-Out (42 CFR part 405, Subpart D)

Section 1802(b)(1) of the Act permits certain physicians and practitioners to opt-out of Medicare. Under opt-out, neither the physician/practitioner nor the beneficiary submits a bill to Medicare for services performed. Instead, the beneficiary pays the physician/practitioner out-of-pocket and neither party is reimbursed by Medicare. A private contract is signed between the physician/practitioner and the beneficiary that states, in essence, that neither can receive payment from Medicare for the services performed. The physician/practitioner must also submit an affidavit to Medicare expressing a decision to opt-out of the program and confirming, as further described in § 405.420, compliance with opt-out requirements. Opt-out periods are for 2 years.

Provisions in 42 CFR part 405, subpart D, govern Medicare opt-out. We proposed the following two regulatory clarifications, both of which reflect current policy.

First, opt-out periods are automatically renewed pursuant to section 1802(b)(3) of the Act unless the physician/practitioner – consistent with § 405.445(a) -- notifies the appropriate MAC not later than 30 days before the end of the 2-year period indicating that they do not want to extend the affidavit's extension for a subsequent 2-year period. In outlining the types of CMS opt-out determinations that are considered "initial" under § 498.3(b) (and thus appealable under 42 CFR part 498), § 405.450(a) includes the individual's failure to "timely renew opt-out". Since opt-out is automatically extended absent the occurrence in § 405.445(a), we proposed to change the quoted language in § 405.450(a) to "timely cancel automatic renewal"; a similar change would be made to § 498.3(b)(19), which lists various initial opt-out-related determinations.

Second, § 405.400 defines "opt-out period" as meaning, in part -- with respect to an affidavit that meets the requirements of § 405.420 -- a 2-year period beginning on the date the affidavit is signed (as specified by § 405.410(c)(1) or (2)). There are instances where the MAC, in reviewing and processing the physician/practitioner's submitted affidavit, needs and requests additional information or clarification from the physician/practitioner. Interested parties have asked whether -- if a new affidavit must be submitted per the MAC's request and it is subsequently approved – the opt-out period begins on the signature date of the second or the first submitted affidavit. To address this, we proposed in § 405.400 to change the "opt-out period" definition that states "the date the affidavit is signed" to "the date the first submitted affidavit is signed." This reflects our existing policy on this issue.

The comments we received on these proposed changes were supportive. No opposition was expressed. Hence, we are finalizing them without modification.

7. Affiliations

Consistent with section 1866(j)(5) of the Act, § 424.519 states that upon a CMS request, an initially enrolling or revalidating provider or supplier (hereafter collectively "provider" unless otherwise noted) must disclose any and all affiliations that it or any of its owning or managing

employees or organizations (per § 424.502's definitions of "owner" and "managing employee") has or, within the previous 5 years, had with a currently or formerly enrolled Medicare, Medicaid, or CHIP provider that has a disclosable event (as defined in § 424.502). If CMS determines that the affiliation poses an undue risk of fraud, waste, or abuse, CMS may deny or revoke the provider's enrollment under § 424.530(a)(13) or § 424.535(a)(19), respectively.

Section 424.502 defines a "disclosable event" as any of the following: (1) a current uncollected debt to Medicare, Medicaid, or CHIP; (2) a payment suspension under a Federal health care program; (3) an OIG exclusion; or (4) a denial, revocation or termination of a Medicare, Medicaid, or CHIP enrollment.

For purposes of § 424.519, an "affiliation" under § 424.502 includes any of the following (outlined in paragraphs (1) through (5) of the "affiliation" definition):

- A 5 percent or greater direct or indirect ownership interest that an individual or entity has in another organization.
- A general or limited partnership interest (regardless of the percentage) that an individual or entity has in another organization.
- An interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including sole proprietorships) -- either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.
- An interest in which an individual is acting as an officer or director of a corporation.
- Any reassignment relationship under § 424.80.

These provisions were established in a final rule published in the Federal Register on September 10, 2019 (84 FR 47794).[41]

[41] "Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process."

Since establishing these affiliation regulations, CMS has emphasized identifying current and past relationships between and among different providers and suppliers and, if an undue risk exists, denying or revoking the applicable provider(s). This helps protect the Trust Funds and beneficiaries from threats that certain provider associations can pose. Nevertheless, we have found three issues in § 424.519 that we believe hinder the provision's effectiveness.

One involves the 5-year lookback period. Situations have arisen where a relationship from more than 5 years ago still presents an undue risk of fraud, waste, abuse. In excluding consideration of these affiliations – and, in turn, being unable to deny or revoke enrollment under §§ 424.530(a)(13) or 424.535(a)(19) – we are effectively permitting a potentially significant fraud, waste, or abuse risk to remain. This is antithetical to our duty to protect the Medicare program.

The second pertains to the "affiliation" definition in § 424.502. While it covers several types of associations, there are other conceivably problematic relationships we have encountered in our program integrity efforts. We cited the following hypotheticals in the proposed rule:

- An individual or entity operates a small building with over 30 HHAs and hospices that list the building address as their practice location. Considering our earlier discussion of the high payment safeguard risk in such situations, the building operator might be involved with these providers in some type of fraud scheme.
- A provider had a relationship with a financial services company that had several high-level officials convicted of fraudulent activity.
- A provider hired Marketing Firm X. X had solicited beneficiaries for four DMEPOS suppliers, all of which were later revoked with a 10-year reenrollment bar.

These and other scenarios demonstrate that associations beyond those listed in the "affiliation" definition can endanger the Medicare program, for nefarious parties of all types constantly seek new means of perpetuating Medicare fraud.

The third issue also involves the "affiliation" definition, though on a narrower level – specifically, an aspect of paragraph (3) thereof warranting additional clarification. As noted, paragraph (3) addresses relationships where an individual or entity has operational or managerial control over (or directly or indirectly conducts) the day-to-day operations of another organization. (This mirrors our current definitions of "managing employee" and "managing organization in § 424.502.) As explained in the proposed rule, a recent situation arose where an individual was a medical director (Dr. A) of two providers – B and C. C was revoked from Medicare. Since a medical director is a managing employee under § 424.502, B was revoked under § 424.535(a)(19) consistent with paragraph (3) of the affiliation definition; that is, Dr. X was an individual with operational or managerial control over another entity – Providers B and C. This established the affiliation between B and C, with Dr. X as the clear link – a view that aligns not only with our longstanding interpretation of paragraph (3) but also with section 1866(j)(5) of the Act. Furthermore, we believe our position helps ensure section 1866(j)(5)'s usefulness. A provider generally acts through its owners, managers, and other personnel. If we applied paragraph (3) only to situations where a provider operates or manages another provider, we would be unable to address other cases where the real fraud, waste, and abuse risk is posed by parties affiliated with both providers. In other words, we need the ability to go within the provider organization to the operators and managers to address threats they present.

With all three issues, we believe the fraud, waste, and abuse risk itself is much more important than when the relationship triggering the risk occurred, whether the provider entity poses the risk or, instead, the managing employee, etc. Hence, we proposed the following revisions to our affiliation provisions in part 424, subpart P:

- Removing the 5-year period from § 424.519(b).
- Adding new paragraph (6) to the "affiliation" definition. This paragraph would include any marketing, business, fulfillment, financial, managerial, or beneficiary relationship.

(The "managerial" relationships in paragraph (6) would be those not otherwise falling within paragraph (3) of the "affiliation" definition.)

- Adding in paragraph (3) of the "affiliation" definition the following language between "individual or entity," and "exercises operational": "or any of its owning or managing employees or organizations,".

- In §§ 424.530(a)(13) and § 424.535(a)(19), insert the following language between "provider or supplier" and "has or has had": "or any of its owning or managing employees or organizations,".

The following is a summary of the comments we received and our responses.

Comment: Many commenters opposed our changes to the affiliation provisions. They believed it would be extremely difficult, if not impossible, to detect various affiliations: (1) from more than 5 years ago; and (2) involving the provider's owners, managers, and other affiliated parties. It could also be challenging to obtain data from more distant parties. They stated that these revisions would impose a massive reporting burden and should either be significantly delayed or not finalized.

Response: We appreciate these comments. While we understand the concerns expressed, we emphasize that affiliation data need only be reported upon a CMS request --- and CMS has, to date, never requested that a provider to do so; this is because we recognize the burden this could present to providers. In utilizing §§ 424.530(a)(13) and § 424.535(a)(19), CMS has instead relied upon its authority under §§ 424.519(i) to apply these two provisions even if the provider has not yet reported (or is not required at that time to report) the affiliation to CMS. To the maximum extent possible, we will continue this approach so as not to impose these disclosure obligations and the associated burden on providers.

Comment: Commenters maintained that regardless of whether our expanded affiliation data must be reported, there will be a substantial burden on providers because they must now research and constantly monitor all parties with whom they have or ever had an affiliation. A

commenter stated that CMS in the aforementioned September 10, 2019, final rule with comment period estimated the annual cost of this activity to be $937,500 – an amount that will be greatly increased if our proposed affiliation provisions are finalized.

Response: We disagree with these comments. Providers are under no obligation to perform this monitoring. If they choose to do so, that is an independent business decision. In addition, the cited $937,500 cost was for the compilation and reporting of affiliation information pursuant to a CMS request. It was unrelated to any internal monitoring that a provider wishes to undertake on its own volition.

Although discussed in more detail in the ICR and RIA sections of this final rule, we maintain our stance that our affiliation revisions would impose no burden on providers. This is because: (1) we do not at this time anticipate making requests for disclosures; and (2) providers are not required to undertake any form of regular research or tracking of actual or potential affiliations.

Comment: Commenters stated that if CMS finalizes its proposed affiliation changes, it should ensure that providers under §§ 424.530(c) and 424.535(e) can demonstrate termination of affiliations, managing employee relationships, or business relationships -- not simply for sanctions, exclusions, debts, or felonies of associated parties.

Response: We appreciate this comment and will consider clarifying this issue in post-final rule guidance.

Comment: Commenters expressed concern that the addition of parties and relationships to § 424.535(a)(19) and § 424.502's "affiliation" definition (and the resulting potential linkages to many different providers) could result in unwarranted revocations. A commenter stated that such downstream revocations should be prohibited under § 424.535(a)(19).

Response: We wish to assure providers that CMS reviews each potential § 424.535(a)(19) case individually, based on its own particular circumstances. This will remain so under revised § 424.535(a)(19). For this same reason, though, we cannot automatically bar these downstream

revocations; if a particular case, judged on its own facts, warrants a § 424.535(a)(19) revocation, we must be able to take action regardless of whether it is downstream.

Comment: Commenters expressed concern about the meaning of "any marketing, business, fulfillment, financial, manag-erial or beneficiary relationship" and that CMS did not define these terms. They stated that this could include virtually any party with which the provider has any dealings, no matter how slight. They maintained that legitimate providers should not be penalized for very tenuous associations or held responsible for the actions of distant parties over which the provider has no control.

Response: We note several things. First, we believe that with respect to the affiliation definition, the six types of relationships in the previously quoted language have their plain meanings. Second, our addition of paragraph (6) to the affiliation definition does not mean that every such relationship will lead to the provider's denial or revocation if a disclosable event exists. We acknowledge that many of these affiliations do not involve an undue risk of fraud, waste, and abuse. As previously mentioned, though, we have seen instances where they do, and for this reason we believe our affiliation expansions are warranted. Third, and in a similar context, the main issue is not: (1) whether the provider could control or even knew of the actions of the other party; or (2) the organizational distance (or tenuousness or materiality of the relationship) between the provider and the affiliate. It is instead the risk the affiliation poses to the Medicare program. This is the main test for whether §§ 424.530(a)(13) and 424.535(a)(19) should apply in a particular situation and is consistent with the language in section 1866(j)(5) of the Act.

All this said, we agree with commenters' concerns about including beneficiary relationships within new paragraph (6) of the "affiliation" definition. We are therefore not finalizing said inclusion.

Comment: Commenters stated that CMS should: (1) limit the definition of "affiliation" to relationships that either have a meaningful nexus to Medicare program integrity or involve a

material connection between the provider on the one hand and the other party and their disclosable event on the other; (2) define the scope of reportable affiliations; (3) require an individualized determination that the affiliation presents a current and undue risk; (4) establish reasonable due diligence expectations that reflect what providers can realistically know and verify through ordinary business practices; and (5) promulgate required factors and thresholds (such as common ownership and control). Some commenters requested that CMS explicitly exclude from reporting (and from potential denial or revocation) all routine commercial, patient care, referral, and vendor relationships. Other associations that commenters stated should be exempted included, but were not limited to, manufacturer, wholesaler, insurance, banking, accreditation, and other ordinary-course dealings. Additional commenters stated that the "affiliation" definition, the associated reporting requirements, and CMS' overall oversight of potentially problematic relationships should be restricted to more proximate associations involving, for example, ownership interests, governance authority, operational control, financial control, coordinated conduct, and program integrity threats. Without such parameters, they maintained, legitimate and routine business transactions could become reportable affiliations.

Response: While we appreciate these comments, we cannot exempt certain categories of affiliations beforehand simply because they might on the surface appear to lack a "meaningful nexus" or other significant connection, or do not meet a materiality (or similar) threshold. There are many types of affiliations – both involving close relationships and those more distant – that can present a program integrity threat. Our obligation to protect the Medicare program consequently requires that we broaden our affiliation definition to include more relationships. Indeed, if we restricted this definition in the manner the commenters requested (for example, ownership, close nexus, financial control, etc.) the hypothetical scenarios previously outlined would remain unaddressed, conceivably harming the Trust Funds and beneficiaries.

We address the scope of the affiliations within the definition of that term. If the commenters are referencing the scope of the "any marketing, business….", language, we restate

that the categories of relationships within this term will – for purposes of §§ 424.530(a)(13) and 424.535(a)(19) – have their plain meaning.

While we are somewhat unclear as to the commenters' reference to "individualized determinations", we emphasize that – as with all §§ 424.530(a)(13) and 424.535(a)(19) decisions – CMS will carefully and thoroughly consider the facts of each case and only take action when justified under the circumstances.

We respectfully decline to establish a "due diligence" threshold for applying §§ 424.530(a)(13) and 424.535(a)(19) because, again, we do not at this time anticipate making disclosure requests, and providers are not required to conduct internal research of possible affiliations.

Regarding factors and thresholds, we repeat our earlier concerns about the restraints that fixed, inflexible criteria impose on our ability to assess each case based its own unique circumstances.

Comment: Numerous commenters opposed the removal of the 5-year lookback period. They stated, in general, that this would increase the burden and complexity of reporting without helping to identify fraud or promote program integrity.

Response: We respectfully disagree. We refer the commenters to our prior statements concerning disclosure requests, and we stress that affiliations older than 5 years can still present a current risk of fraud, waste, or abuse.

Comment: Commenters stated that before denial or revocation occurs, providers should be able to correct or add affiliation data that was inadvertently erroneous or missing in their disclosure submission.

Response: We refer the commenters to our prior statements regarding data disclosure.

Comment: Some commenters stated that CMS should be able to identify affiliations and disclosable events via internal systems without requiring providers to report this information. They noted that providers often will not have access to (or be able to obtain from associated

parties) certain affiliation data. Accordingly, provider disclosure of this data should not be necessary.

Response: While CMS may request submission of provider affiliation data at any time, we agree with the commenters' general position and will, to the extent feasible, utilize existing data when making §§ 424.530(a)(13) and 424.535(a)(19) determinations.

Comment: A commenter stated that CMS should request affiliation disclosures involving specified disclosable events and then evaluate whether an affiliation poses an undue risk (akin to the processes CMS outlined in the aforementioned September 10, 2019, final rule). The commenter believed that a revocation process where CMS assumes affiliations pose undue risk without some reasonable fact-finding in which CMS solicits information from the provider with the affiliation is punitive and unnecessary.

Response: We appreciate the commenter's feedback but note several things. First, and as stated, although we retain the right to do so under § 424.519, we do not anticipate requesting affiliation data due to the provider burden. Second, CMS does not revoke providers under § 424.535(a)(19) without having information on file – the overwhelming majority of which is already on file with CMS based on the provider's various Form CMS-855 submissions and is linked in PECOS to other providers' submissions (for instance, shared managing employees) – demonstrating an undue fraud, waste, and abuse risk. Third, we believe that whether the data is reported via a specific request under § 424.519(b) or is currently on file based on prior submissions or other information is less important than our need to alleviate provider burden.

After reviewing the comments received, we are finalizing our proposed revised affiliation provisions with two modifications, both of which involve proposed paragraph (6) of the "affiliation" definition. The first, as mentioned, is the removal of beneficiary relationshipstherefrom. The second involves adding the following language at the end of said paragraph: "whether direct or indirect (including, for example, common use of the same organization to perform these services." In our view, this additional language – which we do not

believe is different in intended scope from what we proposed and is primarily a clarification -- will help stakeholders more clearly understand the concepts and examples outlined in the proposed and final rules. Such transparency is critical given: (1) the concerns that commenters expressed; and (2) what we perceived to be some provider confusion as to the meaning and scope of certain aspects of our proposal.

In closing, we do not believe that the non-finalization of our proposed changes to §§ 424.530(a)(6), 424.530(a)(7), and 424.535(i) is inconsistent with our finalization of revisions to some of our affiliation provisions. This is because they can address somewhat different factual situations; for example, proposed §§ 424.535(i) referenced a denied provider potentially having its other enrollment applications revoked, whereas our affiliation changes focused more on the wider question of undue risk of fraud, waste, and abuse involving certain relationships.

8. Private Equity Companies (PECs) and Real Estate Investment Trusts (REITs)

In a November 17, 2023, final rule published in the **Federal Register** titled, "Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities; Medicare Providers' and Suppliers' Disclosure of Private Equity Companies and Real Estate Investment Trusts" (88 FR 80141), we implemented section 1124(c) of the Act. This provision -- promulgated in § 424.516(g) -- requires SNFs to report detailed information about their ownership, management, and associated parties. The regulation's purpose was to gain further insight into the SNF's operators and affiliates – a vital need given concerns about nursing home quality of care.

We expressed particular concern in the November 17, 2023, final rule about the prevalence of PEC and REIT ownership of SNFs. We cited reports indicating links between such ownership and substandard SNF care, primarily due to these entities' emphasis on maximizing profits.[42] Hence, we stated in that final rule our intention to revise the Form CMS-

[42] 88 FR 80144.

855A enrollment application [43] to require all certified providers and certified suppliers (not simply SNFs) that complete said form to identify whether an entity they have disclosed thereon is a PEC or a REIT.[44]

The issue goes further, though. PECs and REITs are involved in other health care sectors, too, including physician practices. For instance, the May 2025 edition of the American Medical Association's (AMA) Journal of Ethics (JOE) noted the continued increase in PEC ownership of providers and suppliers. The AMA JOE website (via which the May 2025 edition could be accessed) stated that private equity "aim(s) to maximize profitability while minimizing long-term holdings in such investments . . . One reason private equity investment in the health sector deserves close ethical attention is that private equity firms are, generally, not interested in managing patient panels, clinician personnel, or making service delivery streams work for patients. Another reason is that influx of private equity investment in health care tends to consolidate markets for health services, undermining competition and driving up costs for patients".[45] Various articles in the May 2025 edition expounded on this theme. As noted in the proposed rule, such statements included:

- "Physicians have fiduciary duties to respond with care to patient's clinical needs and vulnerabilities, whereas private equity companies have no such ethical or legal duties to patients and strive to maximize financial returns for their investors."[46]

- "Studies on the impact of PE investment in health care have increased in the last decade, with the preponderance of data suggesting that PE acquisitions are associated with reduced staffing levels and on-hand medical supplies. A 2023 systematic review concluded that PE ownership was associated with increased costs to payers and patients." [47]

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[43] Medicare Enrollment Application – Institutional Providers (OMB Control No. 0938-0635)
[44] 88 FR 80146.
[45] https://journalofethics.ama-assn.org/issue/private-equity-health-care.
[46] Lucy Xu, MD, and Matthew R. Naunheim, MD; "What Are Physicians' Duties to Patients When They Sell Their Practices?"; May 2025.
[47] Ibid.

- "Private equity firms' acquisition and management of health service delivery entities, such as specialty physicians' practices, have been associated with increased cost and diminished quality of care."[48]

- "Private equity margin maximization and profit-making strategies focus on acquisition, short-term ownership, and sale of health care entities, including residency program opportunities. PE ownership durations generally have 3 purposes: reduce staff, sell assets, and refinance debt."[49]

As we explained in the FY 2024 Inpatient Prospective Payment System Long-Term Care Hospital Prospective Payment System proposed rule[50], given the linkage between PEC and REIT ownership and a decline in nursing home quality, we believed it was critical to collect this information from all providers and suppliers that complete the Form CMS-855A, not simply SNFs. Doing so would enable us to: (1) determine whether a similar connection exists with respect to non-SNF providers and suppliers; and (2) help us take measures to improve beneficiary quality of care to the extent such connections exist.[51]

In light of the foregoing, we believe CMS should ascertain the prevalence of PEC and REIT involvement with Medicare Part B suppliers no less than with Part A providers such as SNFs. This is a Medicare-wide issue. Consequently -- and like our approach in the November 17, 2023, final rule – we announced in the CY 2027 HH PPS proposed rule our intention to revise the following provider enrollment applications to require all suppliers completing these forms to identify whether any organizations disclosed thereon are PECs or REITs:

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[48] Cheryl Erwin and Sheryl Tatar Dacso; "When and How Should Patients Be Informed About Clinicians' or Organizations' Sale of a Clinical Practice to a Private Equity Buyer?" May 2025.
[49] Mark Varvares, MD, et al.; "Should Private Equity Firms Own Residency Slots?" May 2025.
[50] "Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership", published in the Federal Register on May 1, 2023.
[51] Ibid.

- Form CMS-855B (Medicare Enrollment Application - Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938-1377).
- Form CMS-855S (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938-1056).
- Form CMS-20134 (Medicare Diabetes Prevention Program (MDPP) Suppliers).

We note that we are relying upon sections 1102, 1866(j), and 1871 of the Act (rather than section 1124(c) of the Act) as authority for this proposal.

As with the November 17, 2023, final rule, our intended form revisions would not involve regulatory changes.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Some commenters supported our planned change, believing that transparency regarding owners of suppliers is important.

Response: We appreciate the commenters' support.

Comment: Several commenters expressed concern that CMS' intended change will require all suppliers that complete the Forms CMS-855B, CMS-855S, and CMS-20134 to now submit the same extensive data that section 1124(c) of the Act requires SNFs to provide on the Form CMS-855A. That is, they believed CMS was attempting to implement section 1124(c) (which only applies to SNFs) for Part B suppliers. Accordingly, they concluded that CMS lacks the statutory authority for its data collection.

Response: While we sincerely appreciate these comments, they are incorrect. We are not seeking to apply section 1124(c) to Part B suppliers or to require suppliers to submit the data referenced in section 1124(c). As we did when revising the Form CMS-855A in 2024, we plan to simply add a checkbox to Forms CMS-855B, CMS-855S, and CMS-20134 by which the supplier identifies whether a reported owner, managing organization, etc. is a PEC or REIT. This change would have no relation to section 1124(c) of the Act and would not require other

provider or supplier types to complete the SNF attachment to the Form CMS-855A enrollment application or a similar attachment.

We also remind stakeholders that we were not relying upon section 1124(c) of Act in establishing the Form CMS-855A PEC and REIT checkboxes. We were instead utilizing our authority under section 1866(j) of the Act. We are doing the same here regarding our checkbox additions to the Forms CMS-855B, CMS-855S, and CMS-20134.

Comment: Some commenters maintained that our change would revise these forms without the public having an opportunity to comment thereon.

Response: Our Form CMS-855B, CMS-855S, and CMS-20134 revisions would be facilitated through the Paperwork Reduction Act (PRA) process. Stakeholders will have a 60-day period in which to comment on the revisions, followed by another 30-day comment period.

Comment: Several commenters stated that CMS in the proposed rule did not adequately justify the need for these checkboxes: (1) with respect to REITs; and (2) on CMS' Part B enrollment forms. They contended that there is insufficient evidence that REITs (and, for that matter, PECs) present program integrity risks to Medicare Part B health care and beneficiaries. They also stated that any collection of this data would unfairly impugn REITs and PECs, especially since such entities provide considerable benefit. They requested a CMS statement that PEC or REIT ownership (or profits stemming from) will not, by itself, result in a supplier's revocation, denial, higher-risk designation under § 424.518, etc.

Response: Our proposal was not intended to impugn PECs and REITs but simply to address the previously expressed concerns about their financial participation in the health-care sector. The checkboxes will give us a better understanding of the scope of such with respect to Medicare Part B; the reports we cited in the proposed rule indicate significant private equity involvement with physician practices, which complete the Form CMS-855B. The commenters noted that no specific examples of REIT involvement with Part B suppliers were included in the

proposed rule. While true, the lack of provider enrollment data on REIT Part B prevalence is precisely why the REIT checkbox is needed given the aforementioned issues.

As of the date of this final rule, CMS does not have the regulatory authority to revoke a provider or raise its § 424.518 risk-level based solely and exclusively on the fact that it has PEC or REIT ownership.

Comment: Several commenters questioned how CMS will use this information and for what purposes.

Response: Like with the checkboxes on the Form CMS-855A, CMS will use it to examine the prevalence of private equity and REITs in the health-care sector in light of the quality of care concerns.

Comment: Several commenters stated that CMS must define the terms "private equity company" and "real estate investment trust" – and provide clear reporting instructions (with examples) – on the three forms it intends to revise.

Response: CMS will include on these forms the same PEC and REIT definitions and instructions listed on the Form CMS-855A. These definitions are consistent with those in § 424.502.

Comment: Several commenters disagreed with the current definitions of "private equity company" and "real estate investment trust." They believed the definitions should be revised to reflect the general understanding of PECs and REITs throughout the business and financial communities.

Response: As we did not propose to revise these definitions, we believe these comments are outside the scope of this final rule.

Comment: Several commenters stated that CMS should: (1) limit providers' reporting responsibilities to PEC and REIT data that can reasonably be identified (particularly a party's REIT status, which the commenters contended can be difficult to obtain); (2) furnish provider

education, guidance, and examples; and (3) delay implementation to give providers time to understand the new requirements.

Response: Regarding the first recommendation, we refer commenters to our prior statements regarding a "due diligence" standard. CMS will, as deemed appropriate, issue guidance on the PEC and REIT checkboxes but respectfully declines to postpone these reporting requirements due to the importance of the information in question.

Comment: A commenter seemingly urged CMS to ensure that: (1) institutional and minority PEC and REIT investors are not inadvertently captured via our planned form changes; and (2) the reporting thresholds are proportionate.

Response: Although we were somewhat uncertain as to the commenter's specific requests, we again state that the provider must indicate via the planned checkboxes whether each disclosed organizational owning or managing party reported on the enrollment application is a PEC or REIT. There are no exceptions for minority or institutional parties, for sections 1124 and 1124A of the Act do not exempt providers from disclosing minority and institutional owners.

Comment: A few commenters stated that CMS should outline in this final rule the ICR burden on Part B suppliers in reporting REIT information, which the commenters believed would be excessive given the potential challenges in securing it.

Response: Akin to our approach in the aforementioned November 17, 2023, final rule, this burden estimate will be addressed in the PRA packages for the Forms CMS-855B, CMS-855S, and CMS-20134 rather than the final rule. Stakeholders will have the opportunity to comment on this projection as part of the PRA process.

After reviewing the comments received, we intend to proceed with proposed revisions to the three aforementioned enrollment applications to collect PEC and REIT data. We welcome additional stakeholder feedback during the PRA notice-and-comment process.

9. Managing Employees (§ 424.502)

The term "managing employee" is defined in § 424.502. It means, in part, a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider. Managing employees have long been required to be disclosed on the provider's Medicare enrollment application. Since managing employees sometimes have as much or more influence over a provider's daily operations as an owner, we must know whether such persons present risks to the Trust Funds.

Yet the risks are not strictly financial. We have repeatedly noted over the years our role in protecting the health and safety of Medicare beneficiaries. From a provider enrollment perspective, part of this involves our current collecting of information on certain medical professionals within a provider organization. This includes, for example: (1) IDTF supervising physicians, interpreting physicians, and technicians; (2) ordering OTP personnel; and (3) hospice and SNF medical directors. The purpose is to ensure that such persons not only pose no payment safeguard threats but also are qualified for their roles (such as meeting State licensure requirements). Unqualified or unvetted medical personnel can harm Medicare patients.

So great is our concern about this matter that we believe additional clinical parties should be disclosed on the provider enrollment application. Hence, we proposed to expand upon our aforementioned inclusion of hospice and SNF medical directors within the "managing employee" definition. The following persons would be added:

- Medical directors (not merely those at SNFs and hospices)
- Clinical directors
- Departmental heads (for example, a hospital's chief of cardiology)
- Supervising physicians (not simply those at IDTFs)
- Nursing directors
- Alternate administrators
- All other clinical personnel that meet the "managing employee" definition.

We noted four things in the proposed rule. First, these categories apply to all provider and supplier types, including SNFs and hospices. Second, we believe the persons in these categories already qualify as "managing employees" and should have always been reported. They clearly have direct or indirect control of the provider's day-to-day operations, and the fact that they are clinical personnel (rather than administrative) is irrelevant for purposes of determining whether a person is a managing employee. Our inclusion of them within the "managing employee" definition is, in large part, a reminder to stakeholders that clinical staff must be disclosed if the definition is met. Third, these seven new bulleted categories do not establish any minimum threshold for disclosure; for example, even if an individual has less influence than a departmental head, the person must still be reported as long as the managing employee definition is met. Fourth, and on the other hand, this does not mean that every clinical employee regardless of influence must be reported. Disclosure is only required if the person is a managing employee.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Many commenters opposed our proposed revision on several grounds. First, they did not believe these persons qualify as managing employees simply because of their title – with some commenters maintaining that they did not qualify at all because they do not fall within the generally understood meaning of "managing employee"; they seemingly contended that the definition is restricted to administrative and non-clinical officials with very high-level leadership and supervisory authority over the provider's entire operation. Second, they stated that the burden of reporting these individuals as managing employees would be enormous, especially for larger providers with many clinical employees. Third, and in a similar vein, they disagreed with our assertions that (i) these individuals should always have been reported as managing employees and (ii) there would thus be no additional reporting burden (as we stated in the ICR and RIA sections of the proposed rule). Fourth, they maintained that our use of phrases such as

"additional clinical parties" and "expand upon" when describing our change in the proposed rule was not only a contradiction but also a *de facto* CMS admission that: (i) these persons never qualified as managing employees; (ii) our revision constitutes a new reporting requirement; and (iii) CMS must calculate the reporting burden accordingly.

Response: We respectfully disagree with all these comments. We believe the clinical parties listed in our proposed revised definition clearly are managing employees. Even if one assumed that a person's title is not absolutely and conclusively dispositive as to whether they meet the "managing employee" definition, we have always viewed it as by far the strongest indicator of such. More importantly, we have long interpreted this definition much more broadly than the commenters apparently have. It has never been limited to the highest administrative officers in the organization, it has never excluded officials who oversee only certain parts or offices of a provider, and we have never indicated that clinical personnel do not fall within its scope. Indeed, the definition encompasses not only those who exercise "operational or managerial control over" the provider's day-to-day operations but also persons "who directly or indirectly conduct" said operations. This covers – and has long covered -- a wide range of parties; as an illustration, a clinical department head at a local hospital, in our view, unquestionably participates in conducting the provider's day-to-day operations. Given all this, we retain our stance that these individuals should always have been disclosed.

The phrases "additional clinical parties" and "expand upon" were merely references to our listing of more officials within the definition as a reminder that they qualify as managing employees. It was neither a contradiction nor an indication that they never before qualified, for we expressly stated in several places in the proposed rule that they already did. In short, it was an addition of language, not an addition or expansion of scope – two very different things, especially since the actual definition itself is not changing but only the listing of parties for clarity purposes. It was no different than our 2023 revision of this definition to list SNF and

hospice medical directors and administrators;[52] this, too, was not an expansion and, we note, generated no public comments during the rulemaking process claiming an additional burden.

We refer commenters to the ICR section of this final rule for a discussion of burden.

Comment: Commenters stated that CMS should apply a due diligence standard to the reporting of clinical and other managing employees. So long as the provider made a reasonable effort to obtain all managing employee data, they believed this should be sufficient for CMS – and that CMS should take no denial, revocation, deactivation, or other measure against the provider. Several commenters believed this approach would comport with CMS' sub-regulatory guidance regarding the reporting of SNF additional disclosable party (ADP) information -- whereby, the commenters maintained, SNFs can outline for MACs its "maximum feasible" but unsuccessful efforts to obtain ADP data.[53]

Response: We disagree with these comments. While we understand it can occasionally be challenging to secure certain managing employee data, CMS has never had a "best efforts" or similar allowance for this information. It must be reported, and CMS can take action if it is not. The SNF guidance comparison is, most respectfully, somewhat fallacious because the "maximum feasible efforts" reference therein: (1) is limited to ADP data and does not apply to the reporting of managing employees; and (2) in no way means that CMS automatically accepts the failure to report certain ADP data so long as the provider made said efforts.

Comment: Several commenters stated that clinical directors, nursing leaders, department heads, and other clinicians may supervise patient care but do not necessarily exercise ownership-level or financial control and may have limited managerial authority over the provider.

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[52] "Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements" (88 FR 77676), published in the **Federal Register** on November 13, 2023.

[53] https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos.

Response: For reasons already stated, we believe the clinical parties identified in our proposed definition revision clearly qualify as managing employees. We add that one need not exercise ownership-level or financial control or wide-ranging, high-level managerial authority to fall within the very broad "managing employee" definition.

Comment: Commenters stated that the proposed "managing employee" definition should be significantly narrowed while containing a clear, minimum threshold for disclosure. Some recommended a threshold of actual decision-making or other substantial authority over, for instance, the provider's organizational operations and decision-making, financial matters, billing, policy, etc. A few added that clinical personnel with limited supervisory duties or who engage in temporary coverage should be excluded from the "managing employee" definition.

Response: We believe both the existing and proposed versions of the definition are plain on their face as to who must be reported. If the individual falls within the definition, they must be disclosed.

Comment: Commenters stated that a person's authority – not their title – should determine who is or is not a managing employee. They maintained that: (1) providers, not CMS, are in the best position to make this determination and that CMS should defer to providers on the matter; and (2) CMS should expressly state that the individuals CMS proposed to list in the "managing employee" definition are not managing employees based solely on their title.

Response: As stated previously, we believe titles are an extremely heavy indicator of one's authority, and, accordingly, that the clinical personnel in question are indeed managing employees; hence, we cannot make the unequivocal statement the commenters request. Moreover, if we deferred the reporting of managing employees entirely to the provider's judgment and prohibited ourselves from even questioning whether all the provider's managing employees were disclosed, providers would have every incentive to avoid reporting certain individuals.

Comment: Several commenters stated that the current "managing employee" definition only lists SNF and hospice medical directors. They implied that these were therefore the only clinical managing employees that traditionally had to be reported.

Response: We respectfully disagree. Our inclusion of SNF and hospice medical directors: (1) was merely a reminder that these persons are managing employees; and (2) never implied that these were only clinical personnel who needed to be disclosed.

Comment: A commenter stated that if CMS finalizes its proposed revised definition, it should increase the timeframe for reporting managing employee changes.

Response: We respectfully disagree. Such changes have long been required to be disclosed within 30 days given this data's vital importance to program integrity.

Comment: Several commenters stated that if CMS finalizes its proposal, it should: (1) provide clear examples of individuals who would and would not qualify as managing employees within different provider types and organizational structures; (2) establish an appropriate implementation timeframe and grace period before initiating enforcement actions, including giving providers time to review and update their enrollment records; and (3) hold providers harmless for failing to report individuals who -- under what they believe is CMS' revised interpretation -- would now be considered managing employees but were not previously understood to fall within the regulatory definition. Other commenters questioned whether all providers must submit enrollment applications to report clinical managing employees who were not previously disclosed.

Response: CMS will, if appropriate, issue guidance regarding the commenters' first request and the last question. However, we cannot commit to a "hold harmless" exception or a delayed implementation because, again, these clinical parties have long met the "managing employee" definition. (This is also why we disagree with the commenters' assertion that our proposal constitutes a "revised interpretation" of the definition.)

Comment: A few commenters stated that CMS' revision to the "managing employee" definition is unnecessary because many of these individuals are already disclosed to CMS via other means, such as certification or accreditation.

Response: We respectfully disagree because provider enrollment requirements – including the reporting of managing employees – are separate and distinct from other requirements (such as CoPs, accreditation requirements, etc.) and must be individually met.

Comment: A commenter urged CMS to clarify that community pharmacy personnel are managing employees only if they exercise actual operational or managerial control over the DMEPOS supplier's day-to-day operations and not merely because they (1) hold a clinical license; (2) supervise a pharmacy practice at a location; or (3) serve as a pharmacist-in-charge.

Response: While CMS cannot establish or commit to blanket "managing employee" exemptions in this final rule, we will, as appropriate, issue guidance on the matter the commenter raised.

After reviewing the comments received, we are finalizing our proposed revised "managing employee" definition without modification.

10. Definition of "Operational" (§ 424.502)

a. Background and Provisions

Per § 424.510(d)(6), a provider must be "operational" to obtain Medicare billing privileges. "Operational" is defined in § 424.502 as meaning the provider meets all of the following:

- Has a qualified physical practice location
- Is open to the public for the purpose of providing health care related services
- Is prepared to submit valid Medicare claims
- Is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) to furnish these items or services.

The "operational" definition's core purpose is to help confirm that the provider is bona fide. Unfortunately, we have discovered instances where a provider appears to meet the definition but turns out to be a fraudulent operation. We believe stronger, broader, and clearer components of the definition would better ensure the provider's operational status and legitimacy and assist us in preventing sham providers from entering Medicare. Therefore, we proposed the following changes to our definition.

First, we proposed an opening sentence to the definition that would read "*Operational* means (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) the provider or supplier meets all of the following:". The parenthetical -- which is in the current definition --– would elucidate for stakeholders that: (1) certain components of our revised definition may not apply to all provider types; and (2) CMS would account for this in applying the definition.

Second, the previously referenced four bulleted components of the existing definition would be designated as new paragraphs (1) through (4) therein. This would improve the definition's readability. (We did not propose changes to the first requirement concerning a qualified physical practice location.)

Third, proposed paragraph (2) would explain that the requirement that the provider "[i]s open to the public for the purpose of providing health care related services" includes, but is not limited to, all of the following:

- The provider's location is fully accessible to all patients and lacks safety hazards.
- The provider's hours of business are sufficient to regularly serve patients.
- Medicare beneficiaries can contact and locate the provider's location based on publicly available information (for example, the Internet).

We believe these three requirements would help verify the provider's compliance with paragraph (2). In our view, a provider whose location threatens patient safety, is inaccessible to

beneficiaries, or cannot be found via public means raises doubts as to whether the location is truly "open."

For purposes of the "operational" definition, we proposed to define "accessible" as meaning both of the following:

- The provider is located in an area and a building that patients can enter with reasonable ease.
- The location is compliant with all Federal Americans with Disabilities Act regulations and all applicable and equivalent State and local laws.

These requirements would make clear that providers must – from an accessibility standpoint -- accommodate beneficiaries with disabilities and those without. We noted in the proposed rule that the phrase "located in an area" does not mean the provider's location must be, for instance, within a short drive or a mere 5-mile radius of the beneficiary's home. "Area" in this context would mean the location's immediate vicinity, such as the parking lot or a larger, multi-building complex in which the provider has its office. Also, nothing in the first bullet would prevent the provider from having security locks or security personnel between its office(s) and the building entrance. It instead references the beneficiary's ability to enter the building once access is granted (for instance, security staff signs in the beneficiary and directs the beneficiary to the provider's office).

Third, we proposed in new paragraph (3) to change "prepared" to "prepared and able". If the provider lacks the administrative or logistical ability to submit valid claims -- even if it may be "prepared" to do so – we do not believe the provider can be considered operational for purposes of Medicare enrollment.

Fourth, and similar to proposed paragraph (2), proposed paragraph (4) would include the following additional requirements concerning the "properly staffed, properly equipped…." criterion:

- Provider staff must be qualified (such as licensed or certified if required under State law) to perform their health care-related functions.

- Equipment must be functional, appropriate for the services and items the provider intends to furnish, and in sufficient quantity to provide these items and services.

- Appropriate medications for the services and items the provider intends to furnish and in sufficient quantity to provide these items and services.

We also believe that operationality should require more than proposed paragraphs (1) through (4), particularly with respect to administration, safety, and patient care. Hence, we proposed in new paragraph (5) that operationality requires the provider to have adequate written policies and records regarding its operations, such as, but not limited to, procedures for patient care, patient safety, medical and patient recordkeeping, and general administration.

We further stated in the proposed rule that the wide variety of provider types and scenarios might at times require us to consider information not addressed in our revised definition in order to determine the provider's operationality. Suppose a case arises where most of the definition's requirements are inapplicable to the provider, but this leaves insufficient remaining criteria for us to determine operational status. We believe we must have the ability to contemplate other information in this and other cases. We hence proposed an additional (though un-numerated) paragraph at the end of our revised definition stating that CMS may consider any information in determining whether the provider is operational.

The following is a summary of the comments we received on this proposal and our responses.

Comment: Several commenters sought CMS confirmation that certain provider types, such as HHAs, would not be required to meet all the "operational" criteria due to those providers' particular characteristics. Another commenter requested that CMS not: (1) interpret "open to the public" to require a home health administrative office to operate as a patient-facing clinical site; (2) require an HHA to stock medications or equipment that it does not lawfully

dispense, own, or routinely furnish; or (3) rely on an unlimited "catch-all" category (referenced previously) allowing CMS to consider "any information" without explaining how that data relates to "operational" regulatory requirements.

Response: Although we are unable in this rule to formally exclude specific provider types from various requirements in the "operational" definition, we recognize that certain provisions may not apply in all instances to all providers and suppliers – hence our "as applicable" reference in the proposed revised definition. We will keep this in mind -- as we do with the current "operational" definition – when enforcing our revised definition. Regarding the "catch-all" category, this is necessary to account for situations not explicitly addressed within the "operational" definition.

Comment: Several commenters supported our proposed revised definition of "operational." A commenter in particular agreed that providers should have adequate written policies and records regarding their operations, including patient care and patient safety.

Response: We appreciate the commenter's support.

Comment: Some commenters requested CMS to: (1) exempt State surveyed and accredited providers and suppliers from the "operational" requirement; or (2) rely on State survey or accreditation findings when determining operationality so as to avoid duplicity and inconsistent requirements. If CMS does neither, a few commenters stated that CMS should explain how: (1) the expanded definition will apply to institutional providers already subject to Federal and State oversight; and (2) overlapping State survey and operationality requirements will be reconciled before a denial or revocation occurs.

Response: We respectfully decline the commenters' first two requests. Again, provider enrollment requirements – such as § 424.510(d)(6) – are separate from State survey and accreditation requirements. The former must be met even if the provider is surveyed or accredited; this has been the case for decades. Insofar as the final two comments, we are respectfully unclear as to the guidance the commenter seeks. We can only reiterate that State

survey, accreditation, and other State and Federal oversight requirements are separate from our consideration of whether a provider is operational.

Comment: Several commenters recommended that CMS issue guidance and examples regarding what does and does not constitute "operational" status under our revised definition.

Response: To the extent we deem necessary, we will release guidance on its expanded definition of "operational."

After reviewing the comments received, we are finalizing our proposed revised "operational" definition without modification. We are making one technical correction to our regulatory text, though. We mentioned previously that we are retaining the requirement that the provider have a "qualified physical practice location." This has been a requirement for decades. Yet paragraph (1) of the proposed revised definition did not include the word "physical", even though it was intended. We are including it in paragraph (1) in our final regulatory text.

11. Signage (§ 424.510(f))

Sections 424.57(c)(7)(i)(D) and 410.33(g)(14)(ii) require DMEPOS suppliers and IDTFs, respectively, to maintain a permanent visible sign in plain view posting their normal hours of operation. The former adds that if the supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building (or the hours can be posted at the entrance of the supplier). We proposed in new § 424.510(f) to expand this requirement to include all providers and suppliers; § 424.510(f) would mirror the current language of § 424.57(c)(7)(i)(D). This would assist beneficiaries and site visit personnel in locating the provider's business, something that has occasionally proven difficult because the location contains no signage. To ensure consistency, we would also revise § 410.33(g)(14)(ii) to duplicate the language in proposed § 424.510(f).

Consistent with our proposed revisions to the definition of "operational", however, § 424.510(f) is not intended to supersede any other Medicare requirements regarding signage. Section 424.510(f) is strictly an enrollment requirement. In addition, we recognize that our

proposed signage requirement may not be practicable in all circumstances. This could be due to, for instance, the type of provider involved, its particular business circumstances, etc. Thus, we proposed the following exceptions to the signage requirement:

- The provider shares office space with another provider (for example, physicians in a group practice sharing a common suite, though the group itself must have signage).
- The provider treats patients in the patients' homes.
- The provider treats patients in the provider's home and only uses the provider's address for administrative purposes.
- The provider performs telehealth services from home.

The following is a summary of the comments we received on this proposal and our responses.

Comment: A number of commenters opposed our proposed requirement, believing it would, in some cases, be burdensome and operationally infeasible for certain provider and supplier types; for example. providers located in large office buildings may be unable to maintain signage due to space limitations, building policies, etc. The commenters accordingly recommended several modifications to our proposal. These included but were not limited to: (1) treating the signage requirement as met if the provider is identifiable via publicly available means, such as a building directory or website; (2) permitting shared or centralized signage for providers in multi-tenant buildings, health system campuses, or similar facilities; (3) clarifying that a periodic signage lapse due to matters outside the provider's control (such as construction or natural disaster) -- or minor signage violations per a materiality standard -- will not result in an adverse CMS finding; (4) limiting CMS enforcement to corrective action by allowing the provider time to remedy the issue (after CMS notification) before denying, revoking, or deactivating the provider; (5) exempting field-based and privacy-sensitive behavioral health sites from the signage requirement; and (6) adding more regulatory exceptions to the signage

requirement, perhaps based on provider type and potentially including hospitals, HHAs, telehealth providers, and providers that furnish services in beneficiaries' homes.

Response: We appreciate these comments and respond as follows:

We respectfully disagree with the commenters' first and second recommendations. We do not believe a public directory or shared signage is an adequate substitute for individual, provider-specific signage; indeed, the former would completely undercut the need for the latter. We also must decline the commenters' third and fourth requests based on our earlier explanations that: (1) any degree of non-compliance still involves non-compliance; and (2) a mandatory pre-appeals cure period could reduce providers' willingness to maintain constant compliance, knowing that they can always correct the problem later. Regarding the fifth and sixth, we are unable to grant additional provider type exceptions in this final rule without further review of the issue. Nonetheless, we will monitor the implementation of § 424.510(f) and, if need be, consider future rulemaking to address.

Comment: Several commenters stated that CMS should deem § 424.510(f) as satisfied if the provider's signage complies with State survey, licensure, local, and other requirements.

Response: We respectfully disagree because Medicare enrollment requirements are – and have always been – separate and distinct from State and local requirements. Compliance with the latter does not mean automatic compliance with the former.

Comment: A few commenters questioned (1) how § 424.510(f) applies to institutional providers that are part of campuses or large medical complexes; (2) what type of signage is acceptable in such cases; and(3) what constitutes "normal business hours" and "visible business signage".

Response: CMS will, as applicable, issue public guidance on these topics as well as others concerning the signage requirement.

Comment: A few commenters stated that when enforcing § 424.510(f), CMS should account for situations such as (but not limited to) landlord restrictions, building types, local

ordinances, or others than might prevent full compliance through no fault of the provider. A commenter requested that CMS explicitly state in the regulatory text that § 424.510(f) may not apply in all situations.

Response: We respectfully decline to add the final commenter's requested statement, for it could give the impression that CMS will grant exceptions in every case where the provider claims it cannot meet § 424.510(f) due to factors outside its control. This said, we recognize that atypical situations involving signage compliance may occur based on the facts involved. CMS will keep this in mind when applying§ 424.510(f)'s requirements.

Comment: A commenter supported our proposed exceptions to the signage requirement.

Response: We appreciate the commenter's support.

After reviewing the comments received, we are finalizing our proposed signage requirements without modification.

12. Retention and Furnishing of Documentation (§ 424.516)

We explained previously that under § 424.516(f)(1), providers and suppliers that furnish covered ordered, certified, referred, or prescribed Part A or B services, items or drugs must:

- Maintain the documentation described in § 424.516(f)(1)(ii) for 7 years from the date of service; and
- Upon CMS' or a Medicare contractor's request, provide access to that documentation.

The documentation described in § 424.516(f)(1)(ii) includes written and electronic documents (including the NPI of the physician or, when permitted, other eligible professional who ordered, certified, referred, or prescribed the Part A or B service, item, or drug) relating to written orders, certifications, referrals, prescriptions, and requests for payments for Part A or B services, items or drugs.

Section 424.516(f)(2) contains a similar documentation retention and submission requirement for physicians (or, when permitted, eligible professionals) who order, certify, refer, or prescribe Part A or B services, items or drugs. Section 424.516(a)(10), meanwhile, permits

revocation if the provider or supplier fails to comply with the documentation and CMS access requirements in § 424.516(f).

In general, § 424.516(f) helps CMS determine, for instance, whether the service was reasonable and necessary, whether fraud, waste, or abuse is involved, and whether the provider is compliant with Medicare requirements.

We proposed to add new § 424.516(f)(3) clarifying that all documentation required to be retained and furnished under § 424.516(f) must be accurate, complete, and compliant with all CMS requirements. In our documentation reviews, we have seen: (1) patient charts missing medical director signatures; (2) hospice certifications signed before the face-to-face encounter; (3) certification end dates preceding the certification start dates; and (4) other types of inaccurate records. This makes it difficult for CMS and its contractors to verify the provider's compliance and the service's necessity; the program integrity benefits of § 424.516(f) are reduced if the documentation is inaccurate or non-adherent. We accordingly believe § 424.516(f)(3) is necessary.

We emphasize that our proposal is not intended to establish any new condition of payment. It would be restricted to the scope of documents addressed in § 424.516(f).

The following is a summary of the comments we received on this proposal and our responses.

Comment: A commenter supported our proposal but suggested that CMS -- in potential § 424.535(a)(10) revocation cases - take into account situations where claims documentation has been lost due to natural disasters or other similar events. Another commenter requested that CMS: (1) confirm that records under § 424.516(f) may be retained and produced electronically; (2) specify accepted electronic formats and a secure transmission channel; and (3) provide a reasonable and defined production before utilizing § 424.535(a)(10).

Response: While we appreciate the commenters' support, recommendations, and requests, our proposal was limited to the need for documentation to be accurate and complete,

rather than whether and how it could or should be furnished in the situations the commenters describe. Consequently, we respectfully believe these comments are outside the scope of this final rule.

Comment: A few commenters requested that CMS clarify that a provider will not be revoked under § 424.535(a)(10) for § 424.516(f)(3) documentation deficiencies that are immaterial (for example, the commenter stated, the error does not materially affect the ability to validate a claim), technical, or inadvertent.

Response: While we cannot make the blanket statement the commenters request, we acknowledge that not all documentation errors are the same. As with all revocations, CMS will carefully evaluate the facts and circumstances of the case.

Comment: A commenter stated that when enforcing § 424.516(f)(3), CMS should recognize that some provider and supplier types, such as HHAs and hospices, furnish services in patients' homes.

Response: While we appreciate this comment, we again state that our proposal only referenced the need for the documentation to be accurate, complete, and compliant – a requirement that we respectfully do not believe should depend on the provider type involved or where or how services are furnished.

Comment: Several commenters stated that CMS should define "accurate, complete, and compliant."

Response: These terms will have plain meanings.

Comment: Several commenters stated that CMS should: (1) implement § 424.516(f)(3) using clear, uniform, and materiality-based standards; (2) clarify whether § 424.516(f)(3) would be limited to documentation already covered by § 424.516(f); and (3) confirm that § 424.516(f)(3) creates neither a new condition of payment nor new or duplicate clinical documentation or record-retention requirements regarding CoPs, claims, etc.

Response: While the first comment was unclear to us, we believe the commenter was requesting the implementation of factors – including a materiality standard – for § 424.535(a)(10) revocations that are based on § 424.516(f)(3) non-compliance. Assuming as such, we refer the commenter to our earlier statements regarding factors and materiality.

Section 424.516(f)(3), again, only applies to the § 424.516(f) documentation's accuracy, compliance, and completeness. It does not create other new requirements or conditions or expand the types of data that § 424.516(f) covers. Regarding the latter portion of the third comment, we cannot ascertain whether the commenters' reference to duplication effectively requests that we rescind § 424.516(f)(3) (and eliminate § 424.516(f) altogether) if other CMS provisions require the accurate submission of provider, physician, or practitioner documentation. If it does, we again remind stakeholders that enrollment requirements are separate from others and must be independently complied with.

After reviewing the comments received, we are finalizing proposed § 424.516(f)(3) without modification.

12. Corrective Action Plans (CAPs), Rebuttals, and Appeals

In certain situations, a provider or supplier may have an opportunity to correct a deficiency or contest a CMS finding regarding its enrollment by submitting, as applicable: (1) a CAP in response to a §§ 424.530(a)(1) or 424.535(a)(1) denial or revocation, respectively; (2) a rebuttal to a stay or deactivation of enrollment under §§ 424.541 or 424.546, respectively; or (3) an appeal of an initial determination under 42 CFR 498.3. We proposed several revisions to these processes.

a. CAPs (§ 405.809)

Sections 424.530(a)(1) and 424.535(a)(1) permit CMS to deny or revoke enrollment, respectively, if the provider is not compliant with the enrollment requirements in Title 42 or in the enrollment application applicable for its provider type. The provider may submit a CAP in response to this denial or revocation, which allows the provider to remedy the deficiency or

deficiencies in question and achieve compliance. As has long been CMS practice, though, §§ 424.530(a)(1) and 424.535(a)(1) are the only denial or revocation reasons under §§ 424.530 and 424.535 for which the provider may submit a CAP. While § 405.809(a)(1) makes this clear with respect to § 424.535(a)(1), it is silent as to § 424.530(a)(1). To incorporate this CAP policy into regulation, we proposed to add § 424.530(a)(1) denials to § 405.809's purview. This would involve the following revisions:

- Section 405.809's title would change from "Reinstatement of provider or supplier billing privileges following corrective action" to "Granting or reinstatement of provider or supplier billing privileges following corrective action."
- In paragraph (a)(1), the language "revocation for noncompliance under § 424.530(a)(1)" would change to "denial or revocation for non-compliance under § 424.530(a)(1) or § 424.535(a)(1)".
- In paragraph (a)(2), "revocation" would change to "denial or revocation".
- In paragraph (b)(1), "Reinstates" would change to "Approves or reinstates".
- Paragraph (b)(1)(i) would be redesignated as paragraph (b)(1)(i)(B).
- Under new paragraph (b)(1)(i)(A), the effective date of the approval is based on the applicable timeframes described in §§ 424.520 and 424.521. This is consistent with existing practice.
- In paragraph (b)(1)(ii), "reinstatement" would change to "approval or reinstatement".
- In paragraph (b)(2), "reinstate" would change to "approve or reinstate".

b. Notification of Determinations

Section 498.3(b) lists several CMS or MAC provider enrollment decisions that are considered "initial determinations". These include, for example, enrollment denials, enrollment revocations, and inclusion of a provider on the preclusion list. The affected provider under § 498.5 may request a reconsideration of the initial determination, for which CMS or, if applicable, the MAC issues a reconsideration determination. Under §§ 498.20(a)(1) and

498.25(a)(1), CMS mails notice of the initial determination or reconsidered determination, respectively, to the provider. Furthermore, § 405.800 requires that denial and revocation notices (as well as notice regarding the addition of years to a reenrollment bar) be sent by certified mail. We proposed to revise §§ 405.800(a), (b)(1), and (c)(1), 498.20(a)(1) and 498.25(a)(1) to include e-mail as an acceptable form of notice. We believe this would facilitate faster notice to the provider without the expense of paper mailing.

c. Appeals of Reactivation Effective Dates

Along with listing types of initial determinations, paragraph (d) of § 498.3 outlines administrative actions that are not initial determinations and thus not appealable under part 498. One type of provider enrollment finding that is not mentioned in either § 498.3(b) or (d) is the effective date of a reactivation under § 424.540(b). Under § 424.540(d)(2), a reactivation effective date is the date on which the Medicare contractor received the provider's reactivation submission that the Medicare contractor processed to approval. Due to lack of clarity among some stakeholders as to whether an assigned reactivation effective date may be appealed or rebutted, we proposed several regulatory changes.

First, we proposed to add new paragraph (3) to § 424.540(d) stating that a provider or supplier may rebut their assigned reactivation effective date via the general deactivation rebuttal procedures in § 424.546. As deactivations are not considered initial determinations – and to ensure consistent approaches -- we do not believe reactivation effective dates should, either. Yet we also believe the provider should have an opportunity to be heard on the matter, and a rebuttal would provide that.

To accommodate reactivation effective date rebuttals within § 424.546, we also proposed to revise the latter as follows:

- Change the title from “Deactivation rebuttals” to “Rebuttals of deactivations and of reactivation effective dates”.

- In paragraph (a)(1), insert the following between "under § 424.540," and "the provider or supplier has 15 calendar days": "or is assigned a reactivation effective date by CMS or its contractor under § 424.540(d)(2),".

- In paragraph (b)(2), insert the following between "effective date," and "and the reasons": "(or with the assigned reactivation effective date)".

- In paragraph (b)(3), insert the following after "deactivation": "or the reactivation effective date".

- Delete existing paragraph (d) and replace with the following: "Upon receipt of a timely and compliant deactivation (or reactivation effective date) rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation and/or the designated effective date (or the assigned reactivation effective date) are correct."

In this vein, we would also revise § 424.545(b) to include assignments of reactivation effective dates as a ground for rebuttal.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Several commenters supported our proposed use of electronic notifications.

Response: We appreciate the commenters' support.

Comment: Several commenters supported our proposed reactivation effective date rebuttal proposals, though a commenter stated that the effective date should be the date of submission, not the date of receipt by the Medicare contractor.

Response: We appreciate the commenters' support but are respectfully uncertain as to the submission and receipt dates the commenter refers to. If, as we suspect, the commenter is stating that the provider has 15 days to submit a rebuttal under § 424.546, this is correct. The use of "receipt" in § 424.546(d) simply means that CMS reviews the rebuttal upon receiving it. Paragraph (d) does not include or reference any effective date.

Comment: Several commenters supported our proposed revisions to § 405.809 regarding CAPs. However, they recommended that CAPs be permitted for additional denial and revocation reasons besides §§ 424.530(a)(1) and 424.535(a)(1).

Response: We appreciate the commenters' support and suggestions. However, we respectfully decline the commenters' request regarding CAP expansion for the same aforementioned reasons we do not have an across-the-board pre-revocation appeals or cure process.

Comment: A few commenters recommended that CMS either continue mailing denial and revocation notices or permit providers to opt into electronic-only notice. They expressed concern that an important notice delivered via a single electronic vehicle might not adequately reach the provider. Other commenters: (1) questioned how CMS will confirm e-mail receipt; (2) recommended that e-mailed letters be sent to multiple individuals listed on the provider's application to help ensure the letter is received; and (3) sought provider protections for failed or untimely transmissions.

Response: While we intend to finalize our changes regarding electronic mail, we recognize the commenters' concerns. We will examine the possibility of e-mailing letters to multiple contacts and will take steps to ensure that e-mailed notices are sent timely. We will also attempt, as applicable, to furnish guidance regarding confirmation of the provider's receipt of the notice.

Comment: Several commenters stated that CMS should e-mail denial and revocation letters on the same day they are dated.

Response: We will strive to do so.

Comment: A commenter stated that for reactivation effective-date disputes, CMS should: (1) specify the evidence and standard of review; (2) allow at least 30 calendar days for rebuttal; (3) provide a written decision; and (4) make additional review available for unresolved material factual disputes.

Response: We refer the commenter to CMS Publication 100-08, Chapter 10 for information regarding the first and third issues. Provider and supplier deactivation and stay rebuttals have always been 15 days, which we continue to believe is adequate time for submission. As rebuttals have never been considered initial determinations under § 498.3(b), there are no further administrative review rights once CMS' rebuttal decision has been made.

Comment: A few commenters requested that CMS: (1) implement delivery practices for notices that ensure providers receive the full response period contemplated by regulation and have a meaningful opportunity to respond within prescribed timeframes; and (2) clarify how notices are delivered when regulatory timeframes are measured in calendar days, since enrollment functions are generally performed during standard business hours and on weekdays.

Response: We respectfully are unsure as to the specific practices the commenters seek, the commenters' interpretation of "meaningful opportunity", which timeframes the commenters are referencing, or the clarification the commenters request. It appeared to us that these comments pertained to CMS' overall, existing enrollment notice delivery process as opposed to the specific e-mail delivery proposal. Hence, we believe these comments go beyond -- and are outside – the scope of this final rule.

Comment: A commenter stated that: (1) CMS should clearly coordinate CAP, rebuttal, reconsideration, and appeal procedures so that the use of one process does not waive or shorten another; and (2) CMS and MAC notices should identify all available options, deadlines, and consequences of concurrent review.

Response: We believe these comments go beyond the matter of reactivation effective date rebuttals to our overall, longstanding appeals and revocation processes. Thus, we believe they are outside the scope of this final rule.

After reviewing the comments received, we are finalizing these CAP, e-mail, and rebuttal proposals without modification.

13. Fingerprinting (§ 424.518(c))

Section 424.518(c)(2)(ii)(A) states that 5 percent or greater individual owners of providers and suppliers in the "high" screening category must submit fingerprints for a national criminal background check. We proposed to revise this paragraph to clarify that individuals subject to fingerprinting must use the CMS-designated fingerprinting contractor for this task. We view this as a technical change because CMS already has a designated provider enrollment fingerprinting contractor that providers must use.

Comment: Several commenters supported our proposed revision to § 424.518(c)(2)(ii)(A).

Response: We appreciate the commenter's support.

Comment: A commenter recommended that CMS delay implementation of revised § 424.518(c)(2)(ii)(A) to give all parties time to prepare.

Response: While we appreciate the commenter's request, we reiterate that CMS already uses a designated fingerprinting contractor; consequently, there is no need to delay our proposed change.

Comment: A commenter stated that CMS should: (1) permit local police departments to perform fingerprinting to avoid bottlenecks to timely fingerprinting, especially in rural and underserved areas; and (2) recognize good-faith compliance efforts when delays are caused by contractor scheduling limitations, processing timelines, and/or geographic access barriers.

Response: We appreciate these comments. For the first, we need consistency in our fingerprinting process, hence the need for a single source, though CMS works to avoid delays. Regarding the second, we are unclear as to whether the commenter is requesting explicit, regulatorily specified exemptions if delays are involved. If the commenter is, we respectfully cannot grant these when we have not reviewed the specific, unique facts of a particular case.

Comment: A commenter stated that: (1) CMS should consider alternative, comparable biometric or identity-verification methods if fingerprinting is not feasible; (2) providers should not face adverse enrollment actions because of contractor processing delays, system issues,

limited access to fingerprinting locations, or other circumstances outside their reasonable control; (3) CMS should apply consistent procedures for documenting and addressing such circumstances before denial or revocation; (4) identify who is subject to fingerprinting, when fingerprinting is required, and how compliance must be demonstrated, including the availability and accessibility of CMS-designated fingerprinting contractors for individuals in rural or underserved areas; (5) provide accommodations for individuals unable to produce readable fingerprints because of disability, age, or occupational wear; and (6) clarify whether fingerprints obtained through other federally accepted or trusted identity-verification programs will be accepted.

Response: The first, second, third, and fifth comments – as well as most of the fourth comment -- are outside the scope of this final rule because they appear to address the overall fingerprinting requirement under § 424.518(d) instead of our specific proposed revision.

CMS, as stated, uses a single, designated fingerprinting contractor. Applicable information can be found at https://cmsfingerprinting.com/. Regarding the sixth comment, all fingerprinting must be done via this contractor.

After reviewing the comments received, we are finalizing proposed revised § 424.518(c)(2)(ii)(A) without modification.

14. DMEPOS Accreditation (§ 424.58)

Consistent with §§ 424.57(c)(22) and 424.58, DMEPOS suppliers must be accredited by a CMS-approved accrediting organization (AO) to enroll and remained enrolled in Medicare. Section 424.58 details the general procedures and policies associated with DMEPOS accreditation. Many of these were added to § 424.58 in the CY 2026 HH PPS final rule (90 FR 55342) in an effort to strengthen CMS' oversight of the DMEPOS accreditation program in general and the DMEPOS AOs in particular. This included requirements regarding information and agreements that AOs must submit to CMS as part of their application/reapplication process. Three of these requirements are as follows:

- Per § 424.58(c)(1)(xxiii)(D), agreeing to notify CMS in writing of any decision to terminate, revoke, withdraw, or amend the accreditation status of a specific DMEPOS supplier within 3 business days of the date the AO took action.

- Per § 424.58(c)(1)(xxii), describing the AO's processes for--

++ Detecting and addressing DMEPOS supplier fraud, waste, and abuse (including identifying the AO's definitions of fraud, waste, and abuse); and

++ Reporting this activity to CMS and, as applicable, law enforcement.

- Per § 424.58(c)(1)(vii)(D), outlining the AO's policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions.

Upon further reflection since these three provisions were promulgated, we proposed the following changes thereto.

One revision would change the 3-business day period in § 424.58(c)(1)(xxiii)(D) to 5 calendar days. This would better align with § 424.58(e)(5)(i), which requires approved AOs to report the same information to CMS within 5 calendar days.

In addition, there currently is no timeframe in § 424.58 for reporting the fraud, waste, and abuse described § 424.58(c)(1)(xxii). We proposed in new § 424.58(c)(1)(xxiii)(N) that the AO must agree to notify CMS in writing (and, if applicable, law enforcement) of suspected fraud, waste, and abuse -- consistent with the AO's CMS-approved definitions of those terms -- within 3 calendar days of the date on which the AO determines that fraud, waste, or abuse may have occurred. (Current § 424.58(c)(1)(xxiii)(N) would be redesigned as new § 424.58(c)(1)(xxiii)(O)).

Notwithstanding the provisions of § 424.58(c)(1)(vii)(D) regarding conflicts of interest, none of them actually require the AO to report in its application/reapplication whether it has such conflicts. To help ensure that CMS makes fully informed AO approval decisions, we proposed to revise § 424.58(c)(1)(vii)(D)(*4*) to require the AO to also disclose to CMS all conflicts of

interest (as described in § 424.58(c)(1)(vii)(D)(*3)* and (5)) it currently has and explain how and when it will terminate them.

The following is a summary of the comments we received on these proposals and our responses.

Comment: Several commenters stated that CMS should: (1) identify the types of conflicts of interest that must be reported to CMS and the vehicle for doing so; (2) specify the phrase "suspected fraud, waste, and abuse" and the reporting requirements associated therewith; and (3) explain how the AOs should contact law enforcement.

Response: CMS will issue separate guidance to the AOs on this matter.

Comment: A few commenters recommended that to account for holidays and weekends, CMS should change its: (1) proposed 3 calendar-day period in § 424.58(c)(1)(xxiii)(N) to, for example, 3 business days or 7 business days; and (2) proposed 5 calendar-day timeframe in § 424.58(c)(1)(xxiii)(D) to 5 business days.

Response: While we appreciate these suggestions, we believe the time periods we proposed are necessary given: (1) the risk that fraud, waste, and abuse can pose to the Trust Funds and beneficiaries; and (2) the importance of us receiving critical information from the AOs as soon as possible.

Comment: A commenter stated that proposed § 424.58(c)(1)(xxiii)(N) risks overwhelming the AOs and CMS with unsubstantiated fraud reports, hence diverting resources from the prevention of actual fraud. The commenter urged CMS to either to raise the reporting threshold or provide guardrails or guidance to avoid this.

Response: We respectfully disagree with the commenters' concern. We do not anticipate a mass of unsubstantiated reports arising from our proposal. Beyond this, we have an obligation to the American people to treat all potential fraud, waste, and abuse (even if it is only suspected and is awaiting investigation) with the utmost seriousness. Waiting to learn from the AO about DMEPOS fraud, waste, and abuse until after it happens reflects the aforementioned, insufficient

"pay and chase" model. Immediately learning when fraud, waste, and abuse is suspected will better enable us to be proactive in our program integrity activities.

Comment: A commenter requested that DMEPOS AOs have direct access to CMS enrollment data.

Response: We appreciate this request but believe it is outside the scope of this final rule.

After reviewing the comments received, we are finalizing our proposed DMEPOS accreditation revisions without modification.

15. Miscellaneous Comments

We received additional comments on our proposals. In general, these pertained to either our proposed enrollment provisions as a whole, multiple provisions regarding a single topic (such as revocations), or our existing provider enrollment process.

Comment: Several commenters supported our proposals to strengthen provider enrollment requirements and combat fraud. A commenter stated that these protections are especially important for vulnerable home health beneficiaries who may have limited ability to identify and report fraudulent or substandard care. The commenter suggested that CMS also consider whether HHAs should be required to document staff training as part of enrollment and ongoing compliance requirements.

Response: We thank the commenters' for their support. While we also appreciate the commenter's recommendation regarding documentation, we believe it is outside the scope of this final rule.

Comment: Many commenters opposed our enrollment proposals overall. They stated that the provisions could: (1) reduce and discourage provider participation; and (2) limit beneficiary health care access, especially in underserved areas. They recommended that CMS implement operational safeguards to avoid abrupt loss of access to care when a provider is revoked, denied, deactivated, etc. Some stated that CMS should clearly distinguish between fraudulent, intentional, or material noncompliance (as well as material risk) on the one hand, and technical,

administrative, inadvertent, or promptly corrected noncompliance on the other – and to limit revocation and denial to the former. (An example commenters cited was failing to timely report changes in enrollment information (such as managing employees), which commenters did not believe should result in revocation.) Other commenters maintained that our proposals, taken together, would make Medicare enrollment substantially less predictable and reliable for providers acting in good faith. They stated that providers make significant investments in their facilities/practices, personnel, compliance, and patient care in the expectation that they will remain Medicare-enrolled absent clear evidence of fraud or intentional misconduct. Additional commenters maintained that the lack of factors, definitions, etc., in some of our new denial and revocation grounds make the latter arbitrary and capricious because they would give CMS unfettered revocation and denial discretion.

Response: We appreciate the concerns expressed. We do not expect provider participation or beneficiary access to be reduced given: (1) the limited number of revocations that traditionally occur; and (2) that previous promulgations of provider enrollment regulations (including those that added new denial and revocation grounds) did not lead to said reductions. Nonetheless, we constantly monitor potential access to care issues and will do with our new enrollment provisions.

As noted earlier, CMS carefully considers each potential denial and revocation situation and often utilizes measures such as deactivations and stays in lieu of revocations. Yet we cannot apply a materiality threshold to revocations or denials because: (1) non-compliance remains non-compliance regardless of the degree thereof; and (2) providers would have little incentive to remain consistently adherent to Medicare enrollment requirements if they knew that CMS only takes action if the non-compliance is material. Indeed, and most respectfully, providers should not assume that their mere avoidance of fraud and intentional misconduct exempts them from remaining compliant with all enrollment requirements.

We do not believe our new revocation and denial grounds would be arbitrary and capricious because, again, CMS will only take action when warranted and as specified in our regulations after a thorough and fair examination of the facts and circumstances of the case.

Comment: Commenters stated that Medicare enrollment enforcement (as well as our proposed enrollment provisions) must be targeted, evidence-based, and accompanied by meaningful procedural protections. Additional commenters stated that CMS should ensure that the consequence is proportionate to the conduct.

Response: We have always ensured that every potential denial or revocation case is meticulously assessed, and we only take action when justified. We do not routinely revoke providers and, as stated, often apply deactivations and stays to avoid the more significant consequences of a revocation and to ensure that the action is proportionate. Too, denied and revoked providers have robust due process rights under 42 CFR part 489, and denial and revocation letters explain the facts and legal basis behind the action.

Comment: Commenters stated that CMS's: (1) proposed denial and revocation reasons should be limited to provider and supplier types for which evidence exists of a program integrity problem; and (2) program integrity efforts should target higher-risk providers rather than burdening lower-risk ones.

Response: Several of our proposed grounds (for example, § 424.530(a)(20) and 424.535(a)(25)) are indeed limited to higher-risk provider and supplier types. The others address provider enrollment issues we have seen that are not limited to a few types of providers. While we appreciate the commenters' feedback, CMS cannot restrict its program integrity activities to higher-risk providers, for provider enrollment non-compliance – as well as fraud, waste, and abuse – can occur with any provider or supplier type.

Comment: Many commenters expressed concern that our enrollment provisions were proposed in the CY 2027 HH PPS proposed rule instead of a stand-alone enrollment rule. They stated that some provider and supplier types do not regularly review home health rules, believing

that its provisions would not apply to them. Since many of our proposals apply to all providers and suppliers, they might not have seen important provisions. Hence, the commenters contended, CMS did not give adequate notice of its enrollment proposals, should withdraw them from the HH PPS proposed rule, and re-propose them in separate enrollment rule. Several commenters noted that CMS previously used stand-alone enrollment rulemaking (such as in 2003 and 2016)[54] to propose requirements applicable to all providers and suppliers. Other commenters stated that CMS should have at least proposed its provisions in the CY 2027 Physician Fee Schedule[55] (91 FR 43842) proposed rule to ensure a wider audience.

Response: We respectfully disagree with the commenters for a number of reasons.

First, the CY 2027 HH PPS proposed rule's title explicitly listed "Provider Enrollment" as one of its topics. Thus, the proposed rule was a provider enrollment rule as well and not merely a proposed regarding home health or hospice payment. This "Provider Enrollment" reference, moreover, was not prefaced by "Hospice" or "Home Health". That is, it was broadly "Provider Enrollment" and not "Home Health and Hospice Provider Enrollment", making clear that the enrollment provisions were not limited to certain provider types.

Second, we proposed significant enrollment provisions applicable to all providers and suppliers in the CY 2022, CY 2024, and CY 2026 HH PPS proposed rules (86 FR 62240, 88 FR 77676, and 90 FR 55342, respectively). These included, for instance: (1) adding roughly 10 new retroactive revocation reasons; (2) expanding the maximum reapplication bar period from 3 years to 10 years; (3) adding in regulation new reasons for which we can return or reject an enrollment application or deactivate a provider's enrollment; (4) reducing the period of non-billing for which we can deactivate a provider from 12 consecutive months to 6 consecutive months; and

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[54] Specifically: (1) "Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges; Proposed Rule" (68 FR 22064), published in the Federal Register on April 25, 2003; and (2) "Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process; Proposed Rule" (81 FR 10720), published in the Federal Register on March 1, 2016.

[55] "Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program", published in the Federal Register on July 16, 2026.

(5) documentation request requirements. No commenters in those proposed rules indicated concern about a lack of adequate notice or requested that our provisions be removed and reproposed in an enrollment-only rule.

Third, the CY 2027 HH PPS proposed rule was especially appropriate for our provisions given: (1) the need to remedy as quickly as possible the serious program integrity issues the proposals address; and (2) the hospice-specific proposals in the rule.

Fourth, we received approximately 375 separate comment submissions on our proposed revisions, as many as we have ever received on any provider enrollment regulation, either as part of a payment rule or an enrollment-exclusive rule. This alone evidences that proper notice was given.

For these reasons, we respectfully decline to withdraw our enrollment provisions from the CY 2027 HH PPS proposed rule.

Comment: Many commenters stated that: (1) some of the information they believe is required under our proposals might be impossible to obtain or confirm; and (2) CMS should not deny or revoke enrollment based on information or conduct involving third parties (including independent contractors) that the provider could not reasonably have known or controlled.

Response: As explained previously: (1) we do not anticipate requesting affiliation data; (2) managing employees must be reported, and there has never been a "due diligence" standard for this requirement; and (3) for denial or revocation reasons based on the conduct of an owner, managing employee, managing organization, etc., we respectfully cannot base our decision on whether the provider knew of or could have controlled said conduct.

Comment: Commenters sought clarification on the following issues: (1) the effective date of any finalized enrollment provisions; (2) how CMS plans to implement its provisions and collect the required data; (3) whether CMS, PECOS, and the MACs will be able to accommodate and have the capacity to carry out these changes; and (4) whether our finalized enrollment provisions affect Programs of All-Inclusive Care for the Elderly providers (PACE).

Response: Our finalized enrollment provisions are effective on January 1, 2027, and we will be able to timely implement them. In addition, and except for our preclusion list revision, our changes do not apply to PACE providers that are not otherwise enrolled in Medicare. .

Comment: A few commenters stated that enrollment actions against individual providers can affect an entire coordinated-care network, including physician-led Accountable Care Organizations (ACOs). They recommended that CMS establish a transition process that: (1) allows care to continue while an appeal is pending; (2) gives an ACO (or other health network) reasonable time to arrange alternative capacity; (3) avoids penalizing the network for disruptions outside its control; and (4) provides appropriate notice when an enrollment determination becomes final and disclosure is legally permissible.

Response: While we appreciate these comments, we are respectfully unclear as to: (1) the transition process, alternative capacity arrangements, penalties, and network disruptions the commenters are referencing; and (2) whether the stakeholders' comments pertain strictly to our proposals or to our larger provider enrollment process. If the commenters are requesting, in effect, a postponement in revocation enforcement until appeal rights are exhausted, we refer the commenters to our earlier statements regarding our inability to do so. We can reiterate, though, that: (1) CMS takes revocation action only when truly warranted and, for this reason, we do not expect our proposals to materially affect ACOs or other provider networks; and (2) providers are notified of any revocation or denial action.

Comment: Commenters stated that our proposed revocation reasons are overreaching. They maintained that CMS' program integrity efforts – both proposed and current -- should instead be directed towards demonstrably fraudulent parties, high-risk providers, and intentional misconduct, not good-faith and historically compliant providers. Several commenters stated CMS should establish a risk-based system that rewards legitimate, compliant providers with fewer administrative requirements. Another commenter stated that Complex Rehab Technology suppliers should be exempt from our proposed denial and revocation reasons.

Response: We respectfully disagree with these comments. Rather than being overreaching, our proposed revocation reasons are principally targeted towards specific scenarios we have seen and are not intended to be widely utilized. Too, we again note the matter of non-compliance with enrollment requirements. Merely because a provider is not, for example, (1) screened at the "high" level under § 424.518, (2) in a traditionally high-risk geographic area, or (3) engaged in intentional misconduct does not mean we should ignore any non-compliance on that provider's part. We must ensure that all providers are compliant irrespective of their relative risk level or provider or supplier type.

Comment: A commenter stated that CMS should not finalize any of its expanded denial and revocation reasons until it publishes data regarding Administrative Law Judge (ALJ) reversal rates for enrollment denials and revocations – in particular, §§ 424.535(a)(1) and 424.535(a)(8)(ii) revocations. The commenter maintained, in essence, that denial and revocation reasons should not be added or broadened until CMS can ensure correct denial and revocation decisions as evidenced by low reversal rates for current grounds.

Response: We respectfully disagree. CMS must take quick action to address program integrity vulnerabilities as they arise, without waiting for a particular ALJ affirmance threshold to be met. We can neither base our payment safeguard efforts on the latter nor avoid imposing a necessary denial or revocation solely because it might be overturned on appeal.

Comment: Commenters stated that providers should have the right to cure any deficiency (other than fraud or intentional misconduct) before a denial or revocation occurs.

Response: We respectfully direct the commenters to our previous statements regarding pre-denial and pre-revocation appeals processes.

Comment: A commenter stated that CMS should update MAC contracts to include defined timelines for review and approval or denial of Form CMS-855A changes.

Response: MACs are required to adhere to the application processing timeframes in CMS Publication 100-08, Chapter 10.

Comment: A commenter stated that CMS should use focused oversight – instead of new across-the-board requirements – to address the program integrity problems in Los Angeles County and elsewhere. The commenter suggested, for instance, revalidation of providers in the risk area, pre-claim review, and examining extreme utilization patterns and patient recertification rates.

Response: We sincerely appreciate these recommendations and note that CMS has indeed taken targeted steps to address Los Angeles County-type situations. However, program integrity is a national issue and, as earlier mentioned, we must be proactive in addressing enrollment non-compliance and potential payment safeguard risks – irrespective of the particular geographic location or the provider or supplier type involved. We cannot wait until misconduct occurs in a certain location before taking action.

Comment: Commenters expressed concern that a provider error on an enrollment application or in enrollment data reporting could keep them out of business for 10 years. They stated that revocation should not be used in response to minor provider errors. Other commenters added that CMS should use a more targeted, data analytics-driven approach to revocations rather than adopting a broader approach that -- the commenter believed -- can penalize providers for small errors. Other commenters suggested that CMS – in lieu of adding or expanding denial or revocation grounds – use other, more focused program integrity measures, such as (but not limited to) increased claims monitoring, Medicare Strike Force operations, civil money penalties, the False Claims Act, etc.

Response: We reaffirm that providers are not revoked or denied as a matter of practice but only when genuinely justified under the case's facts and circumstances and based on the applicable data; we consider this to be a "targeted" approach. Further, and to reiterate, CMS frequently applies deactivations and stays instead of revocations given our acknowledgement of the significance of a revocation.

CMS addresses payment safeguard threats via numerous vehicles. Yet this does not mean that CMS must forgo all others. Program integrity requires a comprehensive approach, and the provider enrollment process - including establishing new denial and revocation grounds directed at specific vulnerabilities -- is a critical component thereof.

Comment: A few commenters requested that CMS explain to certified provider AOs the effects of retroactive revocations.

Response: Given that certain retroactive revocation grounds have existed for some time, we respectfully do not believe such guidance is necessary.

Comment: Several commenters stated that CMS should define the due diligence expected of providers in ascertaining an owner's or manager's criminal or adverse legal history.

Response: Sections 424.500 through 424.575 do not require providers to perform this activity.

Comment: A commenter stated that CMS should use super intelligence -assisted pre-payment claims analytics containing four minimum safeguards: (1) documented training data and known model limitations disclosed to plan sponsors and affected providers on request; (2) human review for every denial recommended previously a defined confidence threshold; (3) quarterly bias and drift monitoring with a public dashboard; and (4) evidentiary appeal rights for providers contesting model outputs. Other commenters suggested that CMS utilize real-time super intelligence fraud detection mechanisms in its enrollment activities, such as in detecting billing patterns.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: A commenter stated that CMS should: (1) return to the 3-year DMEPOS reaccreditation cycle; and (2) implement section 427 of the Benefits Improvement and Protection Act of 2000.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Several commenters maintained that good-faith providers should not be revoked if the matter was based on conflicting or unclear CMS or MAC guidance.

Response: We are respectfully uncertain as to which individual revocation grounds the commenters are referencing. While providers must abide by all CMS enrollment requirements at all times and it is ultimately the provider's responsibility to ensure it understands and follows CMS guidance, we again state that CMS carefully reviews the facts and circumstances of each potential revocation case.

Comment: A commenter requested clarity as to which enrollment provisions are applicable to which provider and supplier types.

Response: As we explained in the proposed rule and section V.C. of this final rule, the provisions apply to all provider and supplier types except as explicitly noted otherwise (for example, § 424.530(a)(20) applies to hospices, the DMEPOS accreditation provisions apply to DMEPOS suppliers, etc.)

Comment: A commenter stated that the proposed rule did not demonstrate significant fraud-risk associated with ambulatory surgical centers.

Response: We appreciate this comment but remind stakeholders that fraud, waste, and abuse can happen within every provider and supplier type. Indeed, even if a particular provider type might traditionally pose less payment safeguard risk than certain others, this does not mean it should be exempt from the same requirements that all providers must adhere to. Regardless of the provider type involved, CMS must halt fraud, waste, and abuse before it begins, not afterwards—and exempting certain providers from important program protections hampers such efforts.

Comment: A commenter supported our efforts to prevent fraudulent providers from circumventing their reenrollment bar and reenrolling in Medicare. This and another commenter

requested that CMS define the situations under which a provider has the same "identity" to avoid unintended consequences of wrongly denied reenrollments.

Response: We appreciate the commenter's support. However, we believe the commenter's request is outside the scope of this final rule because we did not propose any changes to the "different identity" denial and revocation provisions in §§ 424.530(a)(12) and 424.535(a)(18).

Comment: A commenter requested CMS confirmation that co-location does not equate to an affiliation.

Response: We appreciate this comment but are unable to confirm or not confirm this matter without knowledge of the particular facts of the case.

Comment: Some commenters expressed concern about retroactive revocations based on a failure to timely report changes in enrollment. They stated that operational challenges beyond a good-faith provider's control could result in revocation. They requested that: (1) allow multiple concurrent change request submissions in PECOS: (2) enable providers to request an extension when a pending application prevents timely submission of additional updates, and (3) implement automated notifications for expiring licenses, insurance, accreditation, and other enrollment-related information.

Response: We stress again that CMS in every revocation and denial case carefully reviews the facts and circumstances and only takes action when warranted. However, we believe the commenters' three requests are outside the scope of this final rule.

Comment: Several commenters stated that with respect to institutional providers (such as hospitals), a CMS finding regarding geography, an affiliate, or an application filed for a different location does not meet the criteria of section 1866(b)(2) of the Act.

Response: As previously discussed, section 1866(b)(2) of Act is inapplicable to provider enrollment, which is governed by different statutory and regulatory provisions.

Comment: A commenter recommended that CMS: (1) issue guidance on pre-payment control frameworks that reduce the window between fraudulent billing and detection; (2) encourage providers to maintain documented pre-payment verification controls covering beneficiary eligibility confirmation, physician order authentication, and visit documentation validation; and (3) require that newly acquired HHAs maintain enhanced pre-payment review protocols during a defined transition period following ownership changes.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: Given the impact of retroactive revocations, a commenter recommended that CMS: (1) provide written notice and a reasonable opportunity to cure certain application fee deficiencies before revocation; (2) clarify how providers may document timely application fee payment attempts; (3) evaluate the totality of the circumstances in § 424.535(a)(18) cases and require evidence of the provider's intent to circumvent an existing re-enrollment bar; and (4) for § 424.535(a)(20) cases, review the circumstances in their totality and be transparent as to how non-compliance is examined.

Response: We refer the commenter to our prior statements concerning cure opportunities. We believe the second, third, and fourth recommendations are outside the scope of this final rule since they involve revocation reasons and other matters we did not address or propose to revise.

Comment: Several commenters requested that CMS: (1) exempt fixed-site institutional providers (including hospitals), health complexes, provider-based departments, and on-campus locations from the purviews of §§ 424.530(a)(20) and 424.535(a)(24); and (2) exclude from § 424.530(a)(20) all co-location arrangements that predate the other provider's adverse action. Another commenter stated that facility-based, brick-and-mortar providers should be exempt from § 424.535(a)(24).

Response: While we thank the commenter for these requests, CMS does not – and, considering the wide variety of factual scenarios that occur, cannot – automatically exempt

certain providers, locations, and arrangements from §§ 424.530(a)(20) and 424.535(a)(24). However, we again seek to assure providers that CMS recognizes all the concerns they have expressed regarding our enrollment provisions and will fully and thoroughly consider the circumstances of the case before denying or revoking enrollment.

Comment: Several commenters stated that CMS: (1) already has mechanisms for identifying and addressing fraud, waste and abuse; and (2) did not explain in the proposed rule the deficiencies in these existing authorities that prevent CMS from addressing fraudulent providers and suppliers. Existing program integrity mechanisms the commenters cited included (but were not limited to) risk-based screening, collaboration with the HHS-OIG and Department of Justice, and data analytics.

Response: In both the proposed rule and this final rule, we carefully explained the need and justification for each of our proposals – all of which are intended to eliminate program integrity gaps that cannot be addressed via current means.

Comment: Some commenters expressed concern that our proposals would discourage clinical and administrative staff from accepting employment with various providers out of fear that they or the provider may be revoked.

Response: We respectfully do not believe this will take place. We have previously added parties to the scopes of various denial and revocation grounds and are unaware of the scenario the commenter describes having occurred.

Comment: Several commenters stated that our proposed changes will flood CMS, the MACs, and the States with additional paperwork and enrollment transactions; they were especially concerned that this could increase MAC backlogs.

Response: We respectfully disagree, primarily because – as stated -- clinical managing employees must currently be disclosed, and we do not anticipate requesting the submission of affiliation data under § 424.519.

Comment: Commenters stated that several of our proposals at least partly duplicate other, non-enrollment provisions to which providers must adhere. These include, for example, State survey requirements, accreditation standards, and State licensure. They maintained that CMS: (1) should avoid subjecting providers to duplicative requirements; (2) should not establish new enrollment requirements without assessing whether program integrity can be facilitated via other existing regulatory provisions; and (3) should consider these other requirements to which providers must adhere in determining whether to deny or revoke enrollment. Another commenter stated that CMS should treat DMEPOS supplier accreditation as a clear indicator of the supplier's legitimacy and compliance.

Response: We respectfully do not believe: (1) there is duplication between our main proposals and other, non-enrollment requirements; and (2) the issues that our proposals seek to address can be remedied via current authorities. Hence, our proposals are needed. We add that, as already noted, provider enrollment has its own, distinct set of requirements, and providers and suppliers – including DMEPOS suppliers -- can still fail to meet said requirements or can otherwise pose risks even if they are State licensed, accredited, compliant with CoPs, etc.

Comment: A commenter suggested that CMS establish a CMS-compatible provider compliance data model that can, among other things: (1) technologically maintain a continuously updated provider compliance record; (2) enable automated monitoring; (3) alert an organization of upcoming deadlines, requirements, or possible compliance issues (for example, a license is approaching expiration); and (4) provide digital evidence of compliance.

Response: We appreciate this recommendation but believe it is outside the scope of this final rule.

Comment: Several commenters stated that CMS should address the potential Medicaid consequences of these new authorities. They noted that § 455.416(c) requires States to deny or terminate the Medicaid enrollment of any provider revoked under Medicare and is currently included in the termination database under § 455.417. A commenter recommended that CMS

clarify whether (and under what circumstances) our proposed revocation grounds would be considered "for cause" and thus require a Medicaid termination under § 455.416. Another commenter appeared to contend that § 455.416(c) raises due process concerns because the State must terminate enrollment without any independent State review of the case's underlying facts. An additional commenter requested that CMS clarify in the final rule that § 455.416(c) only applies to Medicare revocations based on fraud, gross clinical misconduct, or severe program abuse—not technical, geographic, or affiliate-based administrative revocations. Another commenter stated that CMS should: (1) issue guidance to State Medicaid agencies on how to handle Medicare revocations under our proposed provisions; and (2) recommend that States stay any corresponding Medicaid termination pending exhaustion of the provider's Medicare administrative appeal.

Response: We appreciate the commenters' feedback. CMS did not propose to interpret "for cause" or to clarify the scope or applicability of § 455.416(c). Therefore, we respectfully believe these comments are outside the scope of this final rule. We further do not foresee our proposals having a material overall effect on providers' Medicaid enrollments because we anticipate that only a limited number of them will be revoked thereunder.

While we will issue guidance to the States if deemed necessary, we do not have the authority to direct States to impose the stay the commenter recommends.

Comment: A commenter stated that CMS should collect and publish data on the use of our new authorities, including the number of actions taken, cited grounds, reversal rates, and any identified access concerns.

Response: CMS lists all currently revoked providers (as well as the revocation basis) at https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/revoked-medicare-providers-and-suppliers. Revocations under our new authorities will be included. Although CMS does not publish enrollment-related appeals or beneficiary access data, we will,

as previously mentioned, monitor the latter for potential issues, though we do not expect any to arise.

Comment: Commenters expressed concern that our proposed "managing employee" definition combined with several proposed expansions of existing denial and revocation reasons to include managing employees will increase the number of revocations.

Response: CMS cannot confirm whether this will or will not be so. We can merely repeat what we have stated throughout this final rule that we will carefully evaluate each potential revocation and denial case.

Comment: A commenter stated that providers: (1) are prohibited from employing or contracting with individuals who are OIG-excluded or SAM-debarred; and (2) agree to abide by all Medicare laws upon signing the Form CMS-855 application. While it was somewhat vague, it appears the commenter contended that this sufficiently guarantees that the provider does not have or associate with problematic parties and, if it does, CMS can revoke the provider. Consequently, there is no need for CMS' proposals that pertain to the conduct of the provider's owners, managing employees, etc.

Response: We respectfully disagree for two reasons. First, non-excluded and non-debarred owning, managing, and other parties can still present significant risks to the Medicare program. Second, certain persons and entities other than the provider are required to be reported on the application and carefully screened for said risks (for instance, reviewing a managing employee for felony convictions).

Comment: Commenters stated that denials and revocations based on an owning or managing party's actions should be restricted to situations where said party presents a material risk, and misconduct or program integrity concerns are involved. Another commenter requested that CMS define "associated party" as used in proposed revised § 424.530(a)(6) and (a)(7).

Response: We interpreted these comments as essentially requesting that CMS explicitly exempt providers from denial or revocation if: (1) the other party's conduct was not severe; or

(2) the provider was not involved in it. Every case involving an owner's, manager's, or associate's activity is different, and CMS must weigh the facts and circumstances of each in determining whether to deny or revoke. We cannot exempt certain situations prior to this analysis. We also, again, emphasize that for these denials and revocations, the associate's behavior is the main consideration, not whether the provider was a party thereto.

As we are not finalizing proposed expanded § 424.530(a)(6) and (a)(7), we believe the commenter's request concerning the "associated party" term is moot.

Comment: Several commenters urged that CMS establish various exceptions from (and modifications to) our proposals for small providers.

Response: We respectfully direct the commenters to our prior statements regarding exceptions.

Comment: A commenter recommended that CMS: (1) work with MACs to establish clear and reasonable processing timeframes for provider enrollment and change of ownership requests, with transparent tracking of progress; and (2) require MACs to implement systems that prevent duplicate document requests and ensure that information already submitted is appropriately retained and applied to the pending file.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: Several commenters stated that CMS should meet with stakeholders to develop provisions that promote program integrity without negatively impacting good-faith providers.

Response: CMS regularly communicates with provider organizations on enrollment matters, and we receive valuable suggestions. For reasons already mentioned, though, our proposals are very much needed to address material program integrity vulnerabilities.

Comment: A commenter stated that using data analytics would help CMS detect fraud in real-time and take prompt action instead of only being able to spot fraud months or years later.

The commenter also suggested: (1) having beneficiaries more involved in detecting fraud; and (2) that CMS convene a task force to collaborate on modernizing home health technology infrastructure and on fraud, waste, and abuse measures. Another commenter recommended program integrity enhancements such as: (1) transmitting certain provider enrollment information (such as enrollment status) on crossover claims; (2) targeting pre-payment beneficiary confirmation for high-risk DMEPOS claims to verify medical need and receipt before payment is issued; (3) enhanced identity verification and provider background checks; (4) real-time data sharing and analytics between CMS, MA plans, and supplemental insurers; (5) periodic risk-based revalidation; and (6) expansion of the preclusion list.

Response: While we believe these comments are outside the scope of this final rule, we sincerely appreciate the commenters' recommendations.

Comment: A commenter stated that with respect to SNFs, CMS should: (1) distinguish managerial control from clinical, professional, consulting, or advisory responsibilities; (2) provide examples of both reportable and non-reportable positions and arrangements; (3) clarify the relationship between managing employee and ADP disclosures; and (4) reconcile and update its SNF guidance and Form CMS-855A instructions (including explaining the: (i) difference between a managing employee and a clinical consultant ADP under section 1124(c) of the Act; and (ii) when and how each should be reported). Concerning this fourth request, the commenter stated that the SNF guidance advises SNFs to construe disclosure requirements broadly and to disclose when uncertain, while the proposed rule emphasizes that not every clinical employee is reportable. The commenter believed that CMS should reconcile these approaches so that SNFs do not unnecessarily over-report clinical staff.

Response: As we have indicated, the reporting of managing employees under § 424.502 and of parties (such as ADPs) under section 1124(c) of the Act are separate requirements with separate definitions and principles. The two are unrelated, and each must be met. This has been the case since the commencement of the SNF disclosure requirements in late 2024, and our

proposed clarification in "managing employee" definition does not change this. Hence, we are uncertain as to the precise guidance or reconciliation the commenter seeks.

Comment: A commenter suggested that CMS establish an "enrollment-only" organizational supplier status whereby a supplier can enroll without obtaining Medicare billing privileges. The commenter stated that because other federal health care programs may require Medicare enrollment to participate, allowing suppliers to enroll via an abbreviated process could reduce provider and administrative burden while still permitting CMS to carefully screen the provider during the enrollment process.

Response: We thank the commenter for this recommendation but believe it is outside the scope of this final rule.

Comment: Commenters maintained that our proposals would force providers out of Medicare, which in turn could lead to lost employment for physicians, practitioners, administrative staff, etc.

Response: We respectfully disagree. Past provider enrollment rulemaking efforts have not resulted in material numbers of providers or provider staff departing the Medicare program, and we believe this will hold true following this final rule, too.

Comment: A commenter stated that to the extent CMS uses predictive models, risk scoring, or other automated analytics to identify high-risk enrollments or to support denial or revocation determinations, CMS should take several steps including (but not limited to): (1) ensuring transparency about the data and factors it used; (2) ensuring that the case is reviewed by a qualified human reviewer before any adverse determination; and (3) periodically auditing the model for accuracy and for disparate impact on small, rural, and safety-net participants. The commenter believed that revocation decisions should rest with CMS and not with a model; the commenter added that no provider should be revoked based on a score it can neither see nor challenge.

Response: While we cannot address the detailed operational aspects of our revocation and denial evaluations, we note that our decisions are made by individuals reviewing the case and not by predictive models or automated analytics.

Comment: A commenter requested clarification on six enrollment-related topics. The first is whether a nurse practitioner or physician assistant furnishing palliative care services under the home health benefit must: (i) be Medicare-enrolled; and (ii) reassign the right to bill Medicare to the HHA or another billing entity. The second is whether such services are considered included within the home health prospective payment system payment, separately billable professional services, or both depending on the service furnished and the billing practitioner. The third seeks guidance on enrollment form requirements, reassignment mechanics, practitioner affiliation with the agency, and the compliance implications when the agency contracts with an external palliative care practitioner or group. The fourth is whether HHAs are responsible for verifying PECOS enrollment for each nurse practitioner, physician assistant, physician, or other allowed practitioner involved in palliative care services. The fifth involves when verification in the prior sentence must occur, how often it must be repeated, what documentation must be retained, and whether claims will be denied if the palliative care practitioner is not properly enrolled, eligible to order and certify, or linked to the billing entity. The sixth seeks operational guidance and edits that HHAs can use prospectively to reduce preventable claim rejections and post-payment denials.

Response: We appreciate these comments but believe they are outside the scope of this final rule.

Comment: Several commenters stated that certain system issues with PECOS should be promptly resolved to help providers comply with CMS' new enrollments requirements.

Response: CMS will ensure that PECOS can effectively accommodate our finalized enrollment provisions.

Comment: A commenter stated that CMS in its provider enrollment activities should consider the approach reflected in the proposed Medicare Home Health Payment Integrity and Protection Act of 2026 (S. 5250), introduced by Senator Susan M. Collins on August 5, 2026.[56]

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter requested that CMS: (1) confirm that deactivation – not revocation – will be utilized in cases of infrequent billing and that CMS will notify the provider thereof; and (2) allow Bill for Denial claims to be considered active participation.

Response: We appreciate these requests but believe they are outside the scope of this final rule.

Comment: Several commenters stated that CMS should always consider potential access to care impact in its denial and revocation determinations, especially for rural and underserved areas. Others expressed broader concerns that our proposals will harm patient access.

Response: As previously stated, CMS considers the facts and circumstances in each denial and revocation case and consistently remains alert for any potential beneficiary access issues. Yet we are unaware of any material access to care problems arising from any of our prior enrollment rulemaking efforts, and we do not expect any to emerge from the present one.

Comment: Some commenters stated that a provider enrollment moratorium under § 424.570 impacts both fraudulent and legitimate providers and suppliers and is overly broad. These commenters requested that CMS use a more targeted approach for combatting fraud and abuse –such as focusing on fraudulent actors – to minimize disruption to Medicare patients and bona fide providers.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

[56] https://www.congress.gov/bill/119th-congress/senate-bill/5250/text.

Comment: A commenter stated that CMS should deem a provider's documented attempt to report a change as timely compliance when PECOS limitations, contractor instructions, or a pending application prevent formal submission.

Response: As we have indicated regarding other commenters' requests for preliminary determinations, exemptions, etc., we are unable to pre-judge cases in this final rule. Every situation must be reviewed upon its unique facts and details.

Comment: A commenter stated that administrative or regulatory enrollment disruptions resulting from interactions among Federal healthcare programs, State healthcare programs, accreditation requirements, or payer credentialing systems should not be considered a "termination" or "suspension" for purposes of imposing derivative enrollment consequences on owners, managing employees, or managing organizations.

Response: We are respectfully uncertain as to the specific issue being raised. Our best interpretation is that the commenter believed § 424.530(a)(14)(i) should not apply to a provider if the owning or managing party's program or licensure termination or suspension involved any of the disruptions the commenter mentioned. Assuming this was the commenter's contention, we disagree. Again, we cannot exempt certain providers or owning or managing party actions from denial or revocation consideration before we thoroughly review the facts and circumstances involved.

Comment: A commenter urged CMS to enhance its and the MACs' resources to: (1) answer providers' enrollment questions; (2) process changes in enrollment data; and (3) respond to enrollment-related appeals.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Several commenters stated that CMS should permit expedited review when: (1) a provider presents credible evidence that CMS has made a factual or legal error; (2) the

revocation would materially disrupt beneficiary access; and (3) a small or rural provider is involved (with said appeals containing a binding decision deadline for an ALJ decision).

Response: If, as it appeared to us, the commenters are requesting expedited provider enrollment appeals in these two situations, we respectfully repeat our earlier statement that 42 CFR Part 498 does not provide for such expedited appeals -- or, for that matter, special appeal rights and decision deadlines for certain provider types.

Comment: A commenter stated that although section 1866(j) of the Act directs the Secretary to establish a process for enrolling providers and suppliers, it does not establish the grounds on which a provider may be revoked. Congress, the commenter contended, addressed that question in section 1866(a)(1) of the Act, which states that a provider with a provider agreement that meets certain criteria "shall be qualified to participate [in Medicare] and shall be eligible for payments." Meanwhile, section 1866(b)(2) of the Act states that the Secretary may terminate or refuse to renew a provider agreement based on: (1) noncompliance with the provider agreement or applicable law; (2) failure to substantially meet the applicable provisions of section 1861; (3) an OIG exclusion; or (4) a felony conviction. The commenter maintained that because: (1) Congress only listed these four termination grounds in section 1866 of the Act; and (2) a provider enrollment termination has the same effect as an enrollment revocation, it follows – under the doctrine of *expressio unius* – that Congress only intended for enrollment to be revoked in one of the four section 1866(b)(2) of the Act situations. Accordingly, CMS cannot rely upon section 1866(j) – or, for that matter, sections 1102 and 1871 of the Act, because general rulemaking authority cannot be used to expand a statute – for a number of its proposed revocation grounds, such as § 424.535(a)(16) and (a)(24).

Response: We direct the commenter to our earlier responses that section 1866(b)(2) of the Act does not apply to provider enrollment.

Comment: A commenter stated that CMS should: (1) clarify how the proposed affiliation, ownership, associated-party, and management authorities will apply to value-based care and care

coordination arrangements; (2) provide examples of arrangements that would not create enrollment risk; and (3) establish safe harbors or other protections for good-faith providers seeking to implement innovative care delivery models.

Response: We appreciate these comments. Our requirements would apply to value-based care and care coordination arrangements to the same extent as all other provider types and arrangements. Also, and consistent with our prior statements, we can neither pre-determine cases (such as whether a transaction presents risk) nor establish regulatory exceptions for certain provider types or health care models.

Comment: Commenters stated that CMS should delay (possibly in staged phases, with several commenters suggesting a 1-year postponement for all provisions) implementation of any finalized enrollment provisions to give stakeholders time to prepare. The commenters added that prior to implementation, CMS should: (1) issue detailed, explanatory public guidance to providers and the MACs; and (2) train provider staff on the new provisions. Another commenter stated that CMS should continue to solicit provider input on our provisions.

Response: We respectfully are unable to postpone implementation of our provisions in light of the need to take prompt action to address the program integrity vulnerabilities outlined in the rule. Although CMS will issue guidance to the MACs and, to the extent necessary, stakeholders, CMS does not train provider staff regarding enrollment requirements.

CMS welcomes additional stakeholder feedback regarding our new provisions.

Comment: Several commenters stated that our proposed enrollment provisions (including reporting requirements) would increase provider costs without improving patient care or program integrity.

Response: We respectfully disagree. We previously indicated why our affiliation and managing employee provisions would not add costs, and we believe that program integrity and patient care will be improved by the denial and removal of problematic providers from Medicare.

Comment: A commenter stated that the **Federal Register** notice for the proposed rule encouraged electronic comments, but the stated address ends in the placeholder docket identifier CMS-2026-XXXX, rather than a valid docket destination. The Administrative Procedure Act, the commenter maintained, requires a Federal Register notice that identifies the rulemaking proceeding and then requires the agency to give interested persons an opportunity to participate through written submissions. The commenter concluded that a notice that affirmatively directs stakeholders to an unusable electronic destination -- while also encouraging that route -- does not facilitate meaningful participation.

Response: We disagree. Ample notice of the rulemaking notice was given and providers had multiple ways to submit comments. The fact that we received roughly 375 comments on our enrollment provisions – including, we note, the provider's comments – indicates that meaningful participation was offered.

Comment: With respect § 424.547, a commenter stated that because deactivation of a certifying or ordering provider blocks HHA/hospice billing on affected claims, CMS must maintain accurate, up-to-date enrollment databases and ensure an efficient reactivation process, particularly for hospice physicians covering on-call or absences.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Commenters were concerned about our proposals' possible impact on small, rural, and non-profit entities. They believed these providers may lack the resources to adhere to our provisions, meaning they may depart the Medicare program. They requested exemptions from certain provisions (or other modifications or special considerations) for such entities.

Response: While we appreciate the commenters' concerns, the concept of program integrity applies to all providers and suppliers – whether small, large, rural, etc. All enrolled parties must adhere to Medicare enrollment requirements, and we believe that granting

exceptions based on size or location would be inconsistent with our obligation to ensure such compliance.

Comment: A commenter stated that in FCC v. Fox Television Stations (567 U.S. 239 (2012)), the Supreme Court held that: (1) due process requires agencies to give regulated entities fair notice of the conduct that is prohibited or required; and (2) a rule is constitutionally deficient when an ordinary person cannot tell what facts must be established. Since CMS declined to articulate various standards and terms, providers cannot ascertain what is required to remain compliant. The commenter stated that CMS, in effect, has not given providers fair notice. The commenter cited an example of a provider researching its owners, managers, and affiliates for adverse actions, finding none, and believing it is in compliance -- but CMS nonetheless revokes the provider based on information it internally has and the provider does not. The commenter stated that a provider should not face consequences merely because CMS determines -- based on nonpublic, inaccessible, delayed, or undefined information -- that a relationship created an unarticulated risk.

Response: We respectfully disagree with the commenter because each of our denial and revocation grounds in §§ 424.530 and 424.535 identifies the basis for the action and the conduct or activity involved.

Comment: A commenter stated that CMS should resolve conflicting findings between State survey agencies and MACs before taking an adverse enrollment action.

Response: We again note that provider enrollment requirements are separate from the CoPs. Sections 424.500 through 424.575 are – and have always been – enforced outside of the State survey process, and the former requirements are neither dependent upon nor impacted by the latter.

Comment: A commenter questioned whether additional reviews under our proposals will increase processing times for enrollment applications and, if so, how CMS will minimize them.

Response: Based on our experience with past rulemaking efforts, we do not anticipate

the present final rule causing processing delays. That said, and as always, we will monitor processing times and strive to ensure consistency across the MACs' enrollment processes.

Comment: A number of commenters stated that CMS should not impose denials and revocations under our new provisions without clear definitions, objective standards, and adequate provider education.

Response: We respectfully direct the commenters to our earlier discussions and responses regarding definitions, standards, and stakeholder guidance.

D. DME Benefit Expansion for Infusion Pumps and Drugs

1. Background

a. Home Infusion Therapy Benefit

In section 5012 of the 21st Century Cures Act (Pub. L. 114-255), Congress amended section 1861(s)(2) of the Act and added sections 1834(u) and 1861(iii) of the Act to establish a new Medicare home infusion therapy benefit effective January 1, 2021. This benefit covers certain professional services associated with the provision of home infusion therapy to a beneficiary who is under the care of a physician, nurse practitioner, or physician assistant. Home infusion therapy involves the intravenous or subcutaneous administration of drugs or biologicals to an individual at home through an external infusion pump. As indicated in a final rule we published in the **Federal Register** on November 8, 2019, titled "Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements," the external infusion pump and other supplies, including home infusion drugs necessary for the effective use of the pump, are covered under the Part B DME benefit rather than the home infusion therapy benefit (84 FR 60612). Pursuant to section 1861(iii) of the Act, we published a final rule in the **Federal Register** on November 13, 2018, titled "Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations" (83 FR 56406) to define the scope of "home infusion therapy," "home," "qualified home infusion therapy supplier," and "home infusion drug" at 42 CFR 486 Subpart I.

Section 486.525(a) implements the definition of "home infusion therapy" set forth at section 1861(iii)(1) of the Act, defining the term to include professional services, including nursing services, furnished in accordance with the plan of care described under 42 CFR 486.520,

patient training and education (not otherwise paid for as DME), remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs furnished by a qualified home infusion therapy supplier in the individual's home. Section 486.505 implements the definition of "home" set forth at section 1861(iii)(3)(B) of the Act, defining the term as a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, critical access hospital (CAH), or skilled nursing facility (SNF) as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Section 486.505 implements the definition of "qualified home infusion therapy supplier" set forth at section 1861(iii)(3)(D)(i) of the Act, defining the term to mean a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act: (1) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; (2) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; (3) is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act; and (4) meets such other requirements as the Secretary determines appropriate. A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet these requirements.

Section 486.505 implements the definition of "home infusion drug" set forth at section 1861(iii)(3)(C) of the Act, currently defining the term 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, excluding insulin pump systems and self-administered drugs or biologicals on a self-administered drug exclusion list.

b. Durable Medical Equipment Benefit

Under the Medicare Part B benefit for DME, a limited number of home infusion drugs (as defined under 42 CFR 486.505) are covered if it is determined that it is medically necessary to use an external infusion pump classified as DME for administration of the home infusion drug, and the home infusion drug being used with the pump is, itself, reasonable and necessary for the treatment of an illness or injury (84 FR 60612).

For an external infusion pump and associated supplies to be covered under the Part B DME benefit, the pump must, among other statutory and regulatory requirements, be "appropriate for use in the home" (see 42 CFR 414.202). This requirement means that the equipment must be capable of being safely and effectively used by the beneficiary or caregiver in the home without the assistance of a health care professional (84 FR 60628). As noted previously, section 1861(iii)(3)(C) of the Act limits the home infusion therapy benefit to drugs administered in the patient's home through a pump covered under the DME benefit as defined under section 1861(n) of the Act. Therefore, historically, external infusion pumps and associated home infusion drugs that do not meet the "appropriate for use in the home" requirement have not been eligible for coverage under the DME benefit and services associated with administering the home infusion have not been covered under the Part B home infusion therapy benefit.

2. Current Issues

Section 6222(a) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119-75) amended section 1861(n) of the Act to expand the scope of the Medicare Part B benefit for DME to include certain external infusion pumps and associated home infusion drugs (as defined in section 1861(iii)(3)(C) of the Act) or other associated supplies that would not otherwise qualify as DME because the use of such an item would not meet the "appropriate for use in the home" requirement applied to the DME definition at 42 CFR 414.202. As stated in section V.D.1. of this final rule, CMS has historically interpreted the requirement that DMEPOS must be "appropriate for use in the home" to mean that the equipment must be capable of being

safely and effectively used by the beneficiary or caregiver in the home without the assistance of a health care professional.

Effective for items furnished on or after April 1, 2027, section 6222(a) of the CAA, 2026, states an external infusion pump and associated home infusion drug (as defined in section 1861 (iii)(3)(C) of the Act) or other associated supplies that do not meet the "appropriate for use in the home" requirement applied to the definition of DME under 42 CFR 414.202 (or any successor to such regulation) must be treated as meeting such requirement if each of the following criteria is satisfied:

- The prescribing information approved by the FDA for the home infusion drug associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional;
- A qualified home infusion therapy supplier, as defined in section 1861(iii)(3)(D) of the Act, administers or supervises the administration of the drug or biological in a safe and effective manner in the patient's home, as defined in section 1861(iii)(3)(B) of the Act; and
- The FDA-approved prescribing information instructs that the home infusion drug be infused at least 12 times per year:

++ Intravenously or subcutaneously; or

++ At infusion rates that the Secretary determines would require the use of an external infusion pump.

Section 6222(a) of the CAA, 2026 does not define the term "health care professional." In the proposed rule titled "Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies," which we published in the **Federal Register** on July 6, 2026, we proposed that the term "health care professional" would refer to any of the following clinicians, provided that such clinician is

permitted to administer or supervise the administration of a home infusion drug in accordance with Federal and State law: physician (as defined in section 1861(r) of the Act); a clinical nurse specialist, nurse practitioner, or a physician assistant (as such terms are defined in section 1861(aa)(5) of the Act and regulations at 42 CFR 410.74 through 410.76); or a registered nurse otherwise licensed to practice nursing in the State in which the home infusion drug is administered (91 FR 41305). To ensure consistency across the Medicare program, we proposed to define physician, clinical nurse specialist, nurse practitioner, and physician assistant as such terms are defined under the Medicare home health benefit. Given that sections 1861(r) and (aa)(5) of the Act (as codified at 42 CFR 410.74 through 410.76) do not define "registered nurse," we proposed to define "registered nurse" as a clinician licensed to practice nursing in the State in which the home infusion drug is administered (91 FR 41305).

Because of the risks associated with administering certain home infusion drugs in the home under the expanded DME benefit, we proposed limiting the definition of "health care professional" to these practitioners (91 FR 41305). We stated that we are aware of at least one drug, patisiran, that presents heightened safety risks and that may meet the new criteria and definition of home infusion drug under the revised definition of DME at section 1861(n) of the Act (91 FR 41305). In accordance with the prescribing information for the drug patisiran, adverse reactions during clinical trials included upper respiratory tract infections as well as infusion-related reaction symptoms including dizziness, headaches, chest pain, and other symptoms. Four serious adverse reactions of atrioventricular (AV) heart block (2.7 percent) occurred in patients treated with patisiran, including three cases of complete AV block. Warnings and precautions regarding infusion-related reactions under the highlights of prescribing information include the need to monitor for signs and symptoms of reactions during infusion, slow or interrupt the infusion if clinically indicated, and discontinue the infusion if a serious or life-threatening infusion-related reaction occurs. Infusion-related reactions for other home infusion drugs that may be covered under the expansion of the DME benefit could be even

more serious and require emergency medical assistance in certain situations. Based on our review, we stated that we believe that such safety concerns may be adequately monitored and mitigated if either a physician, clinical nurse specialist, nurse practitioner, physician assistant, or registered nurse administers or supervises the administration of the home infusion drug (91 FR 41305). We stated that we believe any of these clinicians, if available on hand, could address any emergency medical events that occur during the course of the infusion of the drug (91 FR 41305). We solicited comments on the proposal, including whether there are other clinicians that may be equally qualified to administer or supervise the infusions of the drugs in the home and also address any emergency medical events that occur during the course of the infusion of the drug (91 FR 41305).

We note that we did not propose that the term "health care professional" be defined to include a licensed practical nurse (LPN) or licensed vocational nurse (LVN) under the supervision of a registered nurse or physician (91 FR 41305). State law varies in terms of whether an LPN or LVN can perform certain emergency services such as delivering emergency medications. Thus, we stated that it is not clear that addressing the adverse effects associated with the administration of certain home infusion drugs would consistently fall under an LPN's or LVN's scope of practice (91 FR 41305). Additionally, as LPNs and LVNs practice under supervision without the same level of independent clinical authority as the professionals identified previously, we stated that we believe they are less suited to serve as a health care professional for administering complex home infusion drugs under the expanded Medicare DME benefit. In addition, we stated that we do not believe that supervising the administration of the drug in the home should be done remotely as this could violate state laws and compromise the safety of the home infusion therapy as a health care professional would not be present to perform any necessary emergency services (91 FR 41305). In order to be present and able to perform emergency services in the home setting if necessary for the safety and health of the beneficiary, we proposed that the health care professional be on site at the home to administer or directly

supervise the administration of a home infusion drug covered under the expanded DME benefit (91 FR 41305). We solicited comments on the proposal (91 FR 41305).

As stated previously, section 6222(a) of the CAA, 2026 expands the DME benefit category to include external infusion pumps and associated home infusion drugs that the prescribing information instructs should be infused at least 12 times per year: (1) intravenously or subcutaneously (section 1861(n)(3)(A) of the Act); or (2) infused at infusion rates that the Secretary determines would require the use of an external infusion pump (section 1861(n)(3)(B) of the Act). Based on our review, we stated that there do not currently appear to be any home infusion drugs that must be infused at rates that would require the use of an external infusion pump that do not otherwise already fall under the criterion set forth under section 1861(n)(3)(A) of the Act (91 FR 41305). Therefore, we did not propose to include additional drugs under the scope of this DME benefit category expansion that do not already meet the criterion set forth under section 1861(n)(3)(A) of the Act (91 FR 41306). The criterion specified in section 1861(n)(3) of the Act is that the drug must be infused at least 12 times per year. Because of the way dosing information is typically framed in the prescribing information, we proposed that to meet this requirement, the drug must be infused at least once per month (91 FR 41306). We stated that we believe such clarification would be appropriate given that it is aligned with how home infusion drugs are typically framed in the prescribing information. Therefore, we proposed that home infusion drugs covered under this expanded DME benefit must be infused at least once a month (91 FR 41306). We solicited comments on the proposal (91 FR 41306).

We note that we did not propose a minimum or maximum number of times a drug must be infused to qualify as a "home infusion drug" (91 FR 41306). The duration of treatment is not always clear and is often patient-dependent. Prescribing information for infusion drugs will often call for infusions to continue indefinitely, until toxicity, or until adverse reactions preclude further treatment.

Finally, section 6222(b) of the CAA, 2026 requires the Secretary to ensure that patients are notified of the cost sharing for electing home infusion therapy compared to other applicable settings of care for the furnishing of infusion drugs under the Medicare program. We stated that we plan to implement this provision through subregulatory guidance (91 FR 41306).

3. Provisions of the Regulation

We proposed to revise the definition of DME under 42 CFR 414.202 to incorporate the amendments to section 1861(n) of the Act for implementation of section 6222(a) of the CAA, 2026, effective April 1, 2027 (91 FR 41306). Specifically, we proposed to provide that certain external infusion pumps, associated home infusion drugs, and related supplies will be treated as meeting the "appropriate for use in the home" requirement when the following three criteria under paragraphs (1) through (3) of section 1861(n) of the Act are satisfied (91 FR 41306):

- The prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional. The health care professional must be a clinical nurse specialist (as defined in § 410.76), nurse practitioner (as defined in § 410.75), physician assistant (as defined in § 410.74), physician as defined in section 1861(r) of the Act, or a registered nurse otherwise licensed to practice nursing in the State in which the home infusion drug is administered. The health care professional must be on site at the home to administer or supervise the administration of the home infusion drug.

- A qualified home infusion therapy supplier (as defined in § 486.505) administers or supervises the administration of the home infusion drug in a safe and effective manner in the patient's home (as defined in § 486.505).

- The prescribing information instructs that the home infusion drug be infused at least 12 times per year (at least once a month), either intravenously or subcutaneously, or at infusion rates that the Secretary determines would require the use of an external infusion pump. We solicited comments on the proposal. We received comments on the proposed DME benefit

expansion for infusion pumps and drugs from a range of stakeholders, including home infusion and specialty pharmacy organizations, health care providers and health systems, patient advocacy organizations, pharmaceutical manufacturers, DME suppliers, clinician organizations, device and technology stakeholders, and other health care organizations. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported expanding Medicare coverage for certain external infusion pumps, associated home infusion drugs, and related supplies that would not otherwise meet the "appropriate for use in the home" requirement. Commenters stated that the expansion could improve access to home infusion and allow beneficiaries to receive clinically appropriate therapies in the home. Several commenters also expressed concern that the statutory expansion remains limited and may not substantially address the broader difference between home infusion coverage available to Medicare beneficiaries and individuals with commercial insurance.

Response: We thank the commenters for their support for expanding the DME benefit for certain external infusion pumps and associated home infusion drugs and supplies. Section 6222(a) of the CAA, 2026 amended section 1861(n) of the Act to provide that certain external infusion pumps and associated home infusion drugs or other associated supplies that would not otherwise meet the "appropriate for use in the home" requirement are treated as meeting that requirement when the statutory criteria are satisfied. We are finalizing the expansion consistent with section 6222(a) of the CAA, 2026 and as proposed. To the extent comments requested expansion beyond the therapies that satisfy the statutory criteria, those requests are beyond the scope of this rulemaking and, where they would require modification of the statutory criteria, would require legislative action.

Comment: The majority of commenters supported the proposed requirement that the health care professional be physically present in the home to administer or supervise administration of the home infusion drug, emphasizing patient safety and the need for clinical

support when administering therapies that may result in serious infusion reactions or require emergency intervention. A commenter recommended that CMS permit supervision through real-time audio and video technology when clinically appropriate and consistent with FDA approved prescribing information, rather than requiring physical presence in every circumstance.

Response: We thank the commenters for their comments. We continue to believe that requiring the health care professional to be physically present in the home is appropriate for the therapies covered under this expanded DME benefit. As discussed in the proposed rule, certain drugs that may qualify under this provision may present safety risks that require the health care professional to be available in the home to address an adverse event or provide emergency services. Accordingly, we are finalizing the physical presence requirement as proposed. Administration or supervision for purposes of this provision may not be furnished remotely.

Comment: Several commenters supported CMS's proposal to limit the health care professionals who may administer or supervise the administration of home infusion drugs to physicians, clinical nurse specialists, nurse practitioners, physician assistants, and registered nurses, stating that the designated health care professionals have the appropriate clinical training and authority to administer or supervise home infusion drugs. Some commenters also supported excluding licensed practical nurses and licensed vocational nurses because their scope of practice and authority may vary by State.

Several other commenters recommended that CMS not limit the definition to the specific professional categories identified in the proposed rule. Concerns were raised that a fixed list of professional types could restrict access to home infusion, particularly in rural and underserved areas. These commenters recommended allowing appropriately licensed health care professionals to administer or supervise administration when authorized under applicable State scope of practice and licensure requirements. The commenters also emphasized competency, appropriate training, and authority under State law rather than professional title alone.

A commenter recommended that CMS not categorically exclude pharmacists where State law authorizes them to administer parenteral medications and to recognize the role pharmacists may play in infusion therapy. A commenter also requested that CMS clarify that home infusion drugs are administered by health care professionals, while qualified home infusion therapy suppliers remain the entities authorized to furnish and bill for home infusion therapy services.

Response: We thank the commenters for their comments regarding the definition of health care professional. In the CY 2027 HH PPS proposed rule (91 FR 41305), we proposed, that to be covered under the expanded DME benefit, the prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump must instruct that the drug should be administered by or under the supervision of one of the following health care professionals: a clinical nurse specialist (as defined in § 410.76), nurse practitioner (as defined § 410.75), physician assistant (as defined in § 410.74), physician as defined in section 1861(r) of the Act, or a registered nurse otherwise licensed to practice nursing in the State in which the home infusion drug is administered because of the risks associated with administering certain home infusion drugs in the home. We excluded LPNs and LVNs from this definition for two related reasons: (1) State law varies as to whether LPNs and LVNs may independently perform certain tasks associated with home infusion drug administration, such as responding to adverse drug events; and (2) because LPNs and LVNs typically practice under supervision rather than with independent clinical authority, we were concerned that they would be less suited, as a category, to administer complex home infusion drugs.

After further review and consideration of the public comments, we continue to believe that it is important for a health care professional administering or supervising the administration of a home infusion drug to have the clinical authority necessary to safely administer or supervise the administration of the drug and respond to adverse events or other medical events that may occur during the infusion.

However, both concerns are more accurately and more precisely addressed by the independent clinical authority that a State has conferred on a given professional to administer or supervise the administration of the home infusion drug, rather than by a categorical exclusion based on license title. State scope-of-practice determinations already reflect a judgment about which activities a licensed professional—including an LPN or LVN—may perform independently versus only under supervision and categorical exclusions may not adequately account for differences in these state rules and regulations. We also agree with commenters concerned about beneficiary access to the expanded benefit in areas where there may be a shortage of registered nurses and other specific types of health care professionals named in the proposed rule, especially in rural areas, and believe that not limiting the definition of health care professional to the specific categories identified in the proposed rule may prevent certain situations where patients in rural or underserved areas cannot access home infusion therapy simply because their available clinician does not fall within a specifically named profession type. We believe this approach appropriately addresses the safety concerns identified in the proposed rule while also addressing potential beneficiary access concerns.

After consideration of the public comments, we are not finalizing the proposed limitations on the definition of a health care professional and are revising 42 CFR 414.202(2)(i)(A) to state that the administration or supervision of the home infusion drug must be within the scope of the health care professional's practice as specified by applicable Federal and State laws, regulations, and licensure requirements. This would enable any health care professional to provide these services if it is within their scope of practice, in order to more accurately reflect the clinical authority States have already conferred and to address potential access problems in rural areas. Regarding the comment requesting that we clarify that home infusion drugs are administered by a health care professional, we note that the proposed 42 CFR 414.202(2)(i), consistent with section 6222(a)(1) of the CAA, 2026, requires that the FDA-approved prescribing information for the home infusion drug instruct that the drug be

administered by or under the supervision of a health care professional. Separately, 42 CFR 414.202 (2)(ii), consistent with section 6222(a)(2) of the CAA, 2026, requires that a qualified home infusion therapy supplier administer or supervise the administration of the home infusion drug in a safe and effective manner in the patient's home. These requirements address different aspects of the provision. Paragraph (2)(i) addresses the health care professional who may administer or supervise the administration of the drug, while paragraph (2)(ii) addresses the role of the qualified home infusion therapy supplier in furnishing home infusion therapy services.

We also believe that the qualified home infusion therapy supplier will employ, contract with, or coordinate with the health care professional who administers or supervises the administration of the home infusion drug. Section 1861(iii)(3)(D)(i) of the Act permits a qualified home infusion therapy supplier to subcontract with a pharmacy, physician, provider of services, or supplier to meet the applicable qualified home infusion therapy supplier requirements. The qualified home infusion therapy supplier remains responsible for furnishing and billing for the home infusion therapy services in accordance with the applicable requirements. For these reasons, and due to the scope-of-practice standard in 42 CFR 414.202(2)(i)(A), we believe we have appropriately addressed the commenter's concerns.

Comment: Commenters expressed differing views regarding CMS's proposal to interpret the statutory requirement that the prescribing information instruct that the home infusion drug be infused at least 12 times per year to mean at least once per month. Several commenters supported the proposed interpretation, stating that it would provide a reasonable and administratively workable standard for applying the statutory frequency criterion. Some commenters also supported not establishing a separate minimum or maximum number of infusions.

Several other commenters recommended that CMS apply the statutory language of at least 12 times per year without specifying an infusion during every calendar month. These comments stated that annual and monthly frequency requirements are not necessarily equivalent

because dosing schedules may vary based on the drug, treatment phase, clinical response, and other clinical circumstances. A comment provided an example of a therapy administered through treatment cycles that result in more than 12 infusions annually without an infusion occurring during every calendar month. Comments also stated that the "at least once a month" criterion is not what is provided in the statute and that CMS has arbitrarily read additional requirements into the statute that Congress did not include.

Several commenters also raised concerns regarding loading periods, temporary treatment interruptions, illness, travel, scheduling issues, provider shortages, and individualized dosing adjustments. The comments requested flexibility so that these circumstances would not unnecessarily affect access to the benefit.

Other comments sought broader relief from the annual frequency criterion of 12 infusions, stating that the statutory frequency threshold limits the range of therapies that may qualify for the expanded benefit.

Response: We thank the commenters for expressing their thoughts and concerns regarding the frequency criterion. Section 6222(a) of the CAA, 2026 amended section 1861(n) of the Act to require, among other applicable criteria, that the prescribing information instruct that the home infusion drug be infused at least 12 times per year. In the proposed rule, we proposed to interpret this statutory requirement to mean that the drug must be infused at least once per month based on how dosing information for home infusion drugs is typically described in prescribing information.

We agree that the statutory requirement of at least 12 infusions per year does not necessarily require an infusion during every calendar month. A dosing schedule may provide for 12 or more infusions per year while also including treatment cycles or periods during which an infusion does not occur.

After consideration of the public comments expressing concern about our deviation from the statutory language, we are not finalizing our proposed interpretation that at least 12 times per

year means at least once per month. We are not including the parenthetical "at least once a month" in paragraph (2)(iii) of the definition of DME in 42 CFR 414.202, and we are finalizing the regulatory text consistent with the statutory requirement of "at least 12 times per year."

We clarify that this criterion is not based on how often an individual beneficiary receives an infusion, but rather what the applicable prescribing information instructs regarding the frequency of infusion. However, we disagree with comments requesting that CMS waive, reduce, or establish exceptions to the requirement that the prescribing information instruct that the drug be infused at least 12 times per year. Congress expressly established the 12 times per year criterion in section 1861(n)(3) of the Act. We do not have authority through this rulemaking to eliminate or modify that statutory requirement. A change to that requirement would require a change in the statute.

Comment: Commenters expressed concern that Medicare beneficiaries may face higher cost sharing when receiving infusion therapy in the home and recommend that beneficiaries receive clear information regarding expected costs before electing home infusion.

Response: Section 6222(b) of the CAA, 2026 requires the Secretary to ensure that beneficiaries are notified of the cost sharing for electing home infusion therapy compared with other applicable settings of care. We agree that beneficiaries should be appropriately notified of cost sharing implications, and CMS plans to implement this statutory requirement through subregulatory guidance.

Comment: Commenters from home infusion and specialty pharmacy organizations, health care providers, pharmaceutical manufacturers, patient advocacy organizations, DME suppliers, and device and technology stakeholders provided feedback regarding implementation of the expanded DME benefit. Several commenters addressed reasonable and necessary determinations for external infusion pumps, drugs, and associated supplies, pump necessity including a comment that specifically mentioned, titration and dose ramp up periods, and infusion monitoring technology. Several commenters also addressed implementation of the Medicare

home infusion therapy services benefit, including payment categories, HCPCS coding, Medicare Administrative Contractor (MAC) coordination, supplier enrollment and billing, subcontracting and supplier arrangements, claims processing, operational guidance, and implementation timing.

Response: The provisions of this rule address the scope of the DME benefit under section1861(n) of the Act, as amended by section 6222(a) of the CAA, 2026. Reasonable and necessary determinations under section 1862(a)(1)(A) of the Act and issues concerning home infusion therapy payment, coding, supplier arrangements, billing, claims processing, and other operational matters are outside the scope of these provisions. Reasonable and necessary determinations for pumps, drugs, and supplies will be addressed by the DME MACs through the applicable coverage process. CMS is also working to address other implementation issues following publication of this final rule and in advance of the effective date, as appropriate. Additionally, we encourage suppliers to provide beneficiaries with a voluntary advance notice (for example, a voluntary Advance Beneficiary Notice of Non-coverage) when the mode of administration of a drug changes from an external infusion pump to another mode (for example, IV drip) and the requirements set forth under section 1861(n)(3) of the Act are not met, so that beneficiaries understand the potential impact of such a change on Medicare coverage and payment. We believe this notice will support beneficiary understanding about their financial responsibility and informed decision-making.

After consideration of the public comments, we are finalizing modifications to the definition of DME under 42 CFR 414.202 to incorporate the amendments to section 1861(n) of the Act by section 6222(a) of the CAA, 2026, effective April 1, 2027. Specifically, we are finalizing that certain external infusion pumps, associated home infusion drugs, and related supplies will be treated as meeting the "appropriate for use in the home" requirement when the following criteria under paragraphs (1) through (3) of section 1861(n) of the Act are satisfied:

- The prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump instructs that the drug should be administered by

or under the supervision of a health care professional. The health care professional must be on site at the home to administer or supervise the administration of the home infusion drug, and the administration or supervision must be within the health care professional's scope of practice as specified by applicable Federal and State laws, regulations, and licensure requirements.

- A qualified home infusion therapy supplier (as defined in § 486.505) administers or supervises the administration of the home infusion drug in a safe and effective manner in the patient's home (as defined in § 486.505).

- The prescribing information instructs that the home infusion drug be infused at least 12 times per year either intravenously or subcutaneously, or at infusion rates that the Secretary determines would require the use of an external infusion pump.

E. DMEPOS Competitive Bidding Program--Country of Origin

In the CY 2027 HH PPS proposed rule, CMS discussed requiring Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) contract suppliers to report the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance. Under section 1847(b)(3)(A) of the Act and 42 CFR 414.422(a), CMS specifies the terms and conditions of DMEPOS CBP contracts.

During an active round of the DMEPOS CBP, contract suppliers are required, as a term of their contracts, to use a reporting form, known as Form C, to provide product information (manufacturer name, model name, and model number) for the lead item they furnish. The information provided in the form is included in the Medicare Supplier Directory on the Medicare.gov website with the products the supplier plans to provide during the next 6-month period. Contract suppliers are also required to maintain the accuracy of their product information for the lead item they furnish using Form C. Form C includes an attestation that all the reported information is accurate and up to date. This attestation needs to be completed to fulfill a Form C submission requirement.

We will request that the information collection be revised to include the country of origin for each lead item they report on a new "country of origin" field on Form C. As done historically with the other product information reported on Form C by a contract supplier, the reported country of origin information would also be populated on the Medicare Supplier Directory for the contract supplier during the contract period of performance. This information would allow beneficiaries and interested parties to have access to the information on the country from which the DMEPOS item originated, if interested.

Contract suppliers would identify the country of origin based on the markings on the product for the lead item, or where an exemption to marking applies, obtain documentation from the manufacturer or distributor. Under U.S. Customs and Border Protections rules (19 CFR §§ 134.11, 134.46), imported goods must be properly marked to indicate the country of origin (for

example): “Made in [Country]”), unless an exemption applies (for example, an item that is incapable of being marked, like a catheter), as explained at 19 CFR 134.32.

To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to obtain documentation from the manufacturer or distributor indicating the country of origin for its product, which could include one or a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification.

The details for this update to Form C will be included under OMB Control Number 0938-1408 (CMS-10744).

We received public comments on these revisions. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the increased transparency that the discussed change would provide to beneficiaries, stating that transparency regarding product sourcing helps beneficiaries make informed decisions.

*Response***:** CMS appreciates commenters’ support and agrees that transparency regarding a product’s country of origin helps beneficiaries make informed decisions about their DMEPOS suppliers and the DMEPOS they purchase. CMS views this requirement as a complement to the manufacturer and model information that contract suppliers have historically provided and is available in the Medicare Supplier Directory during an active round of the DMEPOS CBP.

Comments: Several commenters opposed the proposal. Commenters discussed that the country of origin offers limited value to beneficiaries because suppliers already report the manufacturer and model information beneficiaries actually care about; that manual entry of information via Form C will create unnecessary burden for contract suppliers; that responsibility for verifying manufacturer information should not shift to home health agencies; and that it is questionable whether beneficiaries would actually inquire about the country of origin.

Response: Manufacturer and model information does not indicate where a product is made, so country of origin remains a distinct, complementary data point that supports beneficiaries who wish to consider the country of origin when selecting a supplier and the DMEPOS they want to purchase. CMS acknowledges concerns about the burden of manual Form C entry and will explore options, including a bulk data entry method, to streamline reporting. CMS did not intend, and does not intend, to shift verification responsibility to home health agencies as the reporting obligation applies to contract suppliers, which are best positioned to confirm country of origin information. Finally, even if not all beneficiaries actively seek country of origin information, making it available increases transparency and supports informed decision-making for those who do.

Comments: Commenters raised several concerns: some stated that the discussed change does not explain how country of origin information will be used and asked for clarification on whether it will inform future policy or enforcement actions; some noted that the discussed change does not identify enforcement actions, and another commenter expressed concern that country of origin reporting alone would not be enough to address concerns related to ownership structures, supply chain security, or other policy objectives. Commenters also discussed that the competitive bidding program's cost-driven structure could let unvetted foreign manufacturers supply substandard or non-compliant products, risking beneficiary safety. Commenters expressed concern that reporting only on the lead item would give beneficiaries an incomplete understanding of the country of origin, since non-lead items can fall under the same HCPCS code as a lead item yet may have a different country of origin; beneficiaries unfamiliar with country of origin distinctions may incorrectly assume all products under a HCPCS code share the lead item's origin.

Response: CMS clarifies that the primary purpose of this discussed change is to increase beneficiary-facing transparency about a product’s country of origin, not to establish a new enforcement mechanism. CMS may use aggregate country of origin data to inform future policy

considerations, such as identifying whether reliance on limited number of countries for certain DMEPOS items creates supplier chain vulnerabilities, in later rulemaking. CMS acknowledges that country of origin reporting alone will not fully address broader ownership structure or supply chain security objectives and will continue to explore complementary policy approaches. Regarding beneficiary safety, existing supplier standards and product quality standards remain in effect regardless of a product's country of origin, and this discussed change does not change the bid evaluation or supplier qualification criteria that bidders must meet to be awarded a DMEPOS CBP contract. CMS acknowledges that beneficiaries may assume all items under a HCPCS code share the lead item's country of origin and, therefore, intends to provide education clarifying that the lead item's country of origin does not necessarily apply to non-lead items furnished under the same HCPCS code. Regarding the availability and reliability of country of origin data, CMS notes that under U.S. Customs and Border Protection rules, imported goods must generally be marked “Made in [Country]” unless an exemption applies as provided at 19 CFR 134.32. Where a marking is absent or requires verification, contract suppliers may need to obtain documentation from the manufacturer or distributor identifying the product's country of origin, which could include manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification, individually or in combination.

Comments: Commenters offered several recommendations. Commenters suggested that CMS should include more than just the lead item's country of origin, with several recommending that the Medicare Supplier Directory display the country of origin for all products, not only the lead item. Additionally, commenters recommended CMS specify a clear definition of the "country of origin" field, use uniform definitions and reliable documentation standards, and permit suppliers to rely on documentation provided by manufacturers or distributors. Commenters also recommended that CMS require prospective reporting of country of origin, displayed in advance and updated promptly whenever products change, with a couple of these

commenters also recommending a correction or audit process for information changes. Furthermore, commenters recommended educational materials. These recommendations included beneficiary education explaining what country of origin information means and the distinction between lead and non-lead items, as well as providing educational materials before the bidding window opens. Another commenter requested that CMS display manufacturer, model, and interoperability information alongside country of origin. A commenter suggested CMS allow bulk data entry to reduce burden associated with the discussed changes. Finally, a commenter recommended that, rather than country of origin reporting, CMS focus on stronger supplier vetting, manufacturer quality standards, and product approval safeguards.

Response: We appreciate these recommendations. The Medicare Supplier Directory will display the country of origin information, but CMS believes requiring contract suppliers to report on both lead items and non-lead items is too burdensome. However, we can expand the policy later, if needed. CMS agrees that a clear, uniform definition of "country of origin" and reliable documentation standards will improve consistent reporting. CMS believes the proposed rule provided guidance to contract suppliers on identifying country of origin and the types of documentation that may be used, as follows: “Contract suppliers would identify the country of origin based on the markings on the product for the lead item, or where an exemption to marking applies, obtain documentation from the manufacturer or distributor.” Under U.S. Customs and Border Protection’s rules (19 CFR 134.11 and 134.46), imported goods must be properly marked with: “Made in [Country],” unless an exemption applies (for example, an item that is incapable of being marked, like a catheter), as explained at 19 CFR 134.32. To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to obtain documentation from the manufacturer or distributor indicating the country of origin for its product, which could include one or a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff

Schedule classification. CMS agrees that timely, prospective reporting improves usefulness for beneficiaries and will provide guidance on the expected timeframe for updates following a product change, and will consider establishing a correction process suppliers can use to promptly amend inaccurate entries. CMS agrees that education supports successful implementation and plans to provide materials explaining country of origin information and the lead/non-lead item distinction in advance of the next competitive bidding contract period of performance, which is expected to start no sooner than January 1, 2028. CMS will display manufacturer, model, and country of origin information on the Medicare Supplier Directory to give beneficiaries a more complete product view. CMS notes that the comments about interoperability information are out of scope. Finally, CMS agrees that supplier vetting and product quality standards are important complements to transparency measures, and country of origin reporting is not intended to replace, but instead strengthen, existing vetting and quality requirements under the DMEPOS CBP.

After considering all comments, we will proceed with the information collection revision through the standard PRA process.

F. Revising Covered Document Review Date (CDRD) Evaluation and Notification for the DMEPOS CBP --Technical Corrections to 42 CFR 414.414(d)

In the CY 2026 HH PPS final rule (90 FR 55554 and 55555), we finalized revisions to § 414.414(d) to reflect changes to the required financial documents. As part of those revisions, the provisions governing the covered document review date (CDRD), previously located at § 414.414(d)(2), were redesignated as § 414.414(d)(3). We also intended to revise § 414.414(d)(3)(ii)(B) so that it would align with the CDRD changes that were finalized in the CY 2026 Home Health final rule. The regulation text was updated correctly with the required financial documents at § 414.414(d)(1) and (2), but the CDRD regulation text was inadvertently omitted from the Code of Federal Regulations at § 414.414(d)(3).

In this CY 2027 HH PPS final rule, we are making the technical corrections to § 414.414(d), by adding the CDRD regulation text that was inadvertently omitted when § 414.414(d)(2) was redesignated as § 414.414(d)(3) and updating § 414.414(d)(3)(ii)(B) in accordance with the CY 2026 HH PPS final rule.

VI. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501-3520, we are required to provide a 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, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our 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.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

B. Information Collection Requirements (ICRs)

In the CY 2027 HH PPS proposed rule, we solicited public comment on each of the issues for the following sections of this document that contain information collection requirements (ICRs). Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year would result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

1. ICRs for HH QRP

As discussed in section III of this final rule, we proposed to revise the HH QRP OASIS data submission deadlines beginning with the CY 2027 HH QRP. CMS also proposed to revise

the HH QRP OASIS and HHCAHPS Annual Payment Update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). CMS proposed some revisions to regulatory text in support of rule proposals or to improve digital transfer of information during the reconsiderations process. Finally, we solicited public comments on one Request for Information (RFI) on future measure concepts for the HH QRP.

The net effect of the proposals is no changes to expected burden associated with OASIS data collection.

We received public comment on our OASIS submission proposal. The following is a summary of the comments we received and our responses.

Comment: Commenters raised issues related to burden related to some proposals. Related to the OASIS submission proposal, commenters had concerns about operational and staffing challenges, administrative burden, and data validation, especially for small or rural HHAs that may struggle with staffing challenges and operational issues. A few commenters expressed concerns that providers continue to experience staffing shortages and turnover of HH staff. Some commenters that supported the proposal noted the current clinical and administrative burden around implementing OASIS all-payer submissions and changing payment requirements. Several commenters encouraged CMS to establish a phased implementation or grace period to meet submission requirements, to provide flexibility for the first several data submission cycles. A few other commenters cited recent implementation of the HOPE tool to stress the benefits of a phased implementation.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural HHAs. We do not believe that the proposal adds burden for HHA staff by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Since workflows are in place for the necessary processes, we do not believe a phased implementation approach is necessary.

Comment: Related to the OASIS and HHCAHPS APU proposals, commenters also raised concerns of burden. Commenters who supported the APU calendar updates with concerns commonly raised the issue of burden associated moving to a new APU calendar. They noted that to ensure an effective transition would require investments in quality assurance resources, data analytics, clinical education, software systems, and compliance oversight.

Response: We thank commenters for outlining potential burden issues related to the APU update proposals. We will provide clear guidance around the implementation of this policy that should limit costs associated with the transition and implementation of calendar year APU reporting. We also do not anticipate changes in scoring methodologies associated with this transition to calendar year reporting of APU calculations.

2. ICRs for the Expanded HHVBP Model

We did not propose any changes to the expanded HHVBP Model in the CY 2027 HH PPS proposed rule.

3. ICRs for DMEPOS Requirements for Identical Replacement Items

The proposed clarification neither imposes new information collection requirements nor eliminates existing ones. Rather, it further explains and reinforces the intent of this section when the item furnished is a replacement item. The PRA package for Medicare Fee-for-Service Prepayment Review of Medical Records is CMS-10417 and approved under OMB control number 0938-0969. In section V.B. of this final rule, we clarify that a new face-to-face encounter and related documentation are not required to support payment for replacement durable medical equipment, prosthetic, orthotic and supply (DMEPOS) items. Under existing Medicare requirements, suppliers and providers are already obligated to maintain documentation sufficient to demonstrate compliance with coverage requirements under 42 CFR 410.38 at the time the item is furnished. This rule clarifies that CMS does not consider an additional comprehensive beneficiary examination necessary to "gather subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered"

when the item being furnished is a replacement item. If a claim for a replacement DMEPOS item is subject to audit, the provider must nevertheless submit documentation from the original face-to-face encounter to demonstrate that medical necessity, billing and coverage requirements have been satisfied. Accordingly, the intent of 42 CFR 410.38, which requires a face-to-face encounter for certain DMEPOS items, would continue to apply when the item is initially furnished; however, the requirement would not need to be repeated solely for replacement items. Therefore, we assume this clarification would have a negligible monetary impact.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

4. ICRs for Provider Enrollment

For those enrollment provisions not addressed in this section VI.B.4. of this final rule, we do not believe that any of them would impose an information collection burden on interested parties. Provisions that are addressed as follows either will impose such a burden or will not but require further explanation.

a. Signage

Section 424.510(f) would require all providers and suppliers (regardless of type) to maintain a permanent visible sign in plain view and post their hours of operation. While we believe the vast majority of providers and suppliers already maintain such signage, some do not. For purposes of this ICR statement, we project that: (1) roughly 200,000 providers will need to obtain or revise their signage under § 424.510(f); (2) it would take each provider an average of 5 hours to do so; and (3) this activity – at least for currently enrolled providers -would mostly occur in the first year following § 424.510(f)'s effective date. (The 200,000 figure includes providers and suppliers already enrolled in Medicare and those that may be newly enrolling over the next 3 years.) We believe the supplier's office staff would acquire the signage. Per data from the U.S. Bureau of Labor Statistics' (BLS') May 2025 National Occupational Employment and Wage Statistics for all wage estimates (*https://www.bls.gov/oes/tables.htm*), the mean hourly

wage for the "Office and Administrative Support Workers, All Other" category (43-9199) is $23.40; with fringe benefits and overheard, the figure is $46.80. This results in a total burden over the first three of this requirement of 1 million hours and $46,800,000. The annual cost over the three-year period would be $15,600,000.

This burden estimate will be submitted for OMB review and approval as part of new information collection request -- that is, a request for a new OMB control number. Stakeholders will be able to furnish public comment on this estimate during the PRA process.

b. Clarification of "Managing Employee" Definition

All providers and suppliers must report their managing employees (and any changes in their managing employees) to CMS. This reporting requirement falls within the overall OMB-approved ICR burden for the following forms:

- Form CMS-855A (Medicare Enrollment Application for Institutional Providers; OMB Control No. 0938-0685)[57].
- Form CMS-855B (Medicare Enrollment Application - Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938-1377)[58].
- Form CMS-855I (Medicare Enrollment Application – Physicians and Non-Physician Practitioners; Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938-1355)[59]..
- Form CMS-855S (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938-1056)[60].

We proposed to revise the definition of "managing employee" in § 424.502 to identify certain individuals who fall within this definition. As explained in section V.C. of this final rule,

57 OMB control number 0938-0685 expires September 30, 2027
58 OMB control number 0938-1377 expires September 30, 2027
59 OMB control number 0938-1355 is currently pending OMB reapproval.
60 OMB control number 0938-1056 expires September 30, 2029.

these persons have always qualified as managing employees and thus must be reported. We are simply identifying them in § 424.502 to reiterate this point.

c. Documentation

(1) "Operational"

Paragraph (5) of our revised definition of "operational" in § 424.502 would require, in part, that the provider or supplier have adequate written policies and records regarding its operations. We do not believe this would impose an additional information collection burden on providers and suppliers. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), providers and suppliers typically maintain such policies and records as a usual and customary business practice. Therefore, we have not assigned any burden to this requirement.

(2) Section 424.516(f)

Section 424.516(f) requires providers and suppliers to maintain certain types of documentation. We proposed to revise this paragraph to make clear that said documentation must be accurate, complete, and consistent with CMS requirements. We do not believe this would impose an additional information collection burden on providers and suppliers. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), providers and suppliers typically maintain such policies and records as a usual and customary business practice. Therefore, we have not assigned any burden to this requirement.

d. Private Equity Companies (PECs) and Real Estate Investment Trusts (REITs)

The Form CMS-855A enrollment application for certified providers and certain certified suppliers (Medicare Enrollment Application for Institutional Providers OMB Control No. 0938-0685) requires providers and suppliers to report whether any party listed on the application is a PEC or a REIT. We announced in the proposed rule our intention to expand this requirement to the following Medicare provider and supplier enrollment forms:

- Form CMS-855B (Medicare Enrollment Application - Clinics/Group Practices and Certain Other Suppliers; OMB Control No. 0938-1377).

- Form CMS-855S (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers; OMB Control No. 0938-1056).
- Form CMS-20134 (Medicare Diabetes Prevention Program (MDPP) Suppliers).

Although this announcement would not, in and of itself, impose an information collection burden, the revisions of the Forms CMS-855B and CMS-855S, to collect PEC and REIT data would do so. The Forms CMS-855B and CMS-855S burdens will be addressed in the information collection requests that CMS will submit to the Office of Management and Budget to request revisions to these two forms. However, the Form CMS-20134 is exempt under section 3021 of the Affordable Care Act.

e. Disclosure of Affiliations

As discussed in section V.C. of this final rule, we proposed to revise our affiliation provisions in §§ 424.502 and 424.519. We solicited comments from interested parties as to whether any additional ICR burden would ensue from these changes. . As we explained in section V.C. of this final rule, though, we do not foresee an ICR burden associated with said revisions, for we do not anticipate requesting providers and suppliers to disclose the data referenced in § 424.519.

f. Reactivation Effective Dates

We proposed to permit providers that have been assigned an effective date for their reactivation to submit a rebuttal if they disagree with said date. We believe the rebuttal and the associated burden would be incurred after an administrative action. In accordance with the implementing regulations for the PRA (5 CFR 1320.4(a)(2) and (c)), the burden associated with any information collected subsequent to the administrative action is exempt from the requirements of the PRA (that is, the rebuttal submitted subsequent to the assignment of the reactivation effective date).

g. Comments Received

The vast majority of the comments we received regarding the burden associated with our provider enrollment provisions overlapped between information collection requirements and other burdens normally addressed in the RIA. With the exception of the following comment, which was largely limited to information collection requirements, the burden comments and our responses will be addressed in the RIA section.

Comment: Several commenters expressed concern that CMS did not assess costs for its revised "managing employee" definition. A few stated, as noted in section V.C. of this final rule, that this revision expands the types of reportable managing employees, further asserting that CMS admits as much in its use of terms such as "added" and "expand upon" in the proposed rule. This, they believed, contradicts CMS' statements that the revised definition imposes no additional costs because these persons have always had to be reported. They maintained that this: (1) is a procedural error and reflects "internally inconsistent" decision-making that is arbitrary and capricious; (2) denies the public a meaningful opportunity to comment on the proposal; and (3) fails to consider any benefits that might stem from the revised definition when weighed against what the commenter believes are the associated costs. Another commenter stated that if providers are not currently reporting clinical managing employees, the burden of doing so now is real and should be reported – even if CMS believe no burden exists because these persons should always have been reported.

Response: As we explained in section V.C. of this final rule (to which we refer readers for a more robust discussion), we continue to maintain that the clinical personnel in question always fell within the "managing employee" definition and must be disclosed. Our use of terminology such as "added" and "expand upon" simply referenced the formal listing of these persons in the revised definition as a reminder of this. It is not an expansion of the definition, and we made this point clear in the proposed rule. Accordingly, the revision is neither arbitrary nor capricious and does not represent inconsistent decision making.

Our position that the proposal merely clarified that such individuals have always qualified as managing employees is why we did not include a burden estimate. That said, the revised "managing employee" definition in the present final rule would seemingly increase compliance with a requirement that already exists. Although the resulting costs (and benefits) would be attributable to this final rule, quantification is extremely challenging and infeasible given that the scope of each provider's or supplier's individual reporting circumstances will likely vary widely.

We add that the public had a meaningful opportunity to comment on the proposed revised definition, as evidenced by the significant number of comments we received on this proposal. Insofar as benefits, we explained the reason and need for our revision in the proposed and final rules.

Comment: A commenter stated that: (1) the expanded definition of "operational" would require practices to develop and maintain written policies addressing patient care, patient safety, recordkeeping, and administration; and (2) the signage requirement at proposed § 424.510(f) would require practices to install and maintain compliant signage at each applicable location. The commenter disagreed that these and other requirements would not impose a burden. If the CMS believes that providers are already complying with the aforementioned "written policies" and signage requirements, the commenter believed there would be no reason to include them in regulation.

Response: While we have added a burden estimate for the signage requirement, we believe that providers – as part of their ordinary course of business -- already maintain the written policies in (1). Insofar as the commenter's last statement, it is customary for CMS to promulgate provider enrollment regulatory requirements even if provider already performs this function as part of its day-to-day operations. For instance, when we established the documentation retention requirements in § 424.516(f) in 2010, we stated that the burden

associated with maintaining documentation and furnishing it upon request is a usual and customary business practice and thereby exempt from the PRA under 5 CFR 1320.3(b)(2).[61]

After reviewing the comments received (some of which, again, are addressed in the RIA section of this final rule), we are finalizing the aforementioned projections.

5. ICRs for Country of Origin

When ready, the following changes will be submitted to OMB for approval under control number 0938-1408 (CMS-10744) using the standard, non-rule related PRA process (which includes the publication of 60- and 30-day **Federal Register** notices) to facilitate the change.

As discussed in section V.E. of this final rule, we plan to revise Form C (Semi-Annual Report) to collect the country of origin information for the lead items furnished during the DMEPOS CBP contract's period of performance. Because contract suppliers are required to submit Form C once every 6 months during January and July throughout the DMEPOS Competitive Bidding Program contract's period of performance, contract suppliers will be required to report this information twice a year. A DMEPOS CBP contract supplier will continue to be required as a term of its contract to maintain the accuracy of its product information (manufacturer name, model name, and model number) for the lead item it furnishes on Form C, and they will now be required to also maintain the accuracy of the country of origin for each product it reports in a newly added "country of origin" field on Form C. Form C will continue to require an attestation that all the reported information is accurate and up to date.

Contract suppliers should be able to identify the country of origin based on the markings on the product for the lead item. For example, under U.S. Customs and Border Protections rules, (19 CFR 134.11 and 134.46) imported goods must be properly marked with: "Made in [Country]," unless an exemption applies (for example an item that is incapable of being marked, such as a catheter), as explained at 19 CFR 134.32. To correctly identify the country of origin for

61 "Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements" (75 FR 24437).

a product in the absence of a marking or to verify a marking, contract suppliers may need to refer to readily available documentation from the manufacturer or distributor indicating the country of origin for its product, which could include a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification.

Since the publication of the proposed rule, CMS has published on the Competitive Bidding Implementation Contractor Website the number of contracts to be awarded to suppliers for each product category included in Round 2028 based on the methodology established at 42 CFR 414.414(h)(3)(i) and, therefore, we have updated the burden estimates accordingly. These numbers total 43 contracts. While these figures are expected to reflect the number of contracts awarded for the applicable competition, CMS may award additional contracts to meet the small supplier participation target and to ensure beneficiary demand is met. To account for these potential additional contract awards, CMS estimates that approximately 50 contracts will be awarded for Round 2028. We also estimate that each contract supplier's annual time burden will be 0.2 hours (1 contract supplier/year x 0.1 hr/response x 2 responses/year) at a cost of $21.95 (0.2 hr x $109.74/hr (adjusted by 100 percent for fringe benefits and other indirect costs for an Administrative Services Manager, BLS Occupation Code: 11-3012)). Given that we anticipate that 50 contracts will be awarded for Round 2028, we estimate that the aggregate annual time burden will be 10 hours (50 contract suppliers/year x 0.1 hr/response x 2 responses/year) at a cost of $1,097.40 (10 hr x $109.74/hr) (See Table 22).

TABLE 22: DMEPOS CBP COUNTRY OF ORIGIN ANNUAL BURDEN ESTIMATES

Collection	Respondents	Annual Responses (per respondent)	Total Annual Responses	Time per Response	Total Annual Time (non-aggregate)	Labor Rate ($/hr)	Total Annual Cost ($) (aggregate)
CMS-10744 (OMB 0938-1408)	50 Contract Supplier	2	100	6 min (0.1 hr)	12 min (0.2 hr)	109.74	1,097

We received public comments on these revisions. The following is a summary of the

comments we received and our responses.

Comment: Commenters reported that requiring DMEPOS CBP contract suppliers to provide the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance on Form C is unnecessarily burdensome if they are required to manually enter this information as there are many products from various manufacturers that fall under the lead item for each product category being competitively bid in Round 2028.

Response: We believe that the country of origin information will allow beneficiaries and interested parties to learn where the DMEPOS item originated, if interested. We anticipate a minimal burden for DMEPOS contract suppliers as we believe they will be familiar with the DMEPOS they provide as, per the U.S. Customs and Border Protection rules (19 CFR 134.11 and 134.46), imported goods must generally be marked "Made in [Country]" unless an exemption applies as provided at 19 CFR 134.32. Where a marking is absent or requires verification, contract suppliers may need to obtain documentation from the manufacturer or distributor identifying the product's country of origin, which could include manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification, individually or in combination. The time needed to identify the country of origin in these instances is accounted for in the burden estimate. We also anticipate providing a drop-down list from which DMEPOS contract suppliers would select the country of origin for the lead item in each product category included on their DMEPOS CBP contract. This mechanism would eliminate manual entry and help ensure consistency and accuracy across submissions.

Comment: Commenters noted that country of origin information would be difficult to capture, and that penalties for inaccuracies or missing information could exacerbate supply chain issues and costs.

Response: Our burden estimate assumes suppliers can obtain country of origin data through these existing marking requirements and manufacturer or distributor relationships, and we are not imposing monetary penalties tied to this data collection.

After considering all comments, we will proceed with the information collection revision through the standard PRA process.

VII. Regulatory Impact Analysis

A. Statement of Need

1. HH PPS

Section 1895(b)(1) of the Act requires the Secretary to establish an 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 amount 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 standard 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 require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of 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.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by sections 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of payment, for 30-day periods beginning on and after January 1, 2020. Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, 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. 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. 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 specified by CMS. Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in

the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

3. Expanded HHVBP Model

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) and codified at 42 CFR part 484, subpart F, we finalized our policy to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. CY 2023 was the first performance year in which HHAs individual performance on the applicable measures affected their Medicare payments in CY 2025. We did not propose any expanded HHVBP Model-specific changes in the proposed rule.

4. DMEPOS Encounter Requirements for Identical Replacement Items

In this final rule, we clarify that a new face-to-face encounter and related documentation, as described in 42 CFR 410.38, is not necessary to support the payment of replacement DMEPOS items.

5. Provider Enrollment

Consistent with section 1866(j) of the Act, we finalizing a number of Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) adding and modifying grounds for denying or revoking a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries.

6. DMEPOS Coverage of External Infusion Pumps

With section 6222 of the Consolidated Appropriations Act, 2026, Congress modified section 1861(n) of the Act to expand the scope of the DME benefit to enable coverage for home

infusion of drugs that: (1) must be administered by or under the supervision of a health care professional; (2) are administered by a qualified home infusion therapy supplier; and (3) have prescribing information that requires infusion at least 12 times per year. This regulatory action implements the changes made by section 6222 of the CAA, 2026 to the definition of DME.

7. DMEPOS Competitive Bidding--Country of Origin

For the DMEPOS CBP, we plan to request a revision to the information collection under OMB Control Number 0938-1408 (CMS-10744) to collect from DMEPOS Competitive Bidding contract suppliers the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance.

The reported country of origin information would be populated on the Medicare Supplier Directory for the contract supplier during the contract period of performance so beneficiaries and interested parties may learn where the DMEPOS item originated, if interested.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13132, "Federalism"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96 354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4); and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity,

competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis that presents the cost and benefit of the rulemaking to the best of our ability.

C. Detailed Economic Analysis

1. Effects of the Changes for the CY 2027 HH PPS

This rule finalizes updates to the Medicare payments under the HH PPS for CY 2027. The net transfer impact related to the changes in payments under the HH PPS for CY 2027 is estimated to be $415 million (2.4 percent) above the updated projected CY 2026 baseline of $17.399 billion, leading to total projected spending of approximately $17.8 billion for 2027. The $415 million increase in estimated payments for CY 2027 reflects the effects of the final CY 2027 home health payment update percentage of 2.1 percent ($365 million increase), and an estimated 0.3 percent increase that reflects the updated FDL ($50 million increase).

We use the latest data and analysis available. However, we do not adjust 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 ended on or before December 31, 2025. 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 overall 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 23 represents how HHA revenues are likely to be affected by the finalized policy changes for CY 2027. For this analysis, we used an analytic file with linked CY 2025 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2025. The first column of table 23 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 weight budget neutrality factor. The fourth column shows the payment effects of updating the CY 2027 wage index (that is, the FY 2027 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2022, and before October 1, 2023 (FY 2023 cost report data)) with a 5-percent cap on wage index decreases. The aggregate impact of the changes in the fourth column is zero percent, due to the wage index budget neutrality factor. The fifth column shows the payment effects of the final CY 2027 home health payment update percentage. The sixth column shows the payment effects of the final FDL. The seventh column shows the payment effects of the final temporary adjustment on all payments. The aggregate impact of the final temporary adjustment reflected in the seventh column equals zero percent because both the CY 2026 and CY 2027 payment rates include a 3.0 percent temporary adjustment. The last column shows the combined effects of all the finalized provisions.

Overall, it is projected that aggregate payments in CY 2027 would increase by 2.4 percent, which reflects the final 2.1 percent increase to the home health payment update

percentage and the 0.3 percent increase from the updated FDL. As illustrated in table 23, the combined effects of all 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 2027 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 23: CY 2027 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	CY 2027 Case-Mix Weights Recalibration Neutrality Factor	CY 2027 Updated Wage Index (with 5% cap)	CY 2027 Final HH Payment Update Percentage	CY 2027 Fixed-Dollar Loss (FDL) Update	Temporary Adjustment	Total
All Agencies	**10,082**	**0.0%**	**0.0%**	**2.1%**	**0.3%**	**0.0%**	**2.4%**
Facility Type and Control							
Free-Standing/Other Vol/NP	653	-0.1%	0.4%	2.1%	0.4%	0.0%	2.8%
Free-Standing/Other Proprietary	8,598	0.0%	-0.1%	2.1%	0.3%	0.0%	2.3%
Free-Standing/Other Government	91	0.1%	1.6%	2.1%	0.5%	0.0%	4.3%
Facility-Based Vol/NP	363	0.0%	0.3%	2.1%	0.5%	0.0%	2.9%
Facility-Based Proprietary	20	0.3%	0.7%	2.1%	0.4%	0.0%	3.5%
Facility-Based Government	154	0.0%	1.2%	2.1%	0.5%	0.0%	3.8%
Subtotal: Freestanding	9,358	0.0%	0.0%	2.1%	0.3%	0.0%	2.4%
Subtotal: Facility-based	537	0.0%	0.5%	2.1%	0.5%	0.0%	3.1%
Subtotal: Vol/NP	1,017	-0.1%	0.4%	2.1%	0.4%	0.0%	2.8%
Subtotal: Proprietary	8,638	0.0%	-0.1%	2.1%	0.3%	0.0%	2.3%
Subtotal: Government	245	0.0%	1.3%	2.1%	0.5%	0.0%	3.9%
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	157	-0.1%	1.5%	2.1%	0.4%	0.0%	3.9%
Free-Standing/Other Proprietary	889	-0.1%	0.0%	2.1%	0.2%	0.0%	2.2%
Free-Standing/Other Government	56	0.4%	0.8%	2.1%	0.5%	0.0%	3.8%
Facility-Based Vol/NP	141	0.0%	0.1%	2.1%	0.5%	0.0%	2.7%
Facility-Based Proprietary	8	0.3%	-0.4%	2.1%	0.5%	0.0%	2.5%
Facility-Based Government	110	0.1%	1.7%	2.1%	0.6%	0.0%	4.5%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	496	-0.1%	0.3%	2.1%	0.4%	0.0%	2.7%
Free-Standing/Other Proprietary	7,709	0.0%	-0.1%	2.1%	0.3%	0.0%	2.3%
Free-Standing/Other Government	35	-0.1%	2.0%	2.1%	0.5%	0.0%	4.5%
Facility-Based Vol/NP	222	0.0%	0.4%	2.1%	0.5%	0.0%	3.0%
Facility-Based Proprietary	12	0.3%	1.3%	2.1%	0.3%	0.0%	4.0%
Facility-Based Government	44	-0.1%	0.8%	2.1%	0.4%	0.0%	3.2%
Facility Location: Urban or Rural							
Rural	1,389	-0.1%	0.3%	2.1%	0.3%	0.0%	2.6%
Urban	8,693	0.0%	0.0%	2.1%	0.3%	0.0%	2.4%
Facility Location: Region of the Country (Census Region)							
New England	303	-0.1%	0.6%	2.1%	0.3%	0.0%	2.9%
Mid Atlantic	361	-0.1%	1.2%	2.1%	0.4%	0.0%	3.6%
East North Central	1,327	-0.1%	-0.5%	2.1%	0.3%	0.0%	1.8%

West North Central	536	-0.2%	0.3%	2.1%	0.4%	0.0%	2.6%
South Atlantic	1,569	-0.1%	-0.4%	2.1%	0.3%	0.0%	1.9%
East South Central	355	-0.2%	-0.5%	2.1%	0.2%	0.0%	1.6%
West South Central	1,938	0.0%	-0.7%	2.1%	0.3%	0.0%	1.7%
Mountain	725	0.1%	-0.5%	2.1%	0.4%	0.0%	2.1%
Pacific	2,924	0.2%	0.4%	2.1%	0.3%	0.0%	3.0%
Outlying	44	0.3%	0.9%	2.1%	0.3%	0.0%	3.6%
Facility Size (Number of 30-day Periods)							
< 100 periods	2,412	0.6%	-0.1%	2.1%	0.4%	0.0%	3.0%
100 to 249	1,611	0.4%	-0.1%	2.1%	0.4%	0.0%	2.8%
250 to 499	1,812	0.3%	-0.1%	2.1%	0.4%	0.0%	2.7%
500 to 999	1,923	0.2%	0.0%	2.1%	0.3%	0.0%	2.6%
1,000 or More	2,324	-0.1%	0.0%	2.1%	0.3%	0.0%	2.3%

Source: CY 2025 Medicare claims data for periods with matched OASIS records ending in CY 2025 (as of July 14, 2026).

Notes: The "Temporary Adjustment" column includes the value of zero because both the CY 2026 and CY 2027 payment rates already include a 3% temporary adjustment. The “CY 2027 Updated Wage Index (with 5% cap)” column reflects a 5-percent cap on wage index decreases. The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.37 to 0.29. Due to missing Provider of Services file information (from which home health agency characteristics are obtained), some subcategories in the impact tables have fewer agencies represented than the overall total (of 10,082): totals involving facility type (only) add up to 9,895 and totals involving control type add up to 9,900.

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

We received public comments on our estimated impact analysis. The following is a summary of the comments we received and our responses.

Comment: Several commenters welcomed CMS's projected 2.4 percent aggregate increase of $420 million in CY 2027 Medicare home health payments, however, these commenters asserted that this national figure masks significant variation and shouldn't be treated as a proxy for any individual HHA's revenue change. A commenter stated that CMS's impact analysis focuses on aggregating national spending and assumes stable future utilization patterns despite individual HHAs often experiencing significantly different results due to wage index changes, case mix distribution, rural service patterns, low utilization payment adjustments, outlier utilization, and local workforce conditions. A commenter stated that these projections are a meaningful stabilizing step, but that they should not be read as evidence that current payment is excessive, as home health providers continue to face sustained labor shortages, wage and benefit inflation, transportation costs, technology and compliance obligations, and increasing patient complexity. Another commenter recommended that CMS provide additional state-level and rural-specific impact analyses to allow stakeholders to better evaluate how payment policies affect provider sustainability and beneficiary access across different geographic regions.

Response: We appreciate the commenters' concerns that the aggregate impacts may not be representative of the impacts that individual providers may face. However, we believe that our impact analysis is reflective of how HHAs are impacted by the provisions of this final rule in that we provide impacts by type of facility, urban/rural, regions and other areas of the country, and facility size. Although we acknowledge that individual providers may experience different results based on differences in such as changes in wage index or case-mix changes, LUPA payments and/or outlier payments, we believe that the information provided in table 23 is sufficient for providers to evaluate how the finalized policies will impact providers. This impact analysis is not designed to predict the exact financial result for every individual HHA. As one commenter pointed out, payment effects naturally vary by wage index area, case-mix

distribution, rural location, LUPA frequency, and outlier use; however, we account for that variation through the design of the payment system itself, not through the impact analysis. We agree that a positive or stable aggregate projection doesn't by itself show that payment levels are excessive, nor does it capture agency-level cost pressures such as wage and benefit inflation, transportation costs, technology and compliance investments, and rising patient complexity. The impact analysis is not intended to answer that broader question. It estimates the effect of this rule's specific policy changes relative to current law. We separately monitor industry financial conditions, access to care, and cost trends through other channels, including the home health market basket update, MedPAC's annual reports to Congress, and ongoing engagement with industry stakeholders. The impact analysis of this final rule represents the projected effects of the changes in home health payments from CY 2026 to CY 2027 using the most recent complete data available at the time of rulemaking, in the case of the proposed rule, we used an analytic file with linked CY 2025 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2025 as of March 15, 2026. For the final rule, we used an analytic file with linked CY 2025 OASIS assessments and CY 2025 home health claims data as of July 14, 2026. Although certain events may limit the scope or accuracy of our impact analysis, because such an analysis is susceptible to forecasting errors due to other changes in the forecasted impact time-period. 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 including the impacts to individual HHAs. We thank the commenters for their recommendations to include different types of impact analyses including, provider level impacts, state level impacts and rural specific impact analysis. We will continue to monitor the impacts of the policies finalized in this rule and may include such analysis in future rulemaking as appropriate.

2. Effects of the Changes for the HH QRP for CY 2027

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. For the CY 2023 program year, 820 of the 11,549 active Medicare-certified HHAs, or approximately 7.1 percent, did not receive the full annual percentage increase because they did not meet assessment submission requirements. The 820 HHAs that did not satisfy the reporting requirements of the HH QRP for the CY 2023 program year represent $149 million in home health claims payment dollars during the reporting period out of a total $16.4 billion for all HHAs.

We proposed to revise the HH QRP data submission deadlines beginning with the CY 2027 HH QRP. We also proposed to revise the HH QRP OASIS and HHCAHPs annual payment update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31). We proposed revisions to regulatory text in support of rule proposals to improve digital transfer of information during the reconsiderations process. Finally, we solicited public comments on one Request for Information (RFI) on future measure concepts for the HH QRP. The net effect of these proposals is no change in burden for OASIS data collection.

Comment: Though we believe our proposals have no additional burden, commenters raised issues related to burden related to some proposals. Related to the OASIS submission proposal, commenters had concerns about operational and staffing challenges, administrative burden, and data validation, especially for small or rural HHAs that may struggle with staffing challenges and operational issues. A few commenters expressed concerns that providers continue to experience staffing shortages and turnover of HH staff. Some commenters that supported the proposal noted the current clinical and administrative burden around implementing OASIS all payer submissions and changing payment requirements. Several commenters encouraged CMS to establish a phased implementation or grace period to meet submission requirements, to

provide flexibility for the first several data submission cycles. A few other commenters cited recent implementation of the HOPE tool to stress the benefits of a phased implementation.

Response: We appreciate the commenters' concerns about operational and staffing challenges, especially for small or rural HHAs. We do not believe that the proposal adds burden for HHA staff by changing the data submission deadline; rather, it shifts the existing workflow from 4.5 months after each quarterly data collection period to the 15th day of the second month after the end of the calendar quarter. Since workflows are in place for the necessary processes, we do not believe a phased implementation approach is necessary.

Comment: Related to the OASIS and HHCAHPS APU proposals, commenters also raised concerns of burden. Commenters who supported the APU calendar updates with concerns commonly raised the issue of burden associated moving to a new APU calendar. They noted that to ensure an effective transition would require investments in quality assurance resources, data analytics, clinical education, software systems, and compliance oversight.

Response: We thank commenters for outlining potential burden issues related to the APU update proposals. We will provide guidance around the implementation of this proposal that we believe will limit costs associated with the transition and implementation of calendar year APU reporting. We also do not anticipate changes in scoring methodologies associated with this transition to calendar year reporting of APU calculations.

3. Effects of the Expanded HHVBP Model

In the CY 2022 HH PPS final rule (88 FR 77676), we estimated that the expanded HHVBP Model would generate a total projected 5-year gross FFS savings of $3,376,000,000. Given that we did not propose any expanded HHVBP Model-specific changes in the proposed rule, these estimates are unchanged.

4. DMEPOS Encounter Requirements for Identical Replacement Items

This proposed provision would clarify that a face-to-face encounter and related documentation, as described in 42 CFR 410.38, is not necessary to support the payment of

replacement DMEPOS items. The fiscal impact of this clarification cannot be estimated as this rule only identifies whether a face-to-face encounter is required for payment for replacement of DMEPOS items. Given the volume of Medicare beneficiaries and associated claims for payment, we do not audit all claim submissions for compliance with Medicare conditions of payment—including the face-to-face encounter. In addition, for those claims audited, it is one of many Medicare coverage requirements, and therefore delineating its compliance rate is not operationally feasible. This situation can only be identified upon medical record review, and replacements were not the sole focus of a medical review audit. Rather, varied medical review decision-making and the need for this clarification was identified anecdotally. As such, we cannot reliably forecast any cost for this limited subset of claims for replacement items.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

5. Provider Enrollment

As previously noted, we proposed a number of provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. This RIA addresses provisions that: (1) we believe will have a financial impact; and (2) will not, in our view, have such an impact but which require explanation. For those provisions not listed in this section VII.C.5. of this final rule, we do not foresee a financial impact.

a. Revocation Effective Dates

Existing § 424.535(g)(1) states that except as described in § 424.535(g)(2) and (3), a revocation becomes effective 30 days after CMS or its contractor mails notice of its determination to the provider or supplier (hereafter occasionally and collectively "providers"). Under current § 424.535(g)(2)(i) through (xv), there are grounds for which CMS can revoke a provider's enrollment retroactively to the date the provider's non-compliance commenced. Retroactive revocation allows CMS to collect monies that have been paid to the provider since the beginning of its non-compliance. We explained in section V.C. of this final rule that we

proposed to make the effective dates of all of our revocation reasons in § 424.535 retroactive. Existing revocation grounds that are currently applied prospectively but would become retroactive are listed as follows (along with their proposed retroactive effective dates):

- § 424.535(a)(1) (Noncompliance with enrollment requirements): The date the non-compliance began (per CMS' or the CMS contractor's determination).
- § 424.535(a)(5)(b)(ii) (Noncompliance with enrollment requirements): The date the Medicare enrollment requirement was not satisfied.
- § 424.535(a)(6) (Application fee noncompliance): The date on which CMS or its contractor determines that the provider should be revoked under paragraph (a)(6).
- §424.535(a)(7): The date on which the conduct resulting the revocation occurred.
- § 424.535(a)(10)(i) (Document retention): The date on which CMS or the CMS contractor determines that the provider has not complied with this retention requirement.
- § 424.535(a)(10)(ii) (Document access to CMS): The day after the date by which the provider was required to furnish access.
- § 424.535(a)(11) (Capitalization): The day after the date by which the provider was required to furnish the requested documentation.
- § 424.535(a)(14) (Abusive prescribing): The date of the last prescription in the applicable pattern or practice.
- § 424.535(a)(15) (False Claims Act judgments): The date of the judgment.
- § 424.535(a)(17) (Referral of debt to Treasury): The date on which CMS referred the debt to the Department of Treasury.
- § 424.535(a)(18) (Revoked under different name or identifier): The effective date of the provider's current enrollment.
- § 424.535(a)(19) (Undue risk): The date on which CMS or its contractor determines that the provider should be revoked under paragraph (a)(19).

- § 424.535(a)(20) (Billing from non-compliant location): The earliest date on the claims for the non-compliant location that are triggering the revocation.

- § 424.535(a)(21) (Abusive ordering, certifying, etc.): The date of the last order, certification, referral, or prescription in the applicable pattern or practice.

- § 424.535(a)(22) (Patient harm): The date of the prior action resulting in the revocation.

- § 424.535(a)(23) (Condition or standard noncompliance): Under § 424.535(g)(xv)(D), the current paragraph (a)(23) revocation effective date for all standard or condition violations other than those listed in § 424.535(g)(xv)(A) through (C) is prospective; that is, it is 30 days after the date that CMS or the CMS contractor mails the revocation letter to the provider or supplier. We proposed to make these (a)(23) prospective effective dates retroactive back to the date of the violation or non-compliance (per CMS' or the CMS contractor's determination).

Table 24 contains several data categories. The first identifies those new retroactive revocation grounds for which we are able to calculate savings to the Medicare program. The second is the average annual number of revocations that occur for each of these revocation grounds. The third is the average length of time between when the non-compliance begins in these situations and 30 days after the revocation letter is sent to the provider in question. For instance, suppose a provider undergoes a change in its billing agency's address effective May 1 but fails to report it to CMS within 90 days. The provider is revoked under § 424.535(a)(9). The revocation letter is mailed to the provider on August 15, meaning the effective date under existing § 424.535(g)(1) is September 15. The period between the date of non-compliance and the effective date under current paragraph (g)(1) is thus 45 days (that is, the period between July 31 (the day after the 90-day reporting deadline) and September 15). Under our proposal, though, the provider would be ineligible for payments for services furnished during this 45-day period because its revocation would now be retroactive back to the date of non-compliance (July 31).

The last two categories address the savings that would accrue to Medicare from the proposed retroactive grounds listed in the first column. Based on internal CMS data, we calculated in the fourth column of table 24 the average amount of actual payments made to the providers in each of the table's proposed retroactive revocation reasons during the time period in the table's third column. To illustrate, table 24 indicates that 17 providers per year are revoked under § 424.535(a)(22), with the third column identifying a 95-day period. The fourth column reflects the average annual payments each of these 17 providers receive during their respective 95-day periods (or $20,586).

The fifth column estimates the total savings for each of our proposed retroactive revocation reasons -- specifically, we multiplied the figures in the second column by those in the fourth. Using our § 424.535(a)(22) example, the total annual savings figure is $349,962 (or 17 x $20,586).

We used this same approach when calculating projected savings for the new retroactive revocation grounds we finalized in the CY 2026 HH PPS final rule (90 FR 55342).

TABLE 24: RETROACTIVE REVOCATION GROUNDS

New Retro Revocation Basis Under § 424.535	Number of Revocations Per Year	Estimated Length of Time (in Days) Between When the Non-Compliance Occurs and 30 Days After the Revocation Letter is Sent	Average Payments Made to the Revoked Provider During Estimated Non-Compliance Time Period ($)	Estimated Total Annual Savings (Number of Revocations x Average Payments) ($)
(a)(1)	10	90	225,896	2,258,960
(a)(5)(ii)	20	45	1,955,854	39,117,080
(a)(10)	19	65	187,087	3,554,653
(a)(13)(i) (for DEA certificate revocations and suspensions)	9	90	18,743	168,687
(a)(14)	1	100	4,721	4,721
(a)(17)	6	730 (2 years)	892	5,352
(a)(19)	255	30	143,153	36,504,015
(a)(22)	17	95	20,586	349,962
TOTALS & AVERAGES	**337**	**156**	**N/A**	**81,963,430**

Accordingly, we project annual savings of $81,963,430 stemming from our retroactive revocation proposals.

b. Expanded and New Revocation Reasons

As discussed in section V.B. of this final rule, we proposed the following expanded and new revocation grounds:

- We would expand existing § 424.535(a)(4) to permit revocation if the provider submits false or misleading information on or associated with any provider enrollment-related CMS or Medicare form (including forms created by and/or submitted to CMS contractors). Section 424.535(a)(4) would no longer be limited to false or misleading information on the enrollment application.

- Revised § 424.535(a)(16) would include a new revocation ground permitting enrollment if the provider -- or any owner, managing employee, managing organization, officer, or director thereof – was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

- New § 424.535(a)(24) would permit revocation if CMS determines that the provider's enrollment presents a high risk of fraud, waste, or abuse due to the provider's location within a limited geographic area that has an excessive number of providers and suppliers.

- New § 424.535(a)(25) would permit revocation if CMS determines that the HHA, hospice, or DMEPOS supplier did not comply with the provisions and requirements of, as applicable, § 424.550(b) or § 424.551.

As we cannot predict the number of instances in which we would utilize these new and expanded grounds, we are unable to establish a savings estimate.

c. Preclusion List

The preclusion list is a compilation of providers that are prohibited from receiving Medicare Advantage or Part D payments. One ground for which a provider can be placed on the preclusion list if it has a felony conviction with the past 10 years. We proposed to expand this to include felony convictions of the provider's owner, managing employee/organization, or corporate officer/director. As with our proposed revocation provisions, though, we are unable to establish a savings estimate for this expansion. This is because we cannot predict the number of

instances where we would place a provider on the preclusion based on an owner's, managing employee's, etc., felony conviction.

d. Hospice Reactivations

Section 424.540(b)(3)(i) states that an HHA whose Medicare billing privileges are deactivated under § 424.540 must obtain an initial State survey or accreditation before its Medicare billing privileges can be reactivated. We proposed to expand § 424.540(b)(3)(i) to include hospices.

An average of roughly 226 hospices each year seek to reactivate their enrollments. Although hospice surveys and accreditation costs vary widely, we project – solely for purposes of this estimate – that the average cost would be $6,000. This results in an annual cost of our proposed § 424.540(b)(3)(i) expansion of $1,356,000. We welcomed comments on this projection.

e. Conclusion

We do not believe our proposals would negatively impact access to care, including in rural areas. We have promulgated numerous denial and revocation provisions in prior CMS provider enrollment regulations with no such impact, and we do not anticipate that our new denial and revocation grounds (and expansions of existing ones) would result in large numbers of denial and revocations.

We solicited comment from interested parties regarding any additional costs that may arise from our proposed enrollment provisions.

The following is a summary of the comments we received on our RIA burden projections and our responses.

Comment: A number of commenters stated that CMS underestimated the burden of its proposed provider enrollment provisions. They maintained that providers would need to expend additional resources to, for example: (1) gather and report information, such as affiliations and managing employees, which may only be attainable from outside parties; (2) review and

consistently monitor personnel and affiliates for adverse history; (3) revise policies and systems; (4) train personnel; (5) involve compliance and legal staff; and (6) retain documentation demonstrating reasonable efforts to comply. They stated that CMS should withdraw its proposed provider enrollment provisions and conduct a revised burden analysis of the cumulative administrative and financial burden imposed across all provider sectors. This should include separate cost analyses: (1) for each of the foregoing activities as well as others that providers will incur; and (2) broken down by provider type (including, a commenter requested, physician practices, along with a separate RFA for these suppliers) and not simply limited to HHAs and hospices. A commenter stated that the SNF Guidance regarding the reporting of data required under section 1124(c) of the Act[62] is indicative of some of the costs that providers will incur under our proposals.

Response: We appreciate these comments. We addressed several of these matters in the preambles to the CY 2027 HH PPS proposed rule and section V.C. of this final rule. We discuss them again here and at somewhat greater length.

First, we reiterate our statement in the preamble and ICR sections of this final rule regarding the revised "managing employee" definition. The revision merely clarifies that such individuals have always qualified as managing employees, which is why we did not include a burden estimate. It would also seemingly increase compliance with a requirement that already exists. While the resulting costs (and benefits) would be attributable to this final rule, quantification is extremely challenging and infeasible because, as stated in the ICR section, the scope of each provider's or supplier's individual reporting circumstances will likely vary widely.

Second, we do not anticipate requesting disclosure of the affiliation data in § 424.519. No reporting burden is thus implicated.

Third, and outside of an explicit reporting requirement, §§ 424.500 through 424.575 have never required providers and suppliers to: (1) perform research to determine whether an

[62] https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos.

associated party (for example, an owner or managing employee) has a criminal conviction, suspension, etc.; or (2) regularly monitor their staff for such actions. Any decision to conduct these functions is the provider's own. Indeed, CMS has promulgated numerous enrollment provisions over the past two decades that added or expanded grounds for which we can deny or revoke enrollment based on certain associates' actions. We did not include research costs in our burden estimates for those rules , but in those cases commenters did not request us to do so. Moreover, any burden estimate would be infeasible because we have no means of knowing which and how many providers would engage in this research.

Fourth, cost estimates for staff training, compliance guide updates, consulting, etc., are challenging to quantify for a variety of reasons, including because they have not been part of previous analyses of provider enrollment regulations. Also of note is that these are not requirements for enrolling and maintaining enrollment in Medicare. We believe that in the provider enrollment realm, these activities are done – if they are done at all -- on the provider's own volition. As such, we cannot know or even roughly estimate: (1) how many providers have compliance guides and, for those that do, what, if any, revisions would be necessary and to what degree; (2) the degree to which staff training would be necessary and the number of impacted personnel or providers; and (3) which providers would need to consult with outside parties.

It is true that in the November 16, 2023, final rule wherein we implemented requirements for SNFs to report certain data on their associated parties, the ICR wage burden included (but was not limited to) the BLS hourly rate for attorneys; we believed that SNFs would consult with legal counsel when preparing data for disclosure. However, this was limited to the specific data reporting requirement. In this same vein, the SNF Guidance that the final previous commenter referenced addressed activities involving the research and disclosure of the affiliation data. The present final rule does not require research or new information disclosures.

Fifth, CMS does not break down costs by provider type in its provider enrollment rulemaking except if the requirement: (1) is specific to a particular provider type (such as

DMEPOS accreditation); or (2) involves the completion of Form CMS-855 applications by different categories of providers (for instance, certified providers that complete the Form CMS-855A). Even in the latter case, though, the Form CMS-855 estimate is per application type, not provider type. The fact is that for enrollment provisions pertaining to all or most provider and supplier types, CMS has no means of sub-dividing, individually assessing, and predicting the costs and impacts for each of the more than 35 provider and supplier types that enroll in Medicare – effectively, 35 separate RIAs and RFAs -- which is why we have not previously done so and have instead utilized an overall estimate.

In sum, we believe that our ICR and RIA estimates reflect an accurate and fair assessment of the burdens associated with our proposals. Most respectfully, we further add that stakeholder disagreement with CMS' assessment that no burden exists does not mean that CMS failed to consider the possible burden, for we indeed did.

Comment: A commenter asked CMS to include a small, solo, and rural provider impact analysis in the RIA and RFA sections that outlines the effect of retroactive revocations and the 15-day reduced claims submission period for revoked providers.

Response: We outlined the retroactive revocation impact in the RIA – specifically, $82 million in transfers from revoked providers and suppliers to the federal requirement. However, we have no way to estimate how much of this will involve small or rural providers because we cannot predict how many of these revoked providers will fall into that category. Insofar as the reduction of the § 424.535(h) claims submission timeframe from 45 days to 15 days, we do not anticipate a burden because only the timeframe is changing, not the requirement that the pre-revocation claims be submitted within a fixed period after revocation.

Comment: A commenter stated that the use of a CMS-designated fingerprinting contractor will increase costs for providers and should be calculated in the RIA.

Response: CMS has utilized a fingerprinting contractor for several years. It is not a new requirement, and our revision to § 424.518(d) merely reflects existing practice. Hence, there is no burden change.

Comment: A commenter recommended that CMS state the burden estimate separately for simple and complex enrollments rather than as a single average.

Response: While we appreciate this comment, there is no means of formally classifying in rulemaking a particular enrollment as "simple", "complex", or something else.

Comment: A commenter stated that our proposed enrollment provisions should be assessed for their population-level, not merely provider-level, effects. The commenter cited the potential impact on the local care ecosystem, with cascading effects on hospital readmission rates, unmet skilled nursing needs, and caregiver strain that are measurable at the population level. The commenter stated that a legal epidemiology framework counsels CMS to pair any expansion of enrollment authority with a published, stratified impact analysis — by geography (such as rural/urban status), county, agency size, and the dual-eligible share of the patient panel — before finalization. The commenter recommended that this be included in the final rule. Another commenter stated that the RIA did not consider the unintended cascading consequences across Medicare enrollments.

Response: We have no means of estimating the impact of our provider enrollment proposals by county, provider size, percentage of dual-eligible population, etc. We cannot predict, for example: (1) the counties in which providers may be revoked or the patient populations of those providers; or (2) the locations and sizes of hospices that will be deactivated, seek to reactivate their billing privileges, and then undergo a State survey or accreditation.

We also explained in the proposed rule that we do not anticipate beneficiary access issues arising from our proposals, in part because (1) revocations will be few; (2) there are well over 2 million enrolled providers and suppliers; and (3) we have not seen beneficiary access problems –

nor, for that matter, the cascading effects the commenters cite – arise from any of our prior enrollment rulemaking efforts.

Comment: A commenter requested that CMS perform an impact analysis specific to non-profit and community-based providers.

Response: We are unable to perform a separate, sub-categorized analysis for non-profit and community-based providers because – consistent with our response to the previous comment -- we cannot gauge, for instance, what percentage of providers revoked under a particular new revocation ground will be non-profit or community-based.

Comment: A commenter stated that the RFA should address the rule's enrollment-enrollment enforcement provisions, including addressing and implementing alternatives such as: (1) prospective effective dates; and (2) exceptions from §§ 424.530(a)(22) and 424.535(a)(25) for certain CIMOs (for example, those involving joint ventures);

Response: We addressed prospective effective dates in the "Alternatives Considered" section of the proposed rule and explained why we believed that making all of our revocation reasons retroactive was necessary. As for §§ 424.530(a)(22) and 424.535(a)(25), we did not consider exceptions to their applicability and, respectfully, were not required to. Indeed, in response to comments received, we address in the preamble to this final rule the bases for our declination to establish said exemptions.

Comment: A commenter stated that CMS should identify the program integrity benefit attributable to each proposal, rather than relying on aggregate savings from retroactive revocations.

Response: We refer the commenter to the preambles to the proposed rule and this final rule, wherein we explain the program integrity reasons for our proposals and what we believe they will help achieve – specifically, the benefits they will furnish.

Comment: A commenter stated that CMS should publish an analysis outlining anticipated revocation and denial rates by the dual-eligible share of each affected provider's patient panel.

Another commenter requested estimates on the number of providers that would be placed on the preclusion list based on our revised "preclusion list" definition.

Response: As we explained in the proposed rule, we cannot predict the number of denials and revocations that would occur under our new provisions because they are new; we have no historical data upon which to base a projection. The same is true for our revisions to the "preclusion" list definition in §§ 422.2 and 423.100; we are unable to estimate how many providers would be placed on the preclusion list as a result.

Comment: A commenter believed that CMS understated the burden of its hospice reactivation survey requirement. The commenter stated that in addition to direct survey or accreditation fees, hospices may incur significant consultant expenses, staff preparation time, and policy and documentation review costs.

Response: The burden we calculated is consistent with the basic formula we used for our DMEPOS reaccreditation provisions in the CY 2026 HH PPS proposed rule.

Comment: A commenter stated that CMS should perform a proposal-specific assessment of the affected universe, estimated frequency of action, compliance and monitoring costs, implementation burden, and beneficiary access implications. Several other commenters stated that CMS must assess the impact on a provision-by-provision basis. Additional commenters contended that the RIA contained little analysis regarding the impact and burden of our proposals on providers.

Response: We disagree. We considered the possible impact of each provision we proposed. We made clear in the proposed rule's ICR and RIA sections that for those provisions not addressed at further length in those sections, we did not anticipate a burden. There were some provisions that we felt would not impose a burden but that we believed required additional explanation in the ICR and RIA sections, which we provided. For the remaining provisions, we outlined the applicable burden. Every provision was therefore reviewed for possible effect.

Comment: A commenter noted CMS's conclusion in the proposed rule's RIA that the proposed denial and revocation grounds will not significantly affect providers, suppliers, or beneficiaries because revocations are infrequent, only a small share of providers are revoked, and CMS expects to use the authorities only when appropriate. The commenter contended that this does not take into account: (1) our newly proposed grounds; (2) expanded affiliation disclosures; (3) the revision to our "managing employee" definition; (4) the extension of reapplication bars; and (5) revised § 424.535(i).

Response: We indeed took into account these items (other than revised § 424.535(i), which we are not finalizing), and we maintain our position that there will not be a significant impact on providers, suppliers, and beneficiaries for the reasons we cited. We also refer the commenter to section V.C. of this final rule for further discussion on this issue.

Comment: A commenter suggested that CMS solicit data on (1) the number of existing shared location arrangements; (2) the prevalence of shared vendors and management relationships; and (3) the operational cost of identifying historic affiliations and newly reportable personnel.

Response: While we appreciate these suggestions, we respectfully do not believe solicitation of this information is necessary – especially the second and third elements because, again, we do not anticipate asking providers to furnish the data referenced in § 424.519, and the clinical personnel referenced in the revised "managing employee" definition must already be reported.

Comment: A commenter contended that because the proposed impact analysis addressed only home health and related entities, CMS should: (1) publish an RFA targeted towards their effect on small physician practices; and (2) seek public comment on that analysis before finalizing any of the enrollment provisions. If applicable, CMS should state the basis for any certification that these provisions will not have a significant economic impact on a substantial number of small entities, specifically physician practices.

Response: The provider enrollment RIA took into account all provider and supplier types, not simply HHAs. Also – and similar to our previous statements regarding the inability to establish separate cost estimates for each provider type -- we respectfully cannot craft an RFA targeted towards only a specific provider type given the need to address all potentially impacted providers and suppliers.

We do not believe our provider enrollment provisions will have a significant economic impact on a substantial number of small businesses, including physician practices. We previously mentioned that: (1) the reporting of clinical managing employees is already required; (2) we do not plan to request the disclosure of affiliation data under § 424.519; and (3) revocations under our proposed provisions will be comparatively few in number. Given that there are well over 2 million enrolled providers and suppliers, the impact of these provisions on the entire provider universe will thus be very small -- even when accounting for the potential (though uncalculatable) effects of our reapplication bar expansion and new denial grounds, which we also believe will impact few providers and suppliers.

Comment: A commenter expressed concern that CMS: (1) assessed beneficiary access according to the number of providers that would remain enrolled; and (2) accordingly concluded that beneficiary access would not be impaired. The commenter believed that access is often localized and specialty specific. Even if 2 million providers remain enrolled, the commenter maintained, a patient that is receiving care from a provider that is later revoked could lose that care, especially if that provider is the only one in a rural area.

Response: While we appreciate the commenter's concern, we believe that – for purposes of our provider enrollment provisions – beneficiary access must be gauged on a national, overall level. This is how we have addressed patient care impact in past provider enrollment regulations, and we believe is the best means of evaluating the provisions' true effect on beneficiaries. Moreover, even in the event that a beneficiary can no longer see a revoked

physician, our experience is that they have been able to obtain care elsewhere considering, again, the millions of existing providers.

Comment: A few commenters stated that our provider enrollment proposals are inconsistent with Presidential Executive Order 14192 ("Unleashing Prosperity Through Deregulation," (90 FR 9065), which direct agencies to reduce burdens.

Response: We refer stakeholders to section IX.J. of this final rule for a discussion of the rule's interaction with this order.

After reviewing the public comments, we are finalizing our p provider enrollment RIA, though the signage requirement burden in the ICR statement will be included in the accounting statement.

6. DMEPOS Coverage of External Infusion Pumps

This final rule expands the scope of the Medicare Part B benefit for DME by revising the interpretation of the "appropriate for use in the home" requirement in the definition of DME at 42 CFR 414.202 for certain drugs or biologicals infused in the home that fulfill specific requirements outlined in the statute. Since drugs or biologicals administered through an external infusion pump that is classified as DME can be covered under the Medicare Part B benefit as supplies necessary for the effective use of the external infusion pump, expanding the scope of the DME benefit has the effect of expanding coverage to drugs or biologicals that were not previously covered through home infusion. At this time, we expect that there is only one drug that did not previously meet the requirements for coverage through home infusion but does meet the requirements as modified by section 6222 of the Consolidated Appropriations Act, 2026, and will be used by a sufficient number of Medicare beneficiaries to warrant consideration: patisiran. While there may be other drugs that meet the basic requirements for coverage, we believe that use through home infusion would be negligible. In addition, it is possible that pharmaceutical makers may introduce new drugs or biologicals, or reformulate existing products, that will qualify for coverage under this expanded scope, but we cannot predict or estimate what impact

this may have.

This expanded scope mirrors changes that had been proposed in 2020 rulemaking, "Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)" (85 FR 70358). At that time, we had estimated Medicare savings of roughly $3 million per year. Since then, claims data show that significantly fewer beneficiaries have been receiving patisiran infusions. Claims data for 2025 show that only 69 beneficiaries received patisiran infusions. As we noted in the previous proposed rule, the primary impact of this expanded scope relates to the difference in beneficiary cost sharing between infusion therapy received in an outpatient clinic setting and home infusion therapy: cost sharing for each outpatient infusion is the normal 20 percent Part B coinsurance limited to the Part A deductible ($1,736 in 2026), while cost sharing for home infusion therapy is not limited.

Claims data show that the annual cost of patisiran for each beneficiary receiving it in 2025 was approximately $313,000. Based on the typical infusion every three weeks, these patients likely received 17 infusions each year. When received in an outpatient setting, the capped cost sharing would apply, so each beneficiary would pay $1,736 per infusion or approximately $29,500 for the year. If, instead, patisiran was received as home infusion, cost sharing for the patisiran alone would be approximately $3,700 per infusion, or $62,900 per year. There would also be additional charges for home infusion (for example, home infusion services, pump rental, other supplies) that exceed the charges for outpatient infusion, and CMS believes these would cost Medicare approximately $7,000 per beneficiary per year, and the beneficiary approximately $2,000 in cost sharing (additional charges for outpatient infusion would cost Medicare approximately $4,000). Taken together, a beneficiary that receives patisiran through home infusion instead of outpatient infusion would save Medicare approximately $31,000 per year because of the higher cost sharing (the beneficiary would pay an additional $34,000) offset by the higher total cost of home infusion (additional $3,000 net cost to Medicare).

Given this substantial cost sharing difference, we believe it is unlikely that beneficiaries would consider home infusion for patisiran unless they are either enrolled in Medicaid or have purchased Medicare supplement insurance (Medigap). While CMS does not directly track how many beneficiaries have enrolled in private Medigap plans, a recent report from the Kaiser Family Foundation ("Key Facts About Medigap Enrollment and Premiums for Medicare Beneficiaries," 2024. Retrieved from https://www.kff.org/medicare/key-facts-about-medigap-enrollment-and-premiums-for-medicare-beneficiaries/) suggests that approximately 40 percent of original Medicare beneficiaries have Medigap plans. CMS data show that approximately 17 percent of Medicare beneficiaries are also enrolled in Medicaid. CMS has no practical way of knowing, specifically, whether beneficiaries receiving infusion therapy are more or less likely than the overall Medicare population to have non-Medicare insurance that limits the impact of Medicare cost sharing. For purposes of estimating regulatory impact, we assume that approximately one-third of beneficiaries receiving patisiran would not consider home infusion because of the higher cost sharing. Of the remainder, we estimate that approximately 50 percent may not switch to home infusion, either because they prefer to receive it in an outpatient setting or because, in consultation with their medical providers, they have concluded that home infusion is not appropriate for them. Therefore, we estimate that roughly one-third of beneficiaries receiving patisiran would switch to home infusion therapy, although there is substantial uncertainty associated with this estimate. Based on this estimate of the number who might switch, and the savings to Medicare of $31,000 per beneficiary who switches, we estimate initial aggregate savings to the Medicare program would be approximately $800 thousand per year.

We note that many Medicare beneficiaries have chosen to receive their Medicare benefits through Part C (Medicare Advantage). The differences in cost sharing discussed here apply strictly to those who have chosen original Medicare (Parts A and B). Medicare Advantage plans set their own cost sharing policies, and we have no way to estimate whether and how these changes in coverage for home infusion therapy would lead Medicare Advantage plans to change

their policies and the cost sharing beneficiaries may face in different settings.

We also note that, by definition, infusion drugs that were not previously covered by Part B in the home infusion setting would have been covered by Part D. However, the drugs that are covered by this new benefit require infusion under the supervision of a medical professional, and the service charges related to such supervised infusion, together with rental of the infusion equipment, would not have previously been payable under Part B or Part D. Therefore, we do not believe that a significant number of beneficiaries would be switching from Part D coverage to this new benefit under Part B, given the significant out of pocket payments that would have been required.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters provider feedback regarding the potential impacts of the expanded DME benefit expansion for infusion pumps and drugs. Specifically, commenters raised concern that the higher cost sharing related to home infusion would impact Medicaid and Medicare Supplement Insurance (Medigap) carriers, and we did not adequately explore these impacts.

Response: We appreciate the comments regarding the potential impacts of the expanded DME benefit. As discussed in this section, the impact of the expanded benefit will depend on the number of drugs that qualify for coverage and the number of beneficiaries who elect to receive infusion therapy in the home. We have described in detail the cost sharing implications for a drug that we believe will be covered under this benefit, and we recognize that there may be others covered under this benefit. However, we do not know at this time which other drugs may be covered now or in the future, what the cost of these drugs would be, and how many beneficiaries would avail themselves of the opportunity to receive the drugs through home infusion. Therefore, we cannot specifically identify what the impact may be to Medicaid or Medigap carriers.

7. DMEPOS Competitive Bidding--Country of Origin

As explained earlier, for the DMEPOS CBP, we will request to revise the collection currently approved under OMB Control Number 0938-1408 (CMS-10744) to collect from DMEPOS Competitive Bidding contract suppliers the country of origin for the lead items furnished during the DMEPOS CBP contract's period of performance.

Specifically, contract suppliers under a DMEPOS CBP contract will continue to be required as a term of their contracts to maintain the accuracy of the product information (manufacturer name, model name, and model number) for the lead item the supplier furnishes on Form C, and would now be required to also include the country of origin for each product it reports on a new "country of origin" field on Form C. Contract suppliers are required to submit Form C once every 6 months during January and July throughout the DMEPOS Competitive Bidding Program Contract's period of performance, and Form C includes an attestation that all the reported information is accurate and up to date. This attestation would need to be completed to fulfill a Form C submission requirement. The details for this update to Form C would be included in advance of the required reporting through an updated CMS-1074.

As done historically with the product information reported on Form C by a contract supplier, the reported country of origin information would be populated on the Medicare Supplier Directory for the contract supplier during the contract period of performance. This information would allow beneficiaries and interested parties to learn the country from which the DMEPOS item originated, if interested.

Contract suppliers should be able to identify the country of origin based on the markings on the product for the lead item. Under US Customs and Border Protections rules (19 CFR 134.11, 134.46), imported goods must be properly marked with: "Made in [Country]," unless an exemption applies (for example, an item that is incapable of being marked, like a catheter), as explained at 19 CFR 134.32. To correctly identify the country of origin for a product in the absence of a marking or to verify a marking, contract suppliers may need to refer to available

documentation from the manufacturer or distributor indicating the country of origin for its product, which could include a combination of the following: manufacturer certifications, bills of materials, manufacturing process descriptions, commercial invoices, U.S. Customs and Border Protection entry documentation, or a Harmonized Tariff Schedule classification.

We did not receive public comments on the regulatory impact analysis of this provision, and therefore, we are finalizing this section as proposed.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this final 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 proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of commenters will be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach used in estimating the number of entities reviewing this proposed rule. We did not receive any public comments specific to our solicitation.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule. Therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

We sought comments on this assumption. We did not receive any public comments specific to our solicitation.

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 $119.10 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 4.61 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $549.05 (4.61

hours × $549.05). Therefore, we estimate that the total cost of reviewing this regulation is $360,726 ($549.05 × 657) [657 is the number of estimated reviewers, which is based on the total number of unique commenters from this year's proposed rule].

E. Alternatives Considered

1. HH PPS

In section II.C.1.e. of this final rule, we describe that to achieve budget neutrality as required by law, we calculated an illustrative permanent adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, 2022, 2023, 2024, and 2025 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes as required by statute. We proposed not implementing a permanent adjustment to the CY 2027 30-day base payment rate. One alternative to not proposing a permanent adjustment included proposing a -1.024 percent permanent adjustment for CY 2027 if we could show that the observed behavior changes in CY 2025 claims could be directly attributed to the implementation of the PDGM as we discussed in the CY 2026 final rule (90 FR 55366 through 55367). However, we continue to believe that implementing a permanent adjustment would not be appropriate because our analysis suggests that the majority of the behavior change related to the implementation of the PDGM occurred in CYs 2020 through 2022 and that the behavior change observed in CYs 2023 through 2025 is related to factors other than the implementation of the PDGM.

We proposed implementing a temporary adjustment to continue reconciling retrospective overpayments from CYs 2020, 2021, 2022, 2023, 2024 and 2025, as discussed in section II.C.1.f. of this final rule. Section 1895(b)(3)(D)(iii) of the Act gives CMS the authority to make a temporary adjustment in a time and manner appropriate through notice and comment rulemaking.

We considered not proposing implementing a temporary adjustment. However, due to the growing temporary adjustment amount calculated from CYs 2020 through 2025, to delay the

implementation of a temporary adjustment would lead to many more years of reductions to the payment rate to reach budget neutrality. Another alternative would be to apply a temporary adjustment factor to the CY 2027 payment rate that would recoup the full calculated temporary adjustment dollar amount, to date, of $4.9 billion. However, we believe that applying a temporary adjustment factor accounting for the temporary adjustment dollar amount of $4.9 billion to the CY 2027 payment rate may adversely affect HHAs given the magnitude of this adjustment to the payment rate in a single year. Although we are not establishing a timeframe to recoup the calculated temporary adjustment dollar amount of $4.9 billion (to date), we believe it is prudent to continue implementing an adjustment to account for some of this amount to slow its continued growth. Postponing any collection of this large dollar amount would lead to an extended duration of temporary adjustments or larger reductions to the payment rates in future years to reach budget neutrality sooner.

Therefore, we believe it is best to finalize implementing a temporary adjustment decrease of 3.0 percent to the CY 2027 base payment rate.

2. HH QRP

With regard to the proposal to revise the HH QRP assessment data submission deadline from 4.5 months to no later than the 15th day of the second month after the end of each quarter, we considered keeping the deadline unchanged. We determined that the revised timeframe is a reasonable amount of time for HHAs to submit data and make any necessary corrections, and that the benefits of this shortened timeframe include making the data timelier and more actionable which increases the value of publicly reported data both for consumers and their families and for HHAs to use in their quality improvement activities.

With regard to the proposal to revise the HH QRP OASIS and HHCAHPs annual payment update (APU) reporting timeframe to report a calendar year of data (January 1 through December 31), we believe this update will provide clarity to HH payment updates and facilitate the alignment of the HH QRP pay-for-reporting policies with other HH payment policies without

adding burden to providers.

3. Provider Enrollment

There were two principal alternatives we considered. First, we considered retaining the existing prospective effective dates for some of our revocation grounds. However, as explained in section V.C. of this final rule, we do not believe that providers are entitled to payment for services and items furnished while non-compliant. Second, and in a similar vein, we contemplated adding no more than a few denial grounds as bases for a reapplication bar. Yet because of the concerning provider conduct behind some denials, we believe we must have the discretion to bar such providers from repeatedly attempting to enter Medicare by submitting multiple applications.

4. DMEPOS Competitive Bidding--Country of Origin

We considered having all DMEPOS suppliers submit the country of information for their product at the time they submit a bid for the DMEPOS CBP, instead of first submitting it on day one of their DMEPOS CBP contract, if awarded. However, this would have presented two issues. First, because the purpose is to make the country of origin available to beneficiaries and interested parties on the Supplier Directory, it would be unnecessary to require all bidders to submit this information at the time they submit a bid when only a subset of bidders will ultimately receive a DMEPOS CBP contract (and have its information available on the Supplier Directory). Secondly, we believe it would be unnecessary to require this information at the time of bid submission, approximately 1 year before contracts are awarded, as it would not be used in the bid evaluation process. As a result, we believe it is most appropriate that only contract suppliers be required on a routine basis to submit accurate and up-to-date country of origin information for its products on Form C.

F. Accounting Statement and Table

Consistent with OMB Circular A-4 (available at https://www.whitehouse.gov/wp-content/uploads/2025/08/CircularA-4.pdf) in table 25, we have prepared an accounting statement showing the classification of the impacts associated with the provisions of this final rule.

TABLE 25: ACCOUNTING STATEMENT

HH PPS (FROM CY 2026 TO CY 2027)		
Category	**Primary Estimate**	
Annualized Monetized Transfers	$415 million	
From Whom To Whom	Federal Government To Medicare HHAs	
PROVIDER ENROLLMENT PROVISIONS (CY 2027)		
Transfers		
Category	**Primary Estimate**	
Annualized Monetized Transfers from New Retroactive Revocation Reasons	-$82 million	
From Whom To Whom	Federal Government To Medicare Providers and Suppliers	
Category	**Primary Estimate**	
Annualized Monetized Transfers for Reactivating Hospices	$1.4 million	
From Whom to Whom	Hospices to State Survey Agencies or Accrediting Organizations	
Costs		
Category	**Primary Estimate**	**Discount Rate**
Signage Requirement Costs for Providers and Suppliers	$13.9 million	3%
	$12.4 million	7%
DMEPOS COVERAGE OF EXTERNAL INFUSION PUMPS (CYs 2027-2031)		
Category	**Primary Estimate**	**Discount Rate**
Annualized Monetized Transfers	-$1.9 million	3%
	-$2.1 million	7%
From Whom To Whom	Federal Government To Beneficiaries	
Category	**Primary Estimate**	**Discount Rate**
Annualized Monetized Transfers	$1.22 million	3%
	$1.34 million	7%
From Whom To Whom	From Beneficiaries To DME and Home Infusion Suppliers	

G. 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 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 19 million[63] and approximately 96 percent of HHAs are considered small entities. We estimate that almost all home infusion therapy suppliers are, similarly, small entities. Table 26 shows the number of firms, revenue, and average revenue per firm for the home health care services category (NAICS 621610). Table 27 shows the number of nonemployer establishments, total, and average revenue per nonemployer establishment.

TABLE 26: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOME HEALTH CARE SERVICES FOR NAICS CODE 621610

NAICS	NAICS Description	Enterprise Size ($1,000)	Number of Firms	Receipts ($1,000)	Average Receipts Per Firm ($1,000)
621610	Home Health Care Services	<100	6,361	232,967	$37
621610	Home Health Care Services	100-499	7,099	1,869,713	$263
621610	Home Health Care Services	500-999	3,866	2,829,374	$732
621610	Home Health Care Services	1,000-2,499	5,218	8,370,496	$1,604
621610	Home Health Care Services	2,500-4,999	2,560	8,833,076	$3,450
621610	Home Health Care Services	5,000-7,499	885	5,275,636	$5,961
621610	Home Health Care Services	7,500-9,999	450	3,789,016	$8,420
621610	Home Health Care Services	10,000-14,999	466	5,256,982	$11,281
621610	Home Health Care Services	15,000-19,999	235	3,621,448	$15,410
621610	Home Health Care Services	>20,000	1,058	73,271,709	$69,255
621610	Home Health Care Services	Total	28,198	113,350,417	$4,020

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2022" (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: *https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx.*
Notes: The 'Average Receipts Per Firm' column is calculated as the Receipts ($1,000)/Number of firms. The 'Total' row represents all the home health care services firms under NAICS 621610. Overall receipts (revenue) for the 28,198 firms (NAICS 621610) are approximately $113 billion.

TABLE 27: NUMBER, TOTAL, AND AVERAGE REVENUE OF NONEMPLOYER ESTABLISHMENTS OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS	NAICS Description	Establishments With Sales, Value of Shipments, or Revenue Size of Establishments Code	Number of Nonemployer Establishments	Total Nonemployer Sales, Value of Shipments, Or Revenue ($1,000)	Average Revenue Per Nonemployer Establishment ($1,000)
621610	Home Health Care Services	All Establishments	412,098	9,525,542	**$23.115**

Source: Data obtained from United States Census Bureau table title "All Sectors: Nonemployer Statistics by Legal Form of Organization and Receipts Size Class for the U.S., States, and Selected Geographies: 2023" (SOURCE: U.S. Census Bureau, 2023 Economic Surveys) Release Date: 05/15/2025: https://data.census.gov/table?q=NONEMP2023.NS2300NONEMP&codeset=naics~62161
Notes: Estimated average revenue is calculated as Total Nonemployer Sales, Value of Shipments, or Revenue ($1,000)/Number of Nonemployer Establishments. For the total, this is the average estimated impact across all number of firms.

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

[63] https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx

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 HHA visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that the payment policies in this final rule will have a significant positive economic impact on a substantial number of small entities.

Specifically, we estimate that the net impact of the payment policies in this final rule will be a positive 2.4 percent impact in the aggregate for CY 2027 or approximately $415 million. As discussed in the preamble, the net increase in CY 2027 is mostly driven by the impact of the final CY 2027 home health payment update percentage and the updated FDL. Table 23 details the total percentage payment increase by number of 30-day periods and impact by facility type, size, and location. As shown in table 23, when examining the distribution of projected payment impacts across individual agency groups, a substantial share of HHAs are projected to receive a payment increase of 3 percent or more. For example, agencies in the Mid-Atlantic (360 agencies, 3.6 percent), Pacific (2,880 agencies, 3.0 percent), and outlying (44 agencies, 3.6 percent) census regions alone account for approximately 3,284 agencies. This represents roughly 33 percent of all 10,082 HHAs which are each projected to receive a total payment impact of at least 3.0 percent. Additional groups projected to receive impacts of 3 percent or more include free-standing/other government (91 agencies, 4.3 percent), facility-based proprietary (20 agencies, 3.5 percent), facility-based government (154 agencies, 3.8 percent), and several rural and urban facility subcategories. Collectively, these groups confirm that more than 5 percent of HHAs are projected to experience a payment impact of 3 percent or more. We estimate that smaller HHAs (those with less than 100 periods of care and thereby lower overall revenues) would receive a 3.0 percent payment impact in CY 2027. Also, we estimate that larger HHAs (those with more than 1,000 periods of care and thereby higher overall revenues) would receive a 2.3 percent payment

impact in CY 2027. We estimate that HHAs located in the Mid-Atlantic and outlying regions would receive the largest impact reflecting a 3.6 percent payment impact. The East South Central and West South Central region would receive the lowest impact reflecting a 1.6 and 1.7 percent increase respectively.

In summary, the payment policies in this final rule will increase Medicare payments to HHAs, with small agencies receiving a slightly larger percentage increase than large ones. We solicited comments on this RFA analysis on small entities and did not receive any public comments.

Regarding options for regulatory relief, we note that section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of differences between the assumed behavior changes finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56455) and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Additionally, section 1895(b)(3)(D)(ii) and (iii) of the Act requires us to make permanent and temporary adjustments to the payment rate to offset for such increases or decreases in estimated aggregate expenditures through notice and comment rulemaking. While our analysis of claims suggests that the majority of the behavior change related to the implementation of the PDGM occurred in CYs 2020 through 2022 and that the behavior change observed in CYs 2023 through 2025 is related to factors other than the implementation of the PDGM, we determined that it was not necessary to implement a permanent adjustment because we do not consider behavior changes directly attributed to the implementation of PDGM. We include the calculations described in section II.C.1.f. of this final rule to illustrate the impact of differences between the assumed behavior changes and actual behavior changes if such behaviors were attributable to the implementation of the PDGM. We note that the law requires us to annually calculate the impact of differences between the assumed behavior changes and actual behavior changes through 2026 claims. We will also continue to

reprice claims, per the finalized methodology, and make any additional adjustments at a time and manner deemed appropriate in future rulemaking.

As discussed previously in the Alternatives Considered section of this final rule, we explored alternatives to the proposed 3.0 percent temporary adjustment including proposing a temporary adjustment factor to the CY 2027 payment rate that would recoup the full calculated temporary adjustment dollar amount, to date, of $4.9 billion. However, we believe that applying a temporary adjustment factor accounting for the temporary adjustment dollar amount of $4.9 billion to the CY 2027 payment rate may adversely affect HHAs given the magnitude of this adjustment to the payment rate in a single year. We solicited comments on the overall HH PPS RFA analysis and did not receive public comments.

This rule does not affect health care enterprises operated by small government entities such as counties or towns with populations 50,000 or less. HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. The RFA threshold analysis, therefore, indicates that there is not a significant economic impact on a substantial number of small entities. Furthermore, the regulation review costs mentioned previously, is de minimis and will not impose any additional burden on these small businesses. The statement of need for the various proposed policies in this rule is discussed in section VII.A. of this final rule. Additionally, the alternatives considered for the various proposed policies in this rule are discussed in section VII.E. of the final rule. We considered potential alternatives for the policies proposed in this rule, including routine technical rate-setting updates and temporary adjustment. The home health payment update percentage is established annually in accordance with existing statutory requirements of section 1895(b) of the Act. We maintain that limiting the application of the permanent adjustment to analysis of data from CYs 2020 through 2022 continues to be the most accurate application of the law. The data continues to show minimal changes that could be attributed to the PDGM implementation after CY 2022 by a large proportion of home health providers. We also continue to acknowledge the difficulty in attributing any behavior change

occurring from CYs 2023 through 2025 directly to the PDGM implementation and its effects on expenditures from the other changes occurring in those years. After completing the analysis required by law, we determined that it was not necessary to apply a permanent adjustment. For the temporary adjustment, we explored alternatives to delay, reduce, or increase the temporary adjustments; however, this would delay progress on the BBA of 2018 requirement and may adversely affect HHAs if reductions to the payment rate are too high in a single year. The proposed policy is expected to increase revenue for small HHAs. Therefore, the Secretary has determined that this final HH PPS rule would have a significant positive economic impact on a substantial number of small entities.

We also mention that regarding our provider enrollment provisions, we identified several alternatives we considered in subsection VII.E.3. of this final rule. Moreover, we are not finalizing our proposed expansions of the denial and revocation grounds at §§ 424.530(a)(6), 424.530(a)(7), and 424.535(i), and have reiterated that we do not anticipate: (1) requesting the submission of the affiliation data in §424.519; and (2) significant numbers of revocations arising from our proposals. We have therefore attempted to limit any impact on small businesses to the maximum extent possible.

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 the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

H. 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 2026, that threshold is approximately $193 million. This final rule will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year.

I. 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 would not impose substantial direct costs on State or local governments.

J. Unleashing Prosperity Through Deregulation

Executive Order 14192, titled "Unleashing Prosperity Through Deregulation" was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations. This final rule is expected to constitute a regulatory action under Executive Order 14192. The rule is estimated to result in annualized costs of approximately $2.3 million, calculated using a 7 percent discount rate and expressed in 2024 dollars over a perpetual time horizon.

K. Conclusion

In conclusion, we estimate that the provisions in this final rule will result in an estimated net increase in home health payments of 2.4 percent for CY 2027 ($415 million). The $415 million increase in estimated payments for CY 2027 reflects the effects of the final CY 2027 home health payment update percentage increase of 2.1 percent ($365 million increase), and an estimated 0.3 percent increase that reflects the effects of an updated FDL ($50 million).

L. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Waiver of Delay in Effective Date

The Congressional Review Act (CRA) (Pub. L. 104-121, Title II) requires a 60-day delay in the effective date for major rules unless an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, in which case the rule shall take effect at such time as the agency determines (5 U.S.C. 801(a)(3) and 808(2)).

We believe that further notice and public procedure are unnecessary, and that it would be impracticable and contrary to the public interest to delay the effective date of the CY 2027 HH PPS final rule for the following reasons.

If the effective date of this final rule is delayed by 60 days, the finalized HH PPS updated policies (including the HH Quality Reporting Program (HH QRP)) would not be effective as of the beginning of the payment year, and CMS would be compelled to continue to use obsolete reimbursement rates, which would disadvantage HHAs. We note that our waiver of the delayed effective date only applies to the policies that are adopted in this final rule. The DMEPOS replacement item, provider enrollment, expanded DME definition for infusion therapies and DMEPOS competitive bidding provisions will take effect as specified in the **DATES** section of this final rule.

In accordance with section 1895(b)(1)(B) of the Act, CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis. We typically issue the HH PPS final rule by November 1 of each year to both comply with the statutory requirement under section 1895(b)(1)(B) of the Act to annually update these payment amounts on a calendar year basis and ensure 60-days' notice so that the payment policies for these systems are effective on January 1, the first day of the calendar year to which the policies are intended to apply. The HH QRP is intended to align with the HH PPS.

In this final rule, we update Medicare home health payment rates and revise other policies that relate to the HH PPS for CY 2027. We find that, in order to comply with the statutory requirement to annually update these payment rates, we must ensure that the rule is effective no later than 1 full year after the effective date of the previous year's update (that is, January 1 of each year). Moreover, it is in the public interest to waive the 60-day delay of the effective date, so that HHAs are appropriately reimbursed starting at the beginning of the calendar year. Therefore, we find good cause exists to waive the 60-day delay in the effective date for this final rule.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 28, 2026.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by reference, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and 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 for title 45 rules amends 42 CFR chapter IV, as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

§ 405.400 [Amended]

2. Section 405.400 is amended in the definition of "opt-out period" by removing the phrase "the date the affidavit is signed" and adding in its place the phrase "the date the first submitted affidavit is signed".

§ 405.450 [Amended]

3. Section 405.450 is amended in paragraph (a) by removing the phrase "renew opt-out" and adding in its place the phrase "cancel automatic renewal".

§ 405.800 [Amended]

4. Section 405.800 is amended by removing the term "certified mail" and adding in its place the phrase "certified mail or e-mail" in paragraphs (a), (b)(1), and (c)(1).

5. Section 405.809 is amended as follows:

a. Revising the section heading and paragraph (a)(1);

b. In paragraph (a)(2), removing the term "revocation" and adding in its place the phrase "denial or revocation";

c. In paragraph (b)(1) introductory text, removing the term "Reinstates" and adding in its place the phrase "Approves or reinstates";

d. Revising paragraph (b)(1)(i);

e. In paragraph (b)(1)(ii), removing the term "reinstatement" and adding in its place the phrase "approval or reinstatement";

f. In paragraph (b)(2), removing the term “reinstate” and adding in its place the phrase “approve or reinstate”.

The revisions are as follows:

§ 405.809 Granting or reinstatement of provider or supplier billing privileges following corrective action.

(a)(1) May only submit a corrective action plan for a denial or revocation for non-compliance under §§ 424.530(a)(1) or 424.535(a)(1) of this chapter; and

* * * * *

(b) * * *

(1) * * *

(i) The effective date of the—

(A) Approval is based on the applicable timeframes described in §§ 424.520 and 424.521; and

(B) Reinstatement is based on the date the provider or supplier is in compliance with all Medicare requirements.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

6. Section 410.33 is amended by revising paragraph (g)(14)(ii) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * *

(g) * * *

(14) * * *

(ii) Maintain a permanent visible sign in plain view and posts hours of operation. If the IDTF's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the IDTF.

* * * * *

7. Section 410.38 is amended by adding paragraph (d)(2)(iii) to read as follows:

§ 410.38 Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS): Scope and conditions.

* * * * *

(d) * * *

(2) * * *

(iii)(A) For purposes of §410.38(d), replacement item means an item identified by the same Healthcare Common Procedure Coding System (HCPCS) code as the original item, that has been--

(*1*) In continuous use by the same beneficiary and is at the end of its reasonable useful lifetime; or

(*2*) Lost, stolen, or irreparably damaged.

(B) Items ordered as replacement items do not require a new face-to-face encounter. All other requirements specified in § 410.38 continue to apply.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

8. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

9. Section 414.202 is amended by revising the definition of ‘‘Durable medical equipment’’ to read as follows:

§ 414.202 Definitions.

* * * * *

Durable medical equipment means:

(1) Equipment, furnished by a supplier or a home health agency that meets the following conditions:

(i) Can withstand repeated use.

(ii) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(iii) Is primarily and customarily used to serve a medical purpose.

(iv) Generally is not useful to an individual in the absence of an illness or injury.

(v) Is appropriate for use in the home except as provided in paragraph (2) of this definition.

(2) On or after April 1, 2027, an external infusion pump that meets all conditions in paragraphs (1)(i) through (iv) of this definition provided that the following criteria are satisfied:

(i) The prescribing information approved by the FDA for the home infusion drug (as defined in § 486.505) associated with the pump instructs that the drug should be administered by or under the supervision of a health care professional.

(A) The administration or supervision of the home infusion drug must be within the scope of the health care professional's practice as specified by applicable Federal and State laws, regulations, and licensure requirements.

(B) The health care professional must be on site at the home to administer or supervise the administration of the home infusion drug.

(ii) A qualified home infusion therapy supplier (as defined in § 486.505) administers or supervises the administration of the home infusion drug in a safe and effective manner in the patient's home (as defined in § 486.505).

(iii) The prescribing information instructs that the home infusion drug be infused at least 12 times per year—

(A) Either intravenously or subcutaneously; or

(B) At infusion rates that the Secretary determines would require the use of an external infusion pump.

* * * * *

10. Section 414.414 is amended by revising paragraph (d)(3) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(d) * * *

(3) *Process for reviewing covered documents*.

(i) *Submission of covered documents for CMS review.* To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) *CMS feedback to a supplier with missing covered documents.*

(A) *For Round 1 bids.* CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to review the submitted covered documents and notify bidders of any covered documents that are missing or provide confirmation that all covered documents were received by the close of the bid window.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

11. The authority continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-21 through 1395w-28, and 1395hh.

12. Section 422.2 is amended by revising paragraph (3) introductory text for the definition of "Preclusion list" to read as follows:

§ 422.2 Definitions.

* * * * *

Preclusion list * * *

(3) The individual or entity – or any owner, managing employee, managing organization, officer, or director thereof (as those terms are defined in § 424.502) -- regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

13. The authority citation continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

14. Section 423.100 is amended by revising paragraph (3) introductory text for the definition of "Preclusion list" to read as follows:

§ 423.100 Definitions.

* * * * *

Preclusion list * * *

(3) The prescriber – or any owner, managing employee, managing organization, officer, or director thereof (as those terms are defined in § 424.502) -- regardless of whether they are or were enrolled in Medicare, has been convicted of a felony under Federal or State law within the

previous 10 years that CMS deems detrimental to the best interests of the Medicare program. Factors that CMS considers in making such a determination under this paragraph (3) are—

* * * * *

PART 424--CONDITIONS FOR MEDICARE PAYMENT

15. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

16. Section 424.58 is amended by—

a. Revising paragraph (c)(1)(vii)(D)(*4*);

b. In paragraph (c)(1)(xxiii)(D), removing the phrase "3 business days" and adding in its place the phrase "5 calendar days";

c. Redesignating paragraph (c)(1)(xxiii)(N) as paragraph (c)(1)(xxiii)(O); and

d. Adding new paragraph (c)(1)(xxiii)(N).

The revision and addition read as follows:

§ 424.58 Accreditation.

* * * * *

(c) * * *

(1) * * *

(vii) * * *

(D) * * *

(4) For notifying CMS when a conflict of interest is discovered. This includes disclosing to CMS all conflicts of interest (as described and defined in § 424.58(c)(1)(vii)(D)(*3*) and (*5*)) it currently has and explaining how and when it will terminate them.

* * * * *

(xxiii) * * *

(N) Agrees to notify CMS in writing (and, if applicable, law enforcement) of suspected fraud, waste, or abuse -- consistent with the accrediting organization's CMS-approved

definitions of those terms per paragraph (c)(1)(xxii) of this section -- within 3 calendar days of the date on which the accrediting organization determines that fraud, waste, or abuse may have occurred.

* * * * *

17. Section 424.502 is amended by--

a. In the definition of "Affiliation" –

i. Republishing the introductory text;

ii. Revising paragraph (3); and

iii. Adding new paragraph (6);

b. In the definition of "Final adverse action";

i. Republishing the introductory text; and

ii. Adding new paragraph (6);

c. Revising paragraph (1) of the definition of "Managing employee"; and

d. Revising the definition of "Operational"

The additions and revisions are as follows:

§ 424.502 Definitions.

* * * * *

Affiliation means, for purposes of applying § 424.519, any of the following:

* * * * *

(3) An interest in which an individual or entity – or any of its owning or managing employees or organizations -- exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including, for purposes of this paragraph (3), sole proprietorships), either under contract or through some other arrangement, regardless of whether or not the managing individual or entity is a W-2 employee of the organization.

* * * * *

(6) Any marketing, business, fulfillment, financial, or managerial relationship, whether direct or indirect (including, for example, common use of the same organization to perform these services).

* * * * *

Final adverse action means one or more of the following actions --

* * * * *

(6) *Misdemeanor conviction*. A conviction of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years preceding enrollment, revalidation or reenrollment.

* * * * *

Managing employee means –

(1) A general manager, business manager, administrator, director, or other individual that exercises operational or managerial control over, or who directly or indirectly conducts, the day-to-day operation of the provider or supplier, either under contract or through some other arrangement, whether or not the individual is a W-2 employee of the provider or supplier. For purposes of this definition, this includes not only a hospice or skilled nursing facility administrator and a hospice or skilled nursing facility medical director but also any of the following:

(i) Medical directors other than skilled nursing facility and hospice medical directors.

(ii) Clinical directors.

(iii) Departmental heads (for example, a hospital's chief of cardiology).

(iv) Supervising physicians (not simply those at independent diagnostic testing facilities).

(v) Nursing directors.

(vi) Alternate administrators.

(vii) All other clinical personnel not listed in paragraphs (1)(i) through (vi) of this definition who meet the "managing employee" definition.

* * * * *

Operational means (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered) the provider or supplier meets all of following requirements:

(1) Has a qualified physical practice location.

(2) Is open to the public for the purpose of providing health care related services, which includes, but is not limited to, all of the following:

(i) The provider's or supplier's location is fully accessible to all patients and lacks safety hazards. For purposes of this paragraph (2)(i), accessible means--

(A) The provider or supplier is located in an area and a building that patients can enter with reasonable ease; and

(B) The location is compliant with all federal Americans with Disabilities Act regulations and all applicable and equivalent state and local laws.

(ii) The provider's or supplier's hours of business are sufficient to regularly serve patients.

(iii) Medicare beneficiaries can contact and locate the provider's or supplier's location based on publicly available information (for example, the Internet).

(3) Is prepared and able to submit valid Medicare claims.

(4) Is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered,) to furnish these items or services. This includes, but is not limited to, the following:

(i) Provider or supplier staff must be qualified (such as licensed or certified if required under state law) to perform their health care-related functions.

(ii) Equipment must be functional, appropriate for the services and items the provider or supplier intends to furnish, and in sufficient quantity to provide these items and services.

(iii) Appropriate medications for the services and items the provider or supplier intends to furnish and in sufficient quantity to provide these items and services.

(5) Has adequate written policies and records regarding its operations, such as, but not limited to, procedures for patient care, patient safety, medical and patient recordkeeping, and general administration.

* * * * *

18. Section 424.510 is amended by adding paragraph (f) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(f) *Signage.* (1) The provider or supplier must maintain a permanent visible sign in plain view and post hours of operation. If the provider's or supplier's place of business is located within a building complex, the sign must be visible at the main entrance of the building or the hours can be posted at the entrance of the provider or supplier.

(2) The requirement in paragraph (f)(1) of this section does not apply if the provider or supplier--

(i) Shares office space with another provider or supplier (for example, physicians in a group practice sharing a common suite, though the group itself must have signage);

(ii) Treats patients in the patients' homes;

(iii) Treats patients in the provider's or supplier's home and only uses the provider's or supplier's address for administrative purposes.

(iv) Performs telehealth services from home.

* * * * *

19. Section 424.516 is amended by adding paragraph (f)(3) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) * * *

(3) All documentation required to be retained and furnished under this paragraph (f) must be accurate, complete, and compliant with all CMS requirements.

* * * * *

20. Section 424.518 is amended by revising paragraph (c)(2)(ii)(A) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers

* * * * *

(c) * * *

(2) * * *

(ii)(A) Using the CMS-designated fingerprinting contractor, requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier; and

* * * * *

§ 424.519 [Amended]

21. Section 424.519 is amended in paragraph (b) by removing the phrase "has or, within the previous 5 years, had" and adding in its place the phrase "has or has had".

22. Section 424.530 is amended by–

a. Revising paragraph (a)(4); (13); (14); and (16);

b. Adding paragraphs (a)(19) through (22);

c. Revising paragraph (f) introductory text;

d. Removing paragraphs (f)(2)(i) through (iv); and

e. Redesignating paragraphs (f)(3)(i) and (ii) as revised paragraphs (f)(2)(i) and (ii).

The revisions and additions read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(4) *False or misleading information*. The provider or supplier submits false or misleading information on or associated with any CMS or Medicare provider enrollment-related form. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.) This includes but is not limited to:

(i) Enrollment-related forms created by or submitted or both to CMS contractors;

(ii) Documentation furnished as part of the completion or submission of the CMS or Medicare enrollment-related form.

(iii) Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement; O.M.B Control Number 0938-0626).

(iv) Documents required to demonstrate compliance with HHA capitalization requirements in § 489.28.

(v) Opt-out affidavits under 42 CFR part 405, subpart D.

(vi) Letters from a provider demonstrating that a particular provider official qualifies as an authorized or delegated official under § 424.502.

(vii) Any other required or requested enrollment-related documentation.

* * * * *

(13) *Affiliation that poses undue risk.* CMS determines that the provider or supplier – or any of its owning or managing employees or organizations -- has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

* * *

(14) *Other program termination or suspension.* (i) The provider or supplier – or any owner, managing employee, or managing organization thereof -- is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other federal health care program, or the provider's or supplier's license is currently revoked or suspended (or voluntarily surrendered in lieu of further action) in a State other than that in which

the provider or supplier is enrolling. In determining whether a denial under this paragraph (a)(14) is appropriate, CMS considers the following factors:

(A) The reason(s) for the termination, suspension, revocation, or surrender.

(B) Whether, as applicable, the provider or supplier – or owner, managing employee, or managing organization thereof –

(*1*) Is currently terminated or suspended (or otherwise barred) from more than one program (for example, more than one State's Medicaid program);

(*2*) Has been subject to any other sanctions during its participation in other programs or by any other State licensing boards; or

(*3*), Has had any other final adverse actions (as that term is defined in § 424.502) imposed against it.

(C) Any other information that CMS deems relevant to its determination.

(ii) CMS may apply paragraph (a)(14)(i) of this section to the provider or supplier under any of the provider's or supplier's – or owner's, managing employee's, or managing organization's -- current or former names, numerical identifiers or business identities, and regardless of whether any appeals are pending.

* * * * *

(16) *Misdemeanor conviction*. The provider or supplier -- or any owner, managing employee, managing organization, officer, or director thereof – was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(19) *Same suite.* The provider's or supplier's practice location is in the same suite or office as another provider or supplier whose Medicare enrollment has been revoked or denied under § 424.535 or § 424.530.

(20) *Hospice medical director or administrator.* A hospice's enrollment may be denied if any of the following apply:

(i) The hospice's medical director is either of the following:

(A) The medical director of multiple other hospices.

(B) Practices at such a distance (for example, in a different state) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR part 418.

(ii) The hospice's administrator is either of the following:

(A) The administrator of multiple other hospices.

(B) Located at such a distance from the enrolling hospice that the administrator cannot realistically perform all administrator functions required under 42 CFR part 418.

(iii) The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

(21) *Misuse of identity.* The provider or supplier is attempting to enroll under another party's identity.

(22) *Change in majority ownership non-compliance*. CMS determines that the HHA, hospice, or DMEPOS supplier has failed to comply with the provisions and requirements of, as applicable, § 424.550(b) or § 424.551.

* * * * *

(f) *Reapplication bar.* CMS may prohibit a prospective provider or supplier from enrolling in Medicare for up to 10 years if their enrollment application is denied for any reason under § 424.530.

* * * * *

23. Section 424.535 is amended by--

a. Revising paragraph (a)(4);

b. Revising paragraph (a)(8)(ii) introductory text;

c. Removing paragraphs (a)(8)(ii)(A) through (D) and (a)(8)(iii);

d. Revising paragraph (a)(16);

e. Revising paragraph (a)(19);

f. Adding paragraphs (a)(24) and (25).

g. Revising paragraphs (g)(1) and (2);

h. Removing paragraph (g)(3);

i. Revising paragraphs (h)(1)(i) and (ii).

The revisions and additions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(4) *False or misleading information*. The provider or supplier submits false or misleading information on or associated with any CMS or Medicare provider enrollment-related form. (Offenders may be referred to the Office of Inspector General for investigation and possible criminal, civil, or administrative sanctions.) This includes but is not limited to--

(i) Forms created by and/or submitted to CMS contractors.

(ii) Documentation furnished as part of the completion or submission of the CMS or Medicare enrollment-related form.

(iii) Form CMS-588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB Control Number 0938-0626), which must be submitted with the enrollment application.

(iv) Documents required to demonstrate compliance with HHA capitalization requirements in § 489.28.

(v) Opt-out affidavits under 42 CFR part 405, subpart D.

(vi) Letters from a provider demonstrating that a particular provider official qualifies as an authorized or delegated official under § 424.502.

(vii) Any other required or requested enrollment-related documentation.

* * * * *

(8) * * *

(ii) CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements.

* * * * *

(16) *Misdemeanor conviction*. The provider or supplier -- or any owner, managing employee, managing organization, officer, or director thereof – was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries.

* * * * *

(19) *Affiliation that poses undue risk.* CMS determines that the provider or supplier – or any of its owning or managing employees or organizations -- has or has had an affiliation under § 424.519 that poses an undue risk of fraud, waste, or abuse to the Medicare program.

* * * * *

(24) *High-risk based on excess providers in area.* CMS determines that the provider's or supplier's enrollment presents a high risk of fraud, waste, or abuse due to the provider's or supplier's location within a limited geographic area that has an excessive number of providers and suppliers.

(25) *Change in majority ownership non-compliance.* CMS determines that the HHA, hospice, or DMEPOS supplier did not comply with the provisions and requirements of, as applicable, § 424.550(b) or § 424.551.

* * * * *

(g)(1) Except as described in paragraph (g)(2) of this section, the effective dates of the revocations identified in this section are as follows:

(i) For revocations under paragraph (a)(1) of this section:

(A) If the revocation is based on non-compliance with the enrollment requirements in Title 42 or in the enrollment application applicable to the provider or supplier type, the date the non-compliance began (per CMS' or the CMS contractor's determination).

(B) If the revocation is based on a State license revocation, suspension, or surrender in lieu of further disciplinary action, the date of the license revocation, suspension, or surrender.

(C) For revocations based on termination of a provider agreement under part 489 of this chapter, and as applicable to the type of provider involved, the later of--

(*1*) The date of the provider agreement termination; or

(*2)* The date that CMS establishes under § 489.55.

(ii) For revocations under paragraph (a)(2) of this section, the date of the exclusion or debarment.

(iii) For revocations under paragraph (a)(3) of this section, the date of the felony conviction.

(iv) For revocations under paragraph (a)(4) of this section, and as applicable to the situation, the date the certification statement was signed or the false or misleading information was submitted.

(v)(A) For revocations under paragraph (a)(5)(i) of this section, the date on which the provider's or supplier's practice location was no longer operational (per CMS' or the CMS contractor's determination).

(B) For revocations under paragraph (a)(5)(ii) of this section, the date the Medicare enrollment requirement was not satisfied.

(vi) For revocations under paragraph (a)(6) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under paragraph (a)(6).

(vii) For revocations under paragraph (a)(7) of this section, the date on which the conduct resulting in the revocation occurred.

(viii)(A) For revocations under paragraph (a)(8)(i) of this section, the earliest date of service on the claim or claims that is or are triggering the revocation.

(B) For revocations under paragraph (a)(8)(ii) of this section, the last date of service on the claims in the applicable pattern or practice.

(ix) For revocations under paragraph (a)(9) of this section, the day following the date by which the provider or supplier was required to report the applicable change, addition, or deletion.

(x)(A) For revocations under paragraph (a)(10) of this section based on a failure to retain documentation, the date on which CMS or the CMS contractor determines that the provider or supplier has not complied with this retention requirement.

(B) For revocations under paragraph (a)(10) of this section based on a failure to provide access to the documentation, the day after the date by which the provider or supplier was required to furnish access.

(xi) For revocations under paragraph (a)(11) of this section, the day after the date by which the HHA was required to submit the requested documentation.

(xii) For revocations under paragraph (a)(12) of this section, the date of the termination, revocation, or bar.

(xiii)(A) For revocations under paragraph (a)(13)(i) of this section, the date of the certificate revocation, suspension, or surrender.

(B) For revocations under paragraph (a)(13)(ii) of this section, the date of the revocation or suspension of the ability to prescribe.

(xiv) For revocations under paragraph (a)(14) of this section, the date of the last prescription in the applicable pattern or practice.

(xv) For revocations under paragraph (a)(15) of this section, the date of the judgment.

(xvi) For revocations under paragraph (a)(16) of this section, the date of the conviction.

(xvii) For revocations under paragraph (a)(17) of this section, the date on which CMS referred the debt to the Department of Treasury.

(xviii) For revocations under paragraph (a)(18) of this section, the effective date of the provider's or supplier's current enrollment.

(xix) For revocations under paragraph (a)(19) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under this paragraph.

(xx) For revocations under paragraph (a)(20) of this section, the earliest date on the claims for the non-compliant location that are triggering the revocation.

(xxi) For revocations under paragraph (a)(21) of this section, the date of the last order, certification, referral, or prescription in the applicable pattern or practice.

(xxii) For revocations under paragraph (a)(22) of this section, the date of the prior action resulting in the revocation.

(xxiii)(A) For revocations under paragraph (a)(23) of this section---

(*1*) If the standard or condition violation involves the suspension, revocation, or termination (or surrender in lieu of further disciplinary action) of the provider's or supplier's Federal or State license, certification, accreditation, or MDPP recognition, the effective date is the date of the license, certification, accreditation, or MDPP recognition suspension, revocation, termination, or surrender.

(*2*) If the standard or condition violation involves a non-operational practice location, the effective date is the date the non-operational status began (per CMS' or the CMS contractor's determination).

(*3*) If the standard violation involves a felony conviction of an individual or entity described in § 424.67(b)(6)(i), the effective date is the date of the felony conviction.

(B) For all other revocations under paragraph (a)(23) of this section based on a condition or standard violation, the effective date is the date of non-compliance with the condition or standard.

(xxiv) For revocations under paragraph (a)(24) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under paragraph (a)(24).

(xxv) For revocations under paragraph (a)(25) of this section, the date on which CMS or its contractor determines that the provider or supplier should be revoked under paragraph (a)(25).

(xxvi) For revocations under paragraph (i) of this section, the effective date of the revocation (or date of the denial) that triggered the revocation(s) of the other enrollment(s).

(2) [To be added]

* * * * *

(h)(1)(i) Except for HHAs as described in paragraph (h)(1)(ii) of this section, a revoked provider or supplier must, within 15 calendar days of the date of the revocation letter, submit all claims for items and services furnished before the effective date of the revocation.

(ii) A revoked HHA must, within 15 calendar days of the date of the revocation letter, submit all claims for items and services furnished before the later of the following:

* * * * *

24. Section 424.540 is amended by—

a. In paragraph (b)(3)(i), removing the term "HHA" and adding in its place the phrase "HHA or hospice"; and

b. Adding paragraph (d)(3).

The addition reads as follows:

§ 424.540 Deactivation of Medicare billing privileges.

* * * * *

(d) * * *

(3) A provider or supplier may rebut their assigned reactivation effective date via the procedures in § 424.546.

* * * * *

25. Section 424.545 is amended by revising paragraph (b) to read as follows:

§ 424.545 Provider and supplier appeal rights

* * * * *

(b) A provider or supplier whose billing privileges are deactivated or has been assigned a reactivation effective date may file a rebuttal in accordance with § 424.546 of this chapter.

* * * * *

26. Section 424.546 would be amended as follows:

a. Revising the section heading, and paragraphs (a)(1) and (b)(2);

b. In paragraph (b)(3), removing the term “deactivation” and adding in its place the phrase “deactivation or reactivation effective date”; and

c. Revising paragraph (d).

The revisions read as follows:

§ 424.546 – Rebuttals of deactivations and of reactivation effective dates.

(a)(1) If a provider or supplier receives written notice from CMS or its contractor that the provider's or supplier’s billing privileges are to be or have been deactivated under § 424.540 or is assigned a reactivation effective date by CMS or its contractor under § 424.540(d)(2), the provider or supplier has 15 calendar days from the date of the written notice to submit a rebuttal to CMS as permitted under § 424.545(b).

* * * * *

(b) * * *

(2) Specify the facts or issues about which the provider or supplier disagrees with the deactivation's imposition and/or the effective date (or with the assigned reactivation effective date), and the reasons for disagreement.

* * * * *

(d) Upon receipt of a timely and compliant deactivation (or reactivation effective date) rebuttal, CMS reviews the rebuttal to determine whether the imposition of the deactivation or the designated effective date (or the assigned reactivation effective date) or both are correct.

* * * * *

27. Section 424.570 is amended as follows:

a. Revising paragraphs (a)(1)(i) and(1)(iii)(C);

b. Redesignating paragraph (a)(1)(iv) as paragraph (a)(1)(iv)(A).

c. Adding paragraph (a)(1)(iv)(B).

The revisions and addition read as follows:

§ 424.570 Moratoria on newly enrolling Medicare providers and suppliers.

(a)* * *

(1)* * *

(i) CMS may impose a moratorium on the enrollment of new Medicare providers and suppliers of a particular type or the establishment of new practice locations of a particular type in a particular geographic area. Solely for purposes of this section, the term "new" means any of the following application types:

(A) Initial enrollment applications.

(B) Change of ownership applications that require an initial enrollment per § 424.570(a)(1)(iii)(C).

(C) Enrollment applications from revoked providers or suppliers whose reenrollment bars under § 424.535(c) have expired and are seeking to enroll again in the Medicare program.

(D) Reactivation applications.

(E) Enrollment applications from voluntarily terminated providers/suppliers seeking to enroll again in the Medicare program.

* * * * *

(iii) * * *

(C) Changes in ownership (except changes in ownership that require an initial enrollment, such as, but not limited to, an HHA, hospice, or DMEPOS supplier change in majority ownership under § § 424.550(b) or § 424.551).

(iv)(A) A temporary moratorium does not apply to any enrollment application that has been received by the Medicare contractor prior to the date the moratorium is imposed.

(B) The date the moratorium is imposed is the moratorium's effective date, which is the date on which the moratorium notice is filed for public inspection at the Office of the Federal Register (OFR).

* * * * *

PART 484 – HOME HEALTH SERVICES

28. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

29. Section 484.245 is amended by—

a. In paragraph (b)(2)(ii)(A), removing the parenthetical phrase "(July 1 through June 30)" and adding in its place the parenthetical phrase "(January 1 through December 31)";

b. In paragraph (d)(1)(i), removing the phrase "a letter of noncompliance" and adding in its place the phrase "receive notification of non-compliance";

c. In paragraph (d)(2) introductory text, removing the hyperlink "*HHAPureConsiderations@cms.hhs.gov* " and adding in its place the hyperlink "*HHAPUReconsiderations@cms.hhs.gov*";

d. In paragraph (d)(2)(v), removing the phrase "non-compliance letter" and adding in its place the phrase "non-compliance notification"; and

e. Revising paragraph (d)(4)(i);

The revision reads as follows:

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

* * * * *

(d) * * *

(4)(i) CMS notifies the HHA of its final decision regarding any reconsideration request through a CMS designated data submission system.

* * * * *

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

30. The authority for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

§ 498.3 [Amended]

31. Section 498.3 is amended in paragraph (b)(19) by removing the term "renew opt-out" and add in its place the phrase "cancel automatic renewal".

§ 498.20 [Amended]

32. Section 498.20 is amended in paragraph (a)(1) by removing the term "mails" and add in its place the phrase "mails or e-mails".

§ 498.25 [Amended]

33. Section 498.25 is amended by revising paragraph (a)(1) to remove the term "mails" and add in its place the phrase "mails or e-mails".

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

[FR Doc. 2026-22750 Filed: 11/4/2026 5:00 pm; Publication Date: 11/9/2026]