

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 414, 424, 455, 484, and 498

[CMS–1828–P]

RIN 0938–AV53

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth routine updates to the Medicare home health payment rates in accordance with existing statutory and regulatory requirements. In addition, this proposed rule proposes permanent and temporary behavior adjustments and proposes to recalibrate the case-mix weights and update the functional impairment levels; comorbidity subgroups; and low-utilization payment adjustment (LUPA) thresholds for CY 2026. Lastly, this proposed rule proposes policy changes to the face-to-face encounter policy. It also proposes changes to the Home Health Quality Reporting Program (HH QRP) and the expanded Health Value-Based Purchasing (HHVBP) Model requirements. In addition, it would update the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). Lastly it proposes: a technical change to the HH conditions of participation; updates to DMEPOS supplier conditions of payment; updates to provider and supplier enrollment requirements; and changes to DMEPOS accreditation requirements.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on September 2, 2025.

ADDRESSES: In commenting, please refer to file code CMS–1828–P. Because of staff and resource limitations, we cannot

accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the instructions under the “submit a comment” tab.

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1828–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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

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

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1828–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

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 HHQRPquestions@cms.hhs.gov.

For more information about the expanded Home Health Value-Based Purchasing Model, please visit the Expanded HHVBP Model web page 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.

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

Katie Parker (410) 786–0537, Emily Calvert (410) 786–4277, or Jessica Martindale (410) 786–1558 for DMEPOS Prior Authorization inquiries.

Alexander Ullman at (410) 786–9671 or DMEPOS@cms.hhs.gov, for DMEPOS Competitive Bidding Program inquiries.

For information about the Home Health Conditions of Participation, send

your inquiry via email to healthandsafetyinquiries@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

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

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at <https://www.regulations.gov/>.

Deregulation Request for Information (RFI): On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 “Unleashing Prosperity Through Deregulation,” which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America’s economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other stakeholders participating in the Medicare program. CMS has made available a Request for Information (RFI) at: (<https://www.cms.gov/medicare-regulatory-relief-rfi>). Please submit all comments in response to this request for information through the provided weblink.

Table of Contents

- I. Executive Summary
 - A. Purpose and Legal Authority
 - B. Summary of the Provisions of This Proposed Rule
 - C. Summary of the Regulatory Impact Analysis
- II. Home Health Prospective Payment System
 - A. Overview of the Home Health Prospective Payment System
 - B. Monitoring the Effects of the Implementation of the PDGM
 - C. Proposed CY 2026 Payment Adjustments Under the HH PPS
 - D. Proposed CY 2026 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights
 - E. Proposed CY 2026 Home Health Payment Rate Updates
 - F. Proposed Regulation Change to Face-to-Face Encounter

- III. Home Health Quality Reporting Program (HH QRP)
 - A. Background and Statutory Authority
 - B. Summary of the Provisions of This Proposed Rule
 - C. Quality Measures Currently Adopted for the CY 2026 HH QRP
 - D. Proposed Removal of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) Measure Beginning With the CY 2026 HH QRP
 - E. Proposed Removal of Four Standardized Patient Assessment Data Elements Beginning With the CY 2027 HH QRP
 - F. Amending the Data Non-Compliance Reconsideration Request Policy and Process Beginning With the FY 2027 HH QRP
 - G. Updates to Requirements for OASIS All-Payer Data Submission
 - H. Proposed HHCAHPS Survey Updates
 - I. HH QRP Quality Measure Concepts Under Consideration for Future Years—Request for Information
 - J. Potential Revision of the Final Data Submission Deadline Period From 4.5 Months to 45 Days—Request for Information (RFI)
 - K. Advancing Digital Quality Measurement in the HH QRP—Request for Information
 - L. Form, Manner, and Timing of Data Submission Under the HH QRP
 - M. Policies Regarding Public Display of Measure Data for the HH QRP
- IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model
 - A. Background
 - B. Proposed Changes to HHVBP Measure Removal Factors
 - C. Proposed Changes to the Expanded HHVBP Model's Applicable Measure Set
 - D. HHVBP Quality Measure Concepts Under Consideration for Future Years—Request for Information
- V. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements
 - A. Statutory Authority and Background
 - B. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))
- VI. Provider Enrollment, Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation Policies, and DMEPOS Prior Authorization
 - A. Provider Enrollment
 - B. DMEPOS Supplier Accreditation Process
 - C. Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(iii))
- VII. DMEPOS Competitive Bidding Program
 - A. Background
 - B. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP
 - C. Adjustments to SPAs
 - D. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected
 - E. Revising the Definition of Item Related to Medical Supplies
 - F. Remote Item Delivery (RID) CBP
 - G. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

- H. Revising the Submission of Financial Document Requirements for the DMEPOS CBP
 - I. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP
 - J. Bid Surety Bond Review Process
 - K. Tribal Exemption From Participating in the DMEPOS CBP
 - L. Addition of a Termination Clause for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) Supplier Contracts
 - M. Technical Change to § 414.408(h)(8)
 - N. Definitions of Competition and Adjusted and Unadjusted Fee Schedule Amounts Under § 414.402
- VIII. Collection of Information Requirements
- A. Statutory Requirement for Solicitation of Comments
 - B. Information Collection Requirements (ICRs)
- IX. Regulatory Impact Analysis
- A. Statement of Need
 - B. Overall Impact
 - C. Detailed Economic Analysis
 - D. Regulatory Review Cost Estimation
 - E. Alternatives Considered
 - F. Accounting Statements and Tables
 - G. Regulatory Flexibility Act (RFA)
 - H. Unfunded Mandates Reform Act (UMRA)
 - I. Federalism
 - J. Unleashing Prosperity Through Deregulation
 - K. Conclusion
- X. Response to Comments

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 proposed rule would update the CY 2026 Medicare payment rates for home health agencies (HHAs). In this proposed 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 rule analyzes the difference between assumed versus actual behavior change on estimated aggregate expenditures and proposes permanent and temporary adjustments to the CY 2026 home health base payment rate. In addition, this rule proposes to recalibrate the PDGM case-mix weights and to update 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 2026. This proposed rule proposes to update the CY 2026 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 proposes changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v) to align with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

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 proposing updated quality reporting policies. We are proposing to remove the COVID–19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure and corresponding data element. CMS is proposing the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. We are also proposing to revise the policy to allow for providers to submit a request for reconsideration of an initial determination of noncompliance if they can demonstrate full compliance. In very limited circumstances, HHAs can request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA (that is, a natural or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day reconsideration period. CMS is also proposing to implement a revised Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey beginning with the April 2026 sample month. This rule would also update regulatory text to account for all-payer data submission of OASIS data. We are seeking information on a change to the final data submission deadline period from 4.5 months to 45 days. We are also seeking feedback on the digital quality measurement (dQM) transition for HHAs. We aim to solicit feedback from the public on the current adoption of health information technology (IT) and standards including Fast Healthcare Interoperability Resources (FHIR), including related challenges or barriers HHAs are facing. Finally, we are seeking input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

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

In accordance with the statutory authority at section 1115A of the Act, we are doing the following for the expanded HHVBP Model: (1) proposing a new measure removal factor for the expanded HHVBP Model applicable measure set; (2) proposing changes to the expanded HHVBP Model applicable measure set; and (3) including a request for information (RFI) related to potential future performance measure concepts.

We propose to add a new measure removal factor for the expanded HHVBP Model applicable measure set for measures that are not feasible to implement. We propose to remove three HHCAHPS Survey-based measures, to align with proposed changes to the HHCAHPS survey. We also propose the addition of four new measures. These additions include the claims-based Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) measure, and three OASIS-based function measures: Improvement in Bathing, Improvement in Upper Body Dressing, and Improvement in Lower Body Dressing. Due to these proposed changes to the applicable measure set, we also propose to revise the weights of the individual HHVBP measures as well as the measure categories. We also include an RFI related to potential future measure concepts for the expanded HHVBP Model.

4. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements

We propose technical regulation text changes to the Home Health Conditions of Participation (CoP). These technical changes update terminology in the Home Health CoPs to further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services.

5. Medicare and Medicaid Provider Enrollment

Consistent with section 1866(j) of the Act, we are proposing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) modifying grounds for denying, revoking, or deactivating 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.

We are also proposing a technical correction to one of our Medicaid provider enrollment provisions in 42 CFR 455.416 to further clarify the scope of § 455.416(c).

6. DMEPOS Supplier Accreditation Organizations

Consistent with provisions in section 1834(a)(20) of the Act, we are proposing to revise and supplement a number of our regulations regarding DMEPOS supplier accreditation and, in particular, requirements that an organization must meet to become and remain a CMS-approved DMEPOS accrediting organization (AO). Our proposed revisions include but are not limited to: (1) requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle); (2) eliminating inconsistencies among AOs in how they oversee DMEPOS suppliers; and (3) strengthening our ability to take action against poorly performing DMEPOS AOs. We believe these changes would help better ensure that DMEPOS AOs closely oversee DMEPOS suppliers for compliance with the DMEPOS quality standards.

7. DMEPOS Prior Authorization

Consistent with provisions in section 1834(a)(15) of the Act and final rule provisions published in the November 8, 2019 **Federal Register** titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 60648), hereinafter referred to as the "2019 ESRD PPS & DMEPOS final rule," we propose to clarify authority at § 414.234(c)(1)(ii) to exempt compliant suppliers, while also establishing notice guidelines for establishing an exemption and withdrawal of an exemption. The 2019 ESRD PPS & DMEPOS final rule created the authority at § 414.234(c)(1)(ii) to exempt suppliers from required prior authorization of DMEPOS items upon compliance with Medicare coverage, coding, and payment requirements. However, to

clarify this process for exemption from prior authorization requirements, CMS is proposing to establish guidelines for granting and withdrawing exemptions. Furthermore, we are proposing to establish notification requirements to put suppliers on notice that the exemption has either been granted or withdrawn.

8. DMEPOS Competitive Bidding Program

We are proposing changes to regulations at subpart C of 42 CFR 414 we believe are necessary for the effective implementation of the DMEPOS Competitive Bidding Program (CBP) mandated by section 1847(a) of the Act.

a. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

The purpose of this proposal is to revise both how single payment amounts (SPAs) are calculated and how CMS determines the number of contracts to award in each "competition," which is a term that we use under the DMEPOS CBP to refer to a competitive bidding area (CBA) and product category combination.

b. Adjustments to SPAs

The purpose of this proposal is to acknowledge the challenge and uncertainty a bidder may face when factoring inflation into its bid. We believe that adding an annual increase to the SPAs to account for inflation would be consistent with Medicare making annual covered item updates for other DMEPOS items and services. This would account for inflation in the cost of doing business for suppliers submitting bids for furnishing items under a multiyear contract.

c. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected

The purpose of this proposal is to revise the methodology used to establish bid limits and establish the conditions for determining when contracts cannot be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act because the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. We believe these proposed changes would better ensure the DMEPOS CBP is responsive to rising costs over time while still ensuring alignment with the statutory requirement for achieving savings.

d. Revising the Definition of “Item” Related to Medical Supplies

The purpose of this proposal is to specify that ostomy, tracheostomy, and urological supplies are medical equipment items mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act.

e. Remote Item Delivery (RID) CBP

The purpose of this proposal is to create two new definitions under § 414.402 for “Remote item delivery CBP” and “Remote item delivery item” for the purpose of establishing one or more RID CBPs wherein contract suppliers would be responsible for furnishing the items and services under the product category primarily on a mail order basis to all Medicare beneficiaries regardless of where they live in the CBA, but could also furnish the items on a non-mail order basis. Any competitively bid item furnished on a non-mail order basis would also need to be furnished by a contract supplier. We are proposing that for a given product category, we could implement one nationwide RID CBP that would include all areas (all States, territories, and the District of Columbia) or we could implement multiple RID CBPs covering different regions of the country. Items included in a nationwide or regional RID CBP would be those that are typically furnished to beneficiaries from remote supplier locations that are hundreds of miles on average from the beneficiary residence where the items are delivered.

f. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

The purpose of this proposal is to make payment under the DMEPOS CBP for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. The technology of products used by beneficiaries to help manage diabetes continues to change rapidly, and without frequent and substantial servicing to ensure that the devices continue to function correctly, the beneficiary might not receive information they need to make correct diabetes treatment decisions or the dosage of insulin administered by the insulin pump could be incorrect, putting the beneficiary in imminent danger. This proposal would eliminate the need to wait 5 years to replace equipment, allowing beneficiaries to use the latest technologically updated items. Payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and

accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis in the same amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

g. Revising the Submission of Financial Documents for the DMEPOS CBP

The purpose of this proposal is to streamline the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers that are offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period.

h. Revising the Covered Document Review Date Evaluation and Notification Process for the DMEPOS CBP

The purpose of this proposal is to streamline the process for evaluating and notifying a bidder who submitted a covered document by the covered document review date if a covered document(s) is missing.

i. Bid Surety Bond Review Process

The purpose of this proposal is to codify the bid surety bond rider process that occurred during the DMEPOS CBP round in 2021 and to correct a regulatory citation error from previous rulemaking.

j. Tribal Exemption From Participating in the DMEPOS CBP

The purpose of this proposal is to add a Tribal exception to the DMEPOS CBP regulations.

k. Addition of a Termination Clause for the DMEPOS CBP Supplier Contracts

The purpose of this proposal is to add a termination clause to the DMEPOS CBP contracts that could be utilized during a public health emergency (PHE), when CMS determines that credible evidence exists of an access problem for beneficiaries, and when CMS believes the termination of an entire DMEPOS CBP contract, the termination of a competition on a DMEPOS CBP contract, or the termination of a defined area(s) within a CBA could improve the situation for the applicable competition(s) or defined areas (for example, ZIP codes) within a CBA.

l. Technical Change to § 414.408(h)(8)

The purpose of this proposal is to make a technical change to § 414.408(h)(8) so that it correctly refers to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

m. Adding Definitions of Adjusted Fee Schedule, Amount Competition, and Unadjusted Fee Schedule Amount to § 414.402

The purpose of this proposal is to add definitions of “Adjusted fee schedule amount,” “Competition,” and “Unadjusted fee schedule amount” to § 414.402 for the purpose of simplifying the regulation text for subpart F.

B. Summary of the Provisions of This Proposed Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this proposed rule, we provide monitoring and data analysis on the PDGM utilization.

In section II.C.1. of this proposed rule, we propose a permanent adjustment and a temporary adjustment to the base payment rate under the HH PPS.

In section II.D. of this proposed rule, we propose to recalibrate the CY 2026 PDGM case-mix weights and to update the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups.

In section II.E. of this proposed rule, we propose to update the home health wage index. We also propose to update the CY 2026 national, standardized 30-day period payment rates and the CY 2026 national per-visit payment amounts by the home health payment update percentage. The proposed home health payment update percentage for CY 2026 is 2.4 percent. Additionally, this rule proposes the CY 2026 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.F. of this proposed rule, we propose changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v).

2. Home Health Quality Reporting Program (HH QRP)

In section III. of this proposed rule, we are proposing to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure. CMS is proposing the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. CMS is also proposing to implement a revised HHCAHPS Survey beginning with the April 2026 sample month. We are also proposing to revise the policy to allow for providers to submit a request for reconsideration of an initial determination of non-compliance with the HH QRP data submission

requirements. They can request this if they believe that they can demonstrate full compliance. We are also proposing that, in very limited circumstances, the HHA could request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA, (that is, a natural disaster or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day period for requesting reconsideration of the initial determination. We are also seeking information on a change to the final data submission deadline period from 4.5 months to 45 days. We are also seeking feedback on the digital quality measurement (dQM) transition for HHAs. We aim to solicit feedback from the public on current adoption of health information technology (IT) and standards, including Fast Healthcare Interoperability Resources (FHIR), and what related challenges or barriers HHAs are facing. Finally, we are seeking input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

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

In section IV. of this proposed rule, we propose to add a new measure removal factor for the expanded HHVBP Model applicable measure set. This ninth measure removal factor would allow CMS to propose removal of a measure when it is no longer feasible to implement the measure specifications. We also propose changes to the expanded HHVBP Model applicable measure set and changes to measure weights. We propose to remove three HHCAHPS Survey-based measures, to align with proposed changes to the HHCAHPS survey. We also propose the addition of four new measures. These additions include the claims-based Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) measure, and three OASIS-based function measures: Improvement in Bathing, Improvement in Upper Body Dressing, and Improvement in Lower Body Dressing. Due to these proposed changes to the applicable measure set, we also propose to revise the weights of the individual HHVBP measures and the measure categories.

We also include an RFI related to potential future measure concepts for the expanded HHVBP Model.

4. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements

In section V. of this proposed rule, we propose technical regulation text changes to the Home Health Conditions of Participation (CoP) to align with the OASIS all-payer submission requirements. These technical changes update terminology in the Home Health CoPs to further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services.

5. Medicare and Medicaid Provider Enrollment

We are proposing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited to, the following:

- Modifying grounds for denying, revoking, or deactivating 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.
- Expanding the reasons for which CMS can apply a stay of enrollment.
- Requiring providers and suppliers to report any adverse legal actions imposed against them, their owners, their managers, etc. within 30 days instead of the current 90 days.

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

6. DMEPOS Supplier Accreditation Organizations

DMEPOS suppliers are required to be accredited by a CMS-approved accrediting organization to enroll in and bill Medicare. The purpose of accreditation is to confirm, typically through an on-site survey of the supplier, that the supplier meets the DMEPOS quality standards. Regulations promulgating our accreditation requirements were enacted in 2006 but have not been updated since then. We are concerned there may be instances where: (1) AOs are accrediting DMEPOS suppliers that do not meet the quality standards; and (2) DMEPOS suppliers are falling out of compliance with the quality standards (sometimes for extended periods) after becoming accredited. To enhance our ability to ensure that AOs are performing DMEPOS accreditation functions effectively and thoroughly, including verifying suppliers' compliance with the

quality standards, we are proposing to add a number of provisions to our DMEPOS accreditation regulations. Among our proposed provisions are:

- Requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle).
- Reducing inconsistencies among AOs in how they oversee DMEPOS suppliers.
- Requiring AOs to furnish more detailed information to CMS when applying or reapplying for approval to become or remain a DMEPOS AO.
- Facilitating greater CMS oversight of the DMEPOS AOs.

We believe these and other changes to the DMEPOS accreditation process would help ensure that unqualified DMEPOS suppliers are not accredited and do not, in turn, receive Medicare payments.

7. DMEPOS Prior Authorization

In section V.C. of this proposed rule, we propose to establish guidelines for granting and withdrawing exemptions from mandatory prior authorization requirements for certain DMEPOS suppliers.

8. DMEPOS Competitive Bidding

a. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

Currently SPAs for the lead item (defined under § 414.402 as the item in the product category with the highest total allowed charges nationwide) are calculated using the maximum winning bid submitted by bidders whose composite bids for the product category that includes the lead item are equal to or below the pivotal bid for that product category. We are proposing to revise this calculation to use the 75th percentile of winning bids for the lead item by bidders whose composite bids for the product category that includes the lead item are equal to or below the pivotal bid for that product category. We are also proposing to change the way the SPAs are calculated for the non-lead items in a product category in certain CBAs. Currently, the ratio multiplied by the SPA for the lead item to calculate the SPA for the non-lead item is based on the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item. This formula uses average fee schedule amounts rather than fee schedule amounts for specific areas, which results in cases where the SPA for a

non-lead item can be higher than the fee schedule amount that would otherwise be paid. To address this situation in CBAs other than remote item delivery CBAs, we are proposing to calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas.

Additionally, the proposed rule would revise how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS suppliers by using contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included under the CBP as well as information on current supplier utilization for new product categories.

b. Adjustments to SPAs

We are proposing to apply an annual update factor to SPAs, starting with year two of the DMEPOS CBP contracts.

c. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected

We are proposing to amend 42 CFR 414.414(f) so contracts could be awarded in a CBA if the amounts to be paid are no greater than 110 percent of the amounts that would otherwise be paid for the items. This rule clarifies that the amounts that would otherwise be paid include payment amounts adjusted in accordance with § 414.210(g). This rule also proposes to modify 42 CFR 414.412(b) to establish bid limits both for items included in the CBP for the first time and for items that have previously been included in the CBP. For items included in the CBP for the first time, the bid limits would be the amounts otherwise paid for the items. For items that have previously been included in the CBP, the bid limits would be the most recent SPA for the items plus 10 percent, or if it has been more than a year since the SPA was last in effect, the inflation-adjusted SPA plus 10 percent. However, we are proposing that in no event would the bid limit be allowed to exceed the unadjusted fee schedule amount. In addition, this rule proposes a technical correction to add reference to subpart Q ("Payment for Lymphedema Compression Treatment Items") to 42 CFR 414.414(f).

d. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

We are proposing to make payment under the DMEPOS CBP for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. We are

proposing that payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis with payments limited to the amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

e. Revising the Definition of "Item" as Related to Medical Supplies

We are proposing to revise the definition of "item" at § 414.402 to clarify that section 1847(a)(2) of the Act includes ostomy, tracheostomy, and urological supplies as "items" subject to the DMEPOS CBP. We are proposing that "medical supplies" under this section is a category of items separate from durable medical equipment that includes ostomy, tracheostomy, and urological supplies.

f. Remote Item Delivery (RID) CBP

We are proposing to create two new definitions under § 414.402 for the purpose of establishing a RID CBP(s) wherein contract suppliers would be required to furnish the items primarily on a mail order basis under the product category to all Medicare beneficiaries regardless of where they live in the CBA. While we expect that the majority of items would be furnished on a mail order basis, a RID competition would not exclude items in the product category that are furnished on a non-mail order basis. Items included in a RID CBP would be those that are typically furnished to beneficiaries from remote supplier locations that are hundreds of miles on average from the beneficiary residence where the items are delivered.

g. Revising the Submission of Financial Document Requirements for the DMEPOS CBP

We are proposing to no longer require the submission of a tax return extract, income statement, balance sheet, or statement of cash flows for the purpose of implementing the financial standards mandated by section 1847(b)(2)(A)(ii) of the Act. This proposal would reduce burden for suppliers submitting bids under the DMEPOS CBP. However, we are proposing to continue requiring suppliers to submit a credit report with a numerical credit score and/or rating from one of the four approved credit reporting agencies during the bid window, and by the CDRD if the supplier wants to be eligible for the process for reviewing covered documents. Additionally, we are proposing to continue using a five-tier

scoring system in the evaluation of the credit report with a numerical credit score and/or rating, which will be utilized to establish a financial score that will indicate if a supplier is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. We are also proposing to no longer use a supplier's financial score to assist in determining the capacity to assign to each supplier to meet projected beneficiary demand. Furthermore, we are proposing to have suppliers attest to the fact that they meet the small supplier threshold in the DMEPOS Bidding System (DBidS), or any successor system, if applicable.

h. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

Since the inception of the DMEPOS CBP, when a bidder has submitted at least one covered document by the CDRD, CMS has notified the bidder within 90 days after the CDRD if they were missing a covered document by the close of the bid window or if a covered document was missing by the CDRD. We are proposing that when a bidder has submitted at least one covered document by the CDRD, CMS will notify the bidder within 90 days after the CDRD if they have any missing covered document(s) by the close of the bid window. The supplier would have 10 days after such notification to provide the missing covered document(s).

i. Bid Surety Bond Review Process

CMS applied a bid surety bond rider process during bid evaluation for the DMEPOS CBP round in 2021, and we are now proposing to codify this process in regulation for all future rounds. Additionally, we are proposing to correct a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph redesignation in 83 FR 57072.

j. Tribal Exemption From Participating in the DMEPOS CBP

We are proposing to add an exception to the DMEPOS CBP that would allow Medicare payment to Indian Health Service (IHS) and tribally operated facilities and suppliers as noncontract suppliers to furnish competitively bid items and services to American Indian/Alaska Native (AI/AN) Medicare beneficiaries who reside in a CBA during a round of the DMEPOS CBP.

k. Addition of a Termination Clause for the DMEPOS CBP Supplier Contracts

We are proposing in § 414.422 to have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries if CMS determines that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts.

CMS is proposing in § 414.422 to have the option to remove items and services furnished in a PHE-impacted areas from the DMEPOS CBP when all of the following qualifying criteria are met: (1) the Secretary declares a PHE; (2) CMS

determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA; (3) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns.

After termination and/or modification of all applicable DMEPOS CBP supplier contracts, CMS is proposing in § 414.422 to revert back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA.

l. Technical Change to § 414.408(h)(8)

We are proposing to make a technical change to § 414.408(h)(8) so that it correctly refers to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

m. Adding Definitions of Adjusted Fee Schedule Amount, Competition, and Unadjusted Fee Schedule Amount to § 414.402

The purpose of this proposal is to add definitions of "Adjusted fee schedule amount," "Competition," and "Unadjusted fee schedule amount" to § 414.402 for the purpose of simplifying the regulation text for subpart F.

C. Summary of the Regulatory Impact Analysis

BILLING CODE 4120-01-P

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

Provision Description	Costs and Cost Savings	Transfers	Other Notes
CY 2026 HH PPS Payment Rate Update		The overall economic impact related to the changes in payments under the HH PPS for CY 2026 is estimated to be -\$1.135 billion (-6.4 percent). The \$1.135 billion decrease in estimated payments for CY 2026 reflects the effects of the CY 2026 proposed home health payment update percentage of 2.4 percent (\$425 million increase), an estimated 3.7 percent decrease* that reflects the effects of the permanent adjustment (\$655 million decrease), an estimated 4.6 percent decrease* that reflects the effects of the temporary adjustment (\$815 million decrease) and an estimated 0.5 percent decrease that reflects the effects of an updated FDL (\$90 million decrease). *The estimated 3.7 percent decrease and the estimated 4.6 percent decrease related to the proposed permanent and temporary adjustments includes all payments, while the proposed -4.059 percent and -5.0 percent adjustments are only applied to the national, standardized 30-Day period payments and does not impact payments for 30-day periods which are LUPAs.	To ensure that home health payments are consistent with statutory payment authority for CY 2026.
HH QRP	The total economic impact of these proposals including the removal of one Living Situation item, two Food items, and one Utilities item as well as the proposal to remove the patient COVID-19 vaccination item, which is proposed for implementation in CY 2026 will result in a reduction of \$17.810,282.		Remove anticipated burden related to the implementation of these items in the OASIS assessment tool.
Expanded HHV/BP Model		The overall economic impact of the expanded HHV/BP Model for CY s 2024 through 2027 is an estimated \$3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to IIHAs competing in the expanded Model. No costs expected.	
HH CoP Technical Updates			Alignment with all-payer requirements provides clarification to HHAs regarding which patients they must collect and submit OASIS information on.

Provision Description	Costs and Cost Savings	Transfers	Other Notes
Medicare and Medicaid Provider Enrollment		We anticipate average annual transfers from providers and suppliers to the Federal Government of approximately \$2.2 billion.	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.
DMEPOS Supplier Accreditation	We estimate a combined average annual cost burden to DMEPOS suppliers and DMEPOS AOs of approximately \$128.3 million.	We anticipate the following average annual transfers: + \$165.8 million in transfers from DMEPOS suppliers to DMEPOS AOs in the form of accreditation fees the suppliers pay to the AOs. + \$3.8 million in transfers from DMEPOS AOs to DMEPOS suppliers in the form of refunds if the AO's approval as a DMEPOS AO is terminated or suspended. + \$664 million in transfers from DMEPOS suppliers to the Federal government based on DMEPOS supplier revocations.	To help better ensure that: (1) DMEPOS AOs are fully qualified to conduct DMEPOS accreditation activities; and (2) all DMEPOS suppliers meet the DMEPOS quality standards.
DMEPOS Prior Authorization	The overall economic impact of the DMEPOS Prior Authorization Exemption provisions is an estimated \$2,497,392 in total savings as a result of reduced workload to the DMEPOS Medicare Administrative Contractors (\$2,243,074) and reduced supplier burden by compliant suppliers not submitting requests for prior authorization (\$254,318).		To reduce supplier burden by not requiring compliant DMEPOS suppliers to submit requests for prior authorization.
DMEPOS Competitive Bidding Program		No economic impact of this regulatory action, thus no associated transfers.	To support the ongoing cost savings and guaranteed beneficiary access offered by the previously implemented DMEPOS CBP. Also, to improve flexibility in providing beneficiaries with the most appropriate medical devices by modifying the payment category of continuous glucose monitors and insulin infusion pumps.

BILLING CODE 4120-01-C

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. Payment 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 home health agencies 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

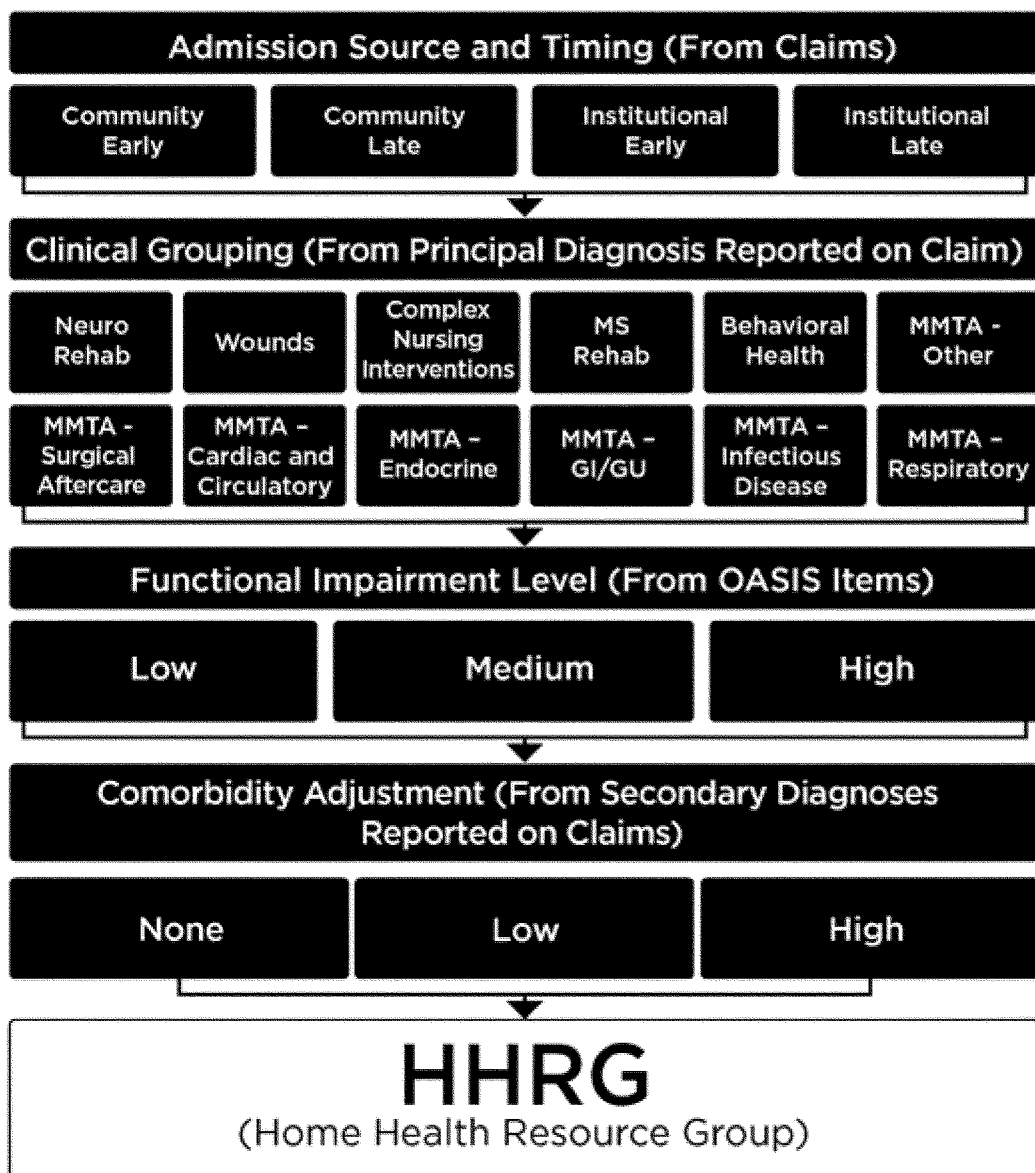
therapy thresholds, through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE20005 available at <https://www.cms.gov/regulations-and-guidance/guidancetransmittals2020-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.

BILLING CODE 4120-01-P

Figure 1: Case-Mix Variables in the PDGM



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

BILLING CODE 4120-01-C

B. Monitoring the Effects of the Implementation of the PDGM

1. Routine PDGM Monitoring

CMS routinely analyzes Medicare home health benefit utilization, including but not limited to, overall total 30-day periods of care and average periods of care per HHA user; distribution of the type of visits in a 30-day period of care; the percentage of periods that receive the LUPA; estimated costs; the percentage of 30-day periods of care by clinical group, comorbidity adjustment, admission source, timing, and functional impairment level; the proportion of 30-

day periods of care with and without any therapy visits, nursing visits, and/or aide/social worker visits, and monitoring of home health visits using telecommunications technology and remote patient monitoring. For the monitoring included in this rule, we examine simulated data for CYs 2018 and 2019 and actual data for CYs 2020, 2021, 2022, 2023, and 2024 for 30-day periods of care. We refer readers to the CY 2022 HH PPS final rule (86 FR 35881) for discussion about simulated data for CYs 2018 and 2019.

(a) Utilization

Table 2 shows the overall utilization of home health services. This data indicates the average number of 30-day

periods of care per unique HHA beneficiary is higher in CY 2024 compared to CYs 2021, 2022, and 2023. The data also indicates that the number of 30-day periods of care decreased between CY 2018 and CY 2024. Table 3 shows the average utilization of visits per 30-day period of care by home health discipline. Table 4 shows the proportion of 30-day periods of care that are LUPAs and the average number of visits per discipline of those LUPA 30-day periods of care over time. The data show a decreasing trend in the average number of visits per 30-day period and average number of visits per discipline for LUPA 30-day periods of care between CY 2018 and CY 2024.

TABLE 2: OVERALL UTILIZATION OF HOME HEALTH SERVICES, CYs 2018-2024

Volume of Periods and Number of Beneficiaries	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
30-Day Periods of Care	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120
Unique Beneficiaries	2,980,385	2,802,560	2,850,916	3,017,464	2,831,138	2,715,010	2,620,520
Average Number of 30-Day Periods per Unique Beneficiary	3.13	3.12	2.95	3.07	3.04	3.06	3.10

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health Limited Data Set (LDS). CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, partial episode payments (PEPs), and outliers).

TABLE 3: UTILIZATION OF VISITS PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE, CYs 2018-2024

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Skilled Nursing	4.53	4.49	4.35	4.05	3.90	3.87	3.84
Physical Therapy	3.30	3.33	2.70	2.74	2.77	2.77	2.73
Occupational Therapy	1.02	1.07	0.79	0.78	0.77	0.76	0.73
Speech Therapy	0.21	0.21	0.16	0.15	0.14	0.14	0.13
Home Health Aide	0.72	0.67	0.54	0.48	0.43	0.42	0.39
Social Worker	0.08	0.08	0.06	0.05	0.05	0.05	0.04
Total (all disciplines)	9.86	9.85	8.59	8.25	8.06	8.00	7.86

Source: CY 2018 and CY 2019 simulated PDGM data with behavior assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 4: THE PROPORTION OF 30-DAY PERIODS OF CARE THAT ARE LUPAs AND THE AVERAGE NUMBER OF VISITS BY HOME HEALTH DISCIPLINE FOR LUPA HOME HEALTH PERIODS, CYs 2018-2024

	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Total LUPA % of Overall 30-day Periods	6.7%	6.8%	8.7%	7.9%	7.8%	6.9%	6.9%
Discipline (Average # visits for LUPA home health periods)							
Skilled Nursing	1.15	1.14	1.19	1.12	1.08	0.99	0.99
Physical Therapy	0.43	0.46	0.53	0.55	0.60	0.51	0.52
Occupational Therapy	0.07	0.07	0.08	0.08	0.09	0.07	0.08
Speech Therapy	0.02	0.02	0.02	0.02	0.02	0.02	0.02
Home Health Aide	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Social Worker	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Total	1.69	1.71	1.84	1.79	1.81	1.61	1.63

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(b) Analysis of 2023 Cost Report Data for 30-Day Periods of Care

In the CY 2025 HH PPS proposed rule (89 FR 55320), we provided a summary of analysis on FY 2022 HHA cost report data, as this was the most recent and complete cost report data at the time of rulemaking, and CY 2023 claims to estimate 30-day period of care costs. Our analysis showed that the CY 2023 national, standardized 30-day period payment rate of \$2,010.69 was

approximately 32 percent more than the estimated CY 2023 estimated 30-day period cost of \$1,527.23.

Using this same process in this proposed rule to compare home health payment to costs, we examined 2023 HHA Medicare cost reports (CMS Form 1728–20, OMB No. 0938–0222), as this is the most recent and complete cost report data at the time of rulemaking. We also examined CY 2024 home health claims to estimate 30-day period of care

costs. We excluded LUPAs and partial payment adjustments when calculating the average number of visits. The 2023 average NRS costs per visit is \$4.58. To update the estimated 30-day period of care costs, we begin with the 2023 average costs per visit with NRS for each discipline and multiply that amount by the CY 2024 home health payment update percentage of 3.0 percent (or a home health payment update factor of 1.03). That amount for

each discipline is then multiplied by the 2024 average number of visits by discipline to determine the 2024

estimated 30-day period costs. Table 5 shows the estimated average costs for 30-day periods of care by discipline

with NRS and the total 30-day period of care costs with NRS for CY 2024.

TABLE 5: ESTIMATED AVERAGE COSTS FOR 30-DAY PERIODS OF CARE IN CY 2024

Discipline	2023 Average Cost per Visit	2024 Average Number of Visits	2024 Market Basket Update Factor	2024 Estimated 30-Day Period Costs
Skilled Nursing	\$184.60	4.05	1.03	\$770.06
Physical Therapy	\$181.18	2.90	1.03	\$541.18
Occupational Therapy	\$178.97	0.78	1.03	\$143.78
Speech Pathology	\$206.56	0.14	1.03	\$29.79
Medical Social Services	\$318.84	0.05	1.03	\$16.42
Home Health Aides	\$109.00	0.42	1.03	\$47.15
Total		8.34		\$1,548.39

Source: 2023 Medicare cost report data obtained during January 2025. Home health visit information came from 30-day periods with a through date in CY2024 (Obtained from the CCW VRDC on March 13, 2025).

Note: The average number of visits in 2024 excludes LUPAs and PEPs.

The CY 2024 national standardized 30-day period payment rate was \$2,057.35, which is approximately 33 percent more than the CY 2024 estimated 30-day period cost of \$1,548.39. Moreover, as shown in table3

in this proposed rule, HHAs have reduced visits under PDGM in CY 2024.

(c) Clinical Groupings and Comorbidities

Each 30-day period of care is grouped into one of 12 clinical groups, which describes the primary reason for which

a patient is receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on the home health claim. Table 6 shows the distribution of the 12 clinical groups over time.

TABLE 6: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY THE 12 PDGM CLINICAL GROUPS, CYs 2018-2024

Clinical Grouping	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Behavioral Health	1.7%	1.5%	2.3%	2.4%	2.3%	2.2%	2.1%
Complex	2.6%	2.5%	3.5%	3.3%	3.2%	3.1%	3.1%
MMTA – Cardiac	16.5%	16.1%	18.9%	18.5%	17.9%	17.5%	17.1%
MMTA – Endocrine	17.3%	17.4%	7.2%	6.9%	6.8%	7.0%	7.1%
MMTA – GI/GU	2.2%	2.3%	4.7%	4.7%	4.9%	5.0%	5.2%
MMTA – Infectious	2.9%	2.7%	4.8%	4.6%	4.6%	4.7%	4.8%
MMTA – Other	4.7%	4.7%	3.1%	3.6%	3.5%	3.7%	3.8%
MMTA – Respiratory	4.3%	4.1%	7.8%	8.0%	7.8%	7.2%	7.0%
MMTA – Surgical Aftercare	1.8%	1.8%	3.6%	3.4%	3.4%	3.5%	3.5%
MS Rehab	17.1%	17.3%	19.4%	19.8%	20.8%	21.2%	21.4%
Neuro	14.4%	14.5%	10.5%	10.9%	11.0%	10.9%	10.8%
Wound	14.5%	15.1%	14.2%	13.9%	13.7%	14.0%	14.0%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

Thirty-day periods of care receive a comorbidity adjustment category based on 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. We refer readers to section II.D. of this proposed rule and the CY 2020 HH PPS final rule with comment period (84 FR 60493) for further information on the comorbidity

adjustment categories. Home health 30-day periods of care can receive a low or a high comorbidity adjustment, or no comorbidity adjustment. Table 7 shows the distribution of 30-day periods of

Care by comorbidity adjustment category for all 30-day periods.

TABLE 7: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY COMORBIDITY ADJUSTMENT CATEGORY FOR 30-DAY PERIODS, CY 2018-2024

Comorbidity Adjustment	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
None	55.6%	52.0%	49.1%	49.6%	37.3%	30.7%	29.1%
Low	35.3%	38.0%	36.9%	36.8%	47.8%	52.6%	55.4%
High	9.2%	10.0%	14.0%	13.5%	14.9%	16.7%	15.4%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(d) Admission Source and Timing

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

admission are designated as institutional admissions. The institutional admission source category also includes patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted. All other 30-day periods of care would be designated as community admissions.

Thirty-day periods of care are classified as “early” or “late” depending on when they occur within a sequence of 30-day periods of care. The first 30-

day period of care is classified as early and all subsequent 30-day periods of care in the sequence (second or later) are classified as late. A subsequent 30-day period of care would not be considered early unless there is a gap of more than 60 days between the end of one previous period of care and the start of another. Information regarding the timing of a 30-day period of care comes from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is “early” or “late”. Table 8 shows the distribution of 30-day periods of care by admission source and period timing.

TABLE 8: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY ADMISSION SOURCE AND PERIOD TIMING, CYs 2018-2024

Admission Source	Period Timing	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Community	Early	13.5%	13.8%	12.4%	11.6%	11.7%	11.6%	11.5%
Community	Late	61.1%	60.9%	61.8%	63.7%	63.1%	63.1%	63.6%
Institutional	Early	18.6%	18.4%	20.0%	18.6%	19.2%	19.3%	18.8%
Institutional	Late	6.8%	6.9%	5.8%	6.1%	6.0%	6.1%	6.1%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(e) Functional Impairment Level

Each 30-day period of care is placed into one of three functional impairment levels (low, medium, or high) based on responses to certain OASIS functional items associated with grooming, bathing, dressing, ambulating, transferring, and risk for hospitalization. The specific OASIS items that are used for the functional impairment level are found in table 7 in the CY 2020 HH PPS final rule with comment period (84 FR 60490). Responses to these OASIS items

are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, “Overview of the Home Health Groupings Model” posted on the HHA web page.¹ The sum of these points results in a functional

¹ <https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-patient-driven-groupings-model>.

impairment score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. A patient’s functional impairment level remains the same for the first and second 30-day periods of care unless there is a significant change in condition that warrants an “other follow-up” assessment prior to the second 30-day

period of care. For each 30-day period of care, the Medicare claims processing system looks for occurrence code 50 on

the claim to correspond to the M0090 date of the applicable assessment. Table

9 shows the distribution of 30-day periods by functional impairment level.

TABLE 9: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY FUNCTIONAL IMPAIRMENT LEVEL. CYs 2018-2024

Functional Impairment Level	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Low	33.9%	31.9%	25.7%	23.3%	28.1%	29.8%	30.3%
Medium	34.9%	35.5%	32.7%	32.6%	33.1%	31.8%	31.8%
High	31.2%	32.6%	41.7%	44.2%	38.8%	38.4%	37.8%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(f) Therapy and Non-Therapy Visits

Beginning in CY 2020, section 1895(b)(4)(B)(ii) of the Act eliminated the use of therapy thresholds in calculating payments for CY 2020 and subsequent years. Prior to implementation of the PDGM, HHAs could receive an adjustment to payment based on the number of therapy visits provided during a 60-day episode of care. We examined the proportion of actual 30-day periods of care with and without therapy visits. To be covered as skilled therapy, the services must require the skills of a qualified therapist

(that is, PT, OT, or SLP) or qualified therapist assistant and must be reasonable and necessary for the treatment of the patient's illness or injury. As shown in table 3, we monitor the number of visits per 30-day period of care by each home health discipline. Any 30-day period of care can include both therapy and non-therapy visits. If any 30-day period of care consisted of only visits for PT, OT, or SLP, then this 30-day period of care is considered "therapy only". If any 30-day period of care consisted of only visits for skilled nursing, home health aide, or social

worker, then this 30-day period of care is considered "no therapy". If any 30-day period of care consisted of at least one therapy visit and one non-therapy, then this 30-day period of care is considered "therapy + non-therapy". Table 10 shows the proportion of 30-day periods of care with only therapy visits, at least one therapy visit and one non-therapy visit, and no therapy visits. Figure 2 shows the proportion of 30-day periods of care by the number of therapy visits (excluding zero) provided during 30-day periods of care.

BILLING CODE 4120-01-P

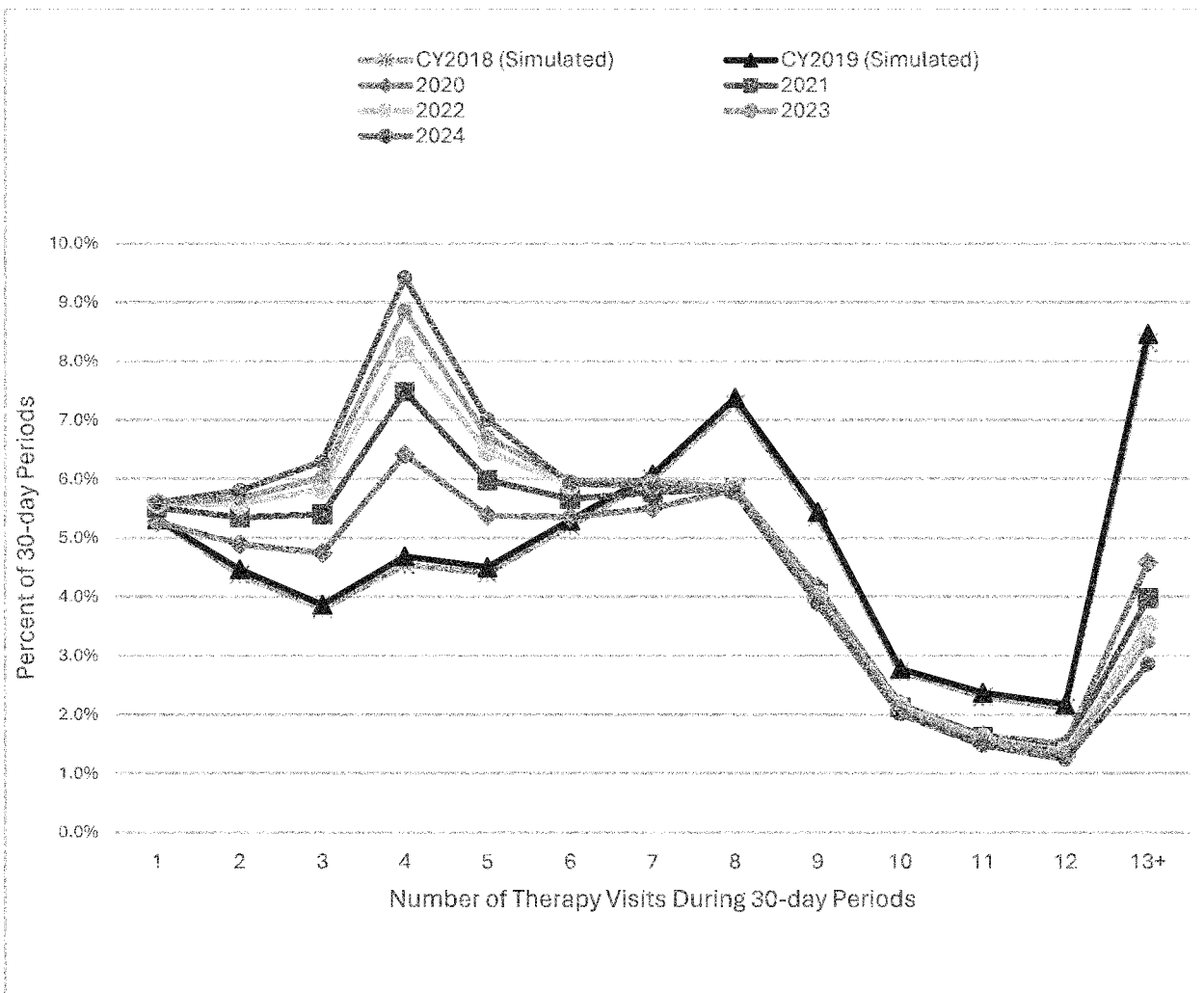
TABLE 10: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY THERAPY, AT LEAST ONE THERAPY VISIT + NON-THERAPY VISIT, AND NO THERAPY VISITS FOR CYs 2018-2024

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Therapy Only	13.5%	14.4%	15.2%	17.7%	19.3%	20.0%	20.4%
Therapy + Non-Therapy	48.2%	48.4%	42.2%	42.5%	42.7%	42.8%	42.7%
No Therapy	38.3%	37.2%	42.6%	39.8%	38.0%	37.2%	36.9%
Total 30-day periods	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on January 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

FIGURE 2: PROPORTION OF 30-DAY PERIODS OF CARE BY THE NUMBER OF THERAPY VISITS DURING 30-DAY PERIODS, CYs 2018-2024



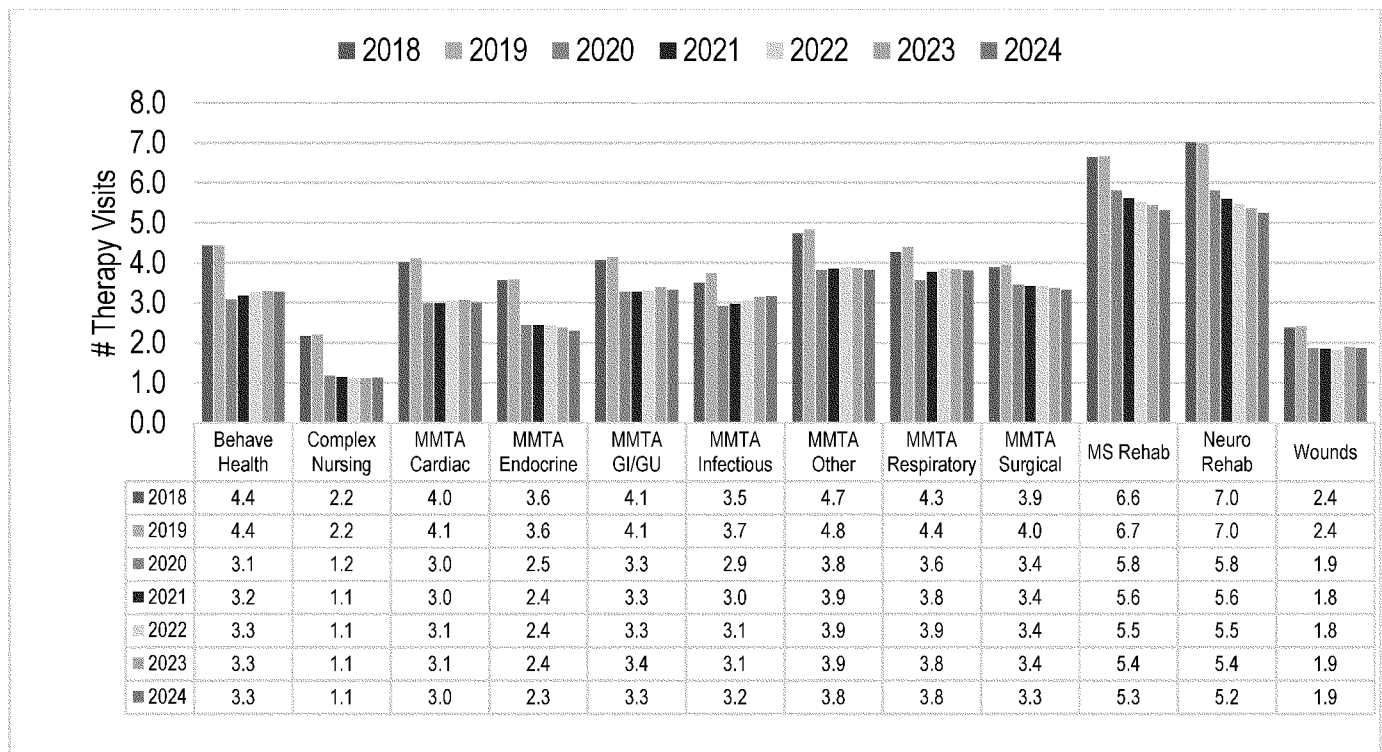
Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

Figures 2 and 3 indicate there have been changes in the distribution of both therapy and non-therapy visits in CY 2024 compared to CY 2023. For example, the proportion of 30-day

periods with one through five therapy visits during a 30-day period increased in CY 2024 compared to prior years. Comparing therapy utilization from before the PDGM (CYs 2018 and 2019)

to after the implementation of the PDGM (CYs 2020–2024), we also see an overall decline in therapy visits across all clinical groups, as shown in Figure 3.

FIGURE 3: AVERAGE THERAPY VISITS PER 30-DAY PERIOD BY CLINICAL GROUP, CYs 2018-2024

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

BILLING CODE 4120-01-C

We also examined the proportion of 30-day periods of care with and without skilled nursing, social work, or home health aide visits. Table 11 shows the

number of 30-day periods of care with only skilled nursing visits, at least one skilled nursing visit and one other visit type (therapy or non-therapy), and no

skilled nursing visits. Table 12 shows the number of 30-day periods of care with and without home health aide or social worker visits.

TABLE 11: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY SKILLED NURSING, SKILLED NURSING + OTHER VISIT TYPE, AND NO SKILLED NURSING VISITS FOR CYs 2018-2024

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Skilled Nursing Only	33.8%	33.1%	38.5%	36.2%	34.7%	34.1%	33.9%
Skilled Nursing + Other	51.6%	51.5%	45.3%	45.0%	45.0%	44.8%	44.6%
No Skilled Nursing	14.7%	15.5%	16.2%	18.8%	20.4%	21.1%	21.5%
Total 30-day periods	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 12: PROPORTION OF 30-DAY PERIODS OF CARE WITH AND WITHOUT HOME HEALTH AIDE AND/OR SOCIAL WORKER VISITS FOR CYs 2018-2024

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023	CY 2024
Any HH aide and/or social worker	16.6%	15.9%	13.2%	12.2%	11.3%	10.9%	10.3%
No HH aide and/or social worker	83.4%	84.1%	86.8%	87.8%	88.7%	89.1%	89.7%
Total 30-day periods	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,319,064	8,118,120

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on July 13, 2023. CY 2023 PDGM data was accessed from the CCW VRDC on July 11, 2024. CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

(g) Home Health Services Using Telecommunications Technology

As discussed in the CY 2023 final rule (87 FR 66858), we began collecting data on the use of telecommunications technology used during a home health period using three G-codes reported on home health claims. Collecting data on services furnished via telecommunications technology on claims allows CMS to analyze the characteristics of patients using services provided remotely. The monitoring discussion illustrates which services are most frequently furnished via telecommunication technology and generally how long remote patient monitoring is utilized.

We began collecting this information from HHAs on a voluntary basis on January 1, 2023, and have required this information to be reported on claims starting on July 1, 2023 (87 FR 66858). The three G-codes help identify when home health services are furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system (G0320); synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications systems (G0321); and the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency, that is, remote patient monitoring

(G0322). We capture the usage and length of remote patient monitoring using the start date of the remote patient monitoring and the number of days of monitoring indicated on the claim. We also looked at the disciplines most often providing remote patient monitoring. We examined the utilization of telecommunications technology devices during a home health period and remote patient monitoring by looking at home health claims that included the three G-codes. Tables 13 and 14 shows that the use of telecommunications services reported on CY 2024 home health claims are low (roughly 2 percent of all CY 2024 claims) and are mainly associated with skilled nursing.

TABLE 13: TELEHEALTH VISITS RECORDED ON HOME HEALTH CLAIMS (CY 2024)

	Claims with at Least 1 Telehealth Visit	Number of Telehealth Visits	Unique Beneficiaries with at Least 1 Telehealth Visit	Unique Providers with at Least 1 Telehealth Visit
Skilled Nursing	139,730	284,854	96,535	1,087
PT	26,362	43,189	20,950	566
OT	5,422	8,805	4,303	325
SLP	1,470	2,312	1,045	166
Aide	1	1	1	1
MSS	4,675	5,337	4,137	285

Source: CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 14: REMOTE PATIENT MONITORING DAYS RECORDED ON HOME HEALTH CLAIMS (CY 2024)

	Claims with at Least 1 Day of Remote Patient Monitoring	Number of Remote Patient Monitoring Days	Unique Beneficiaries with at Least 1 Day of Remote Patient Monitoring	Unique Providers with at Least 1 Day of Remote Patient Monitoring
Skilled Nursing	38,513	679,102	20,786	455
PT	694	11,266	535	108
OT	76	1,253	68	26
SLP	124	2,143	79	14
Aide	29	596	23	13
MSS	176	4,148	117	7

Source: CY 2024 data was accessed from the CCW VRDC on March 13, 2025.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

We will continue to monitor the provision of home health services, including any changes in the number and duration of home health visits, composition of the disciplines providing such services, telecommunications technology used during home health periods, and overall home health payments to determine if refinements to the case-mix adjustment methodology or other policies may be needed in the future.

C. Proposed CY 2026 Payment Adjustments Under the HH PPS

1. Proposed Behavior Adjustments Under the HH PPS

a. Background

As discussed in section II.A.1. of this proposed 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 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 in order 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.

Under the prior 153-group system (and the first three 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 0938-1279,² 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 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 applies 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 and the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims. Additionally, at the end of this section we provide a summary table for the permanent adjustment and temporary dollar amounts calculated for each year.

d. CY 2024 Preliminary Claims Results

We will continue the practice of using the most recent complete home health claims data available at the time of rulemaking. While the CY 2024 analysis presented in this proposed rule uses the most complete data available at the time, it is considered preliminary and, as more data become available from the

latter half of CY 2024, we would update our analysis in the final rule. The CY 2026 final rule would use the complete CY 2024 data for determining any permanent and temporary adjustments needed to the CY 2026 payment rate. However, while the claims data and the permanent and temporary adjustments results would be considered complete for CY 2026, 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 twice each year in the HH PPS LDS file, one for the proposed and one for the final. Accordingly, the HH PPS LDS file released with this proposed rule includes two files: the actual CY 2024 30-day periods and the CY 2024 simulated 60-day episodes.

We remind readers a data use agreement (DUA) is required to purchase the CY 2026 proposed 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.³ In addition, the proposed CY 2026 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH PPS Regulations and Notices web page,⁴ 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 2024 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 2024 Data To Determine the CY 2026 Permanent and Temporary Adjustments

Using the methodology finalized in the CY 2023 HH PPS final rule to apply for all the years in which an adjustment is appropriate, and described most recently in the CY 2024 HH PPS final rule (88 FR 77687 through 77688), as well as the two new assumptions related to the OASIS-E mapping in the CY 2025 HH PPS final rule (89 FR 88360 through 88365), we simulated 60-day episodes using actual CY 2024 30-day periods to

³ https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.

⁴ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices>.

² The current expiration date for this information collection request is December 31, 2027.

determine what the proposed 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.

Using the preliminary CY 2024 dataset, we began with 8,118,120 30-day periods of care and dropped 446,458 30-day periods of care that had a claim occurrence code 50 date after October 31, 2024. We also excluded 842,735 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 4,017 30-day periods were excluded.

Additionally, we excluded 211,772 simulated 60-day episodes, which consist of 391,799 30-day periods 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. Our simulated 60-day

episodes of care produced a distribution of two 30-day periods of care (69.5 percent) and single 30-day periods of care (30.5 percent) that was similar to what we found when we simulated two 30-day periods of care for implementation of the PDGM. After all exclusions and assumptions were applied, the final dataset for this proposed rule included 6,433,111 actual 30-day periods of care and 3,794,744 simulated 60-day episodes of care for CY 2024.

Using the preliminary dataset for CY 2024 (6,433,111 actual 30-day periods which made up the 3,794,744 simulated 60-day episodes) we determined the estimated aggregate expenditures under the pre-PDGM HH PPS were lower than the actual estimated aggregate expenditures under the PDGM HH PPS. As shown in table 15, aggregate expenditures under the PDGM were higher than if the 153-group payment system were still in place in CY 2024 and therefore, we determined the CY 2024 30-day base payment rate should have been \$1,916.77 based on actual behavior changes.

As stated in the CY 2025 HH PPS final rule (89 FR 88367) we determined for CYs 2020 through CY 2023 a total of – 3.95 percent permanent adjustment was needed (after accounting for the – 3.925 percent applied to the CY 2023 payment rate and the – 2.890 applied to the CY 2024 payment rate). In order to determine behavior changes only to CY

2024, we simulated what the CY 2024 base payment rate would have been if the – 3.95 percent adjustment that we determined using CY 2023 claims data had been implemented.

To do so, we started with the recalculated CY 2023 base payment of \$1,875.46 (as published in the CY 2025 HH PPS final rule (89 FR 88366)) and applied the CY 2024 case-mix weights recalibration neutrality factor (1.0124), the CY 2024 wage index budget neutrality factor (1.0012), the CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030). We determined the CY 2024 base payment rate for assumed behavior would have been \$1,957.63.

For the CY 2024 annual permanent adjustment, we calculated the percent change between the two payment rates for only CY 2024. For the CY 2024 annual temporary adjustment we calculated the difference in aggregate expenditures in dollars for all CY 2024 PDGM 30-day claims using the two payment rates. This difference is shown as the retrospective dollar amount we will need to offset payment using one or more temporary adjustments in future years. Our results for the CY 2024 annual (single year) permanent and temporary adjustment calculations using CY 2024 preliminary claims data is shown in table 15.

TABLE 15: CY 2024 PROPOSED PERMANENT AND TEMPORARY ADJUSTMENT CALCULATIONS

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	CY 2024 Only Adjustment
Base Payment Rate	\$1,957.63*	\$1,916.77	Permanent –2.087%
Aggregate Expenditures	\$16,237,950,874**	\$15,397,801,406	Temporary –\$840,149,468

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.

*The \$1,957.63 (shown in table 15) is equal to the recalculated budget neutral 30-day base payment rate of \$1,875.46 for CY 2023 multiplied by the CY 2024 recalibration factor (1.0124), CY 2024 wage index budget neutrality factor (1.0012), CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030).

**The estimated aggregate expenditures for assumed behavior (\$16.2 billion), uses the actual CY 2024 payment rate of \$2,038.13 as finalized in the CY 2024 HHA PPS final rule (88 FR 77746).

As shown in table 15, a permanent prospective adjustment of – 2.087 percent to the CY 2026 30-day payment rate (assuming all adjustments from prior years were applied) for CY 2024 would be required to offset for such increases in estimated aggregate expenditures in future years. We remind

readers, the permanent prospective adjustment of – 2.087 percent is for illustrative purposes only and the annual (single year) permanent adjustment cannot be added to previous annual adjustments.

As shown in table 15, we determined that our initial estimate of the CY 2024

base payment rate (\$2,038.13) resulted in excess expenditures of approximately \$840 million in CY 2024.

Section 1895(b)(3)(D)(ii) of the Act requires us to annually analyze data from CY 2020 through CY 2026. We now have five years of claims data (CYs 2020 through 2024) under the PDGM,

and we have applied three partial permanent adjustments to the 30-day payment rate (CYs 2023 through 2025), which we summarize in table 16. We remind readers these annual adjustments cannot be added or

multiplied together to determine the total permanent adjustment needed for CY 2026 because each individual year requires an assumption that all prior adjustments were taken. We remind readers that equation may result in

slightly different results due to the underlying assumptions (for example, all prior year adjustments were taken) each year and rounding.

TABLE 16: TOTAL ANNUAL PERMANENT ADJUSTMENT FOR DISCRETE CLAIMS IN CYs 2020 - 2024

Claims Data	Annual Permanent Adjustment	HH PPS Final Rule Citation
CY 2020	-6.52%	87 FR 66805
CY 2021	-1.42%	87 FR 66806
CY 2022	-1.767%	88 FR 77692
CY 2023	-1.004%	89 FR 88366
CY 2024	-2.087%	TBD

Note: These annual permanent adjustments are for illustrative purposes only and are not what was implemented.

f. CY 2026 Proposed Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we describe how we annually analyzed CY 2024 preliminary claims data to determine the effects of actual behavior change on estimated aggregate expenditures. Again, that analysis included simulations that assumed the full – 3.95 percent payment adjustment was already taken. We note that CMS implemented a payment adjustment of – 1.975 percent for CY 2024, 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 are still needed.

Therefore, the calculation in this section includes any of the remaining adjustments not applied in previous years (that is, CYs 2020 through 2023 claims data), as well as the adjustment needed to account for CY 2024 claims. In calculating the full permanent adjustment needed to the CY 2026 30-day payment rate, we compare estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 16, we do not assume the full adjustment from prior years had been taken.

As discussed in section II.C.1.d. of this proposed rule, using the preliminary dataset for CY 2024 (6,433,111 actual 30-day periods which

made up the 3,794,744 simulated 60-day episodes) we determined the CY 2024 30-day base payment rate should have been \$1,916.77 based on actual behavior. We then compared the \$1,916.77 CY 30-day base payment rate based on actual behavior to the CY 2024 30-day base payment rate of \$2,038.13 we paid based on assumed behaviors. The percent change, as summarized in table 17, between the actual CY 2024 base payment rate of \$2,038.13 (based on assumed behaviors) and the CY 2024 recalculated base payment rate of \$1,916.77 (based on actual behaviors) is the total permanent adjustment reflecting CYs 2020 through 2024 claims.

TABLE 17: TOTAL PERMANENT ADJUSTMENT FOR CYs 2020 THROUGH 2024 CLAIMS

Actual CY 2024 Base Payment Rate (Assumed Behavior)	Recalculated CY 2024 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
\$2,038.13	\$1,916.77	-5.954%*

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.
*This is the total permanent adjustment based on CY 2024 data which includes the previous permanent adjustment of -2.89% applied. However, as described later, we recognize that for CY 2026 we must also account for adjustment made in CY 2025.

As shown in table 17 a permanent prospective adjustment of – 5.954 percent to the CY 2026 30-day payment

rate would be required to offset for such increases in estimated aggregate

expenditures in future years. To illustrate this calculation:

$$\frac{(\$1,916.77 - \$2,038.13)}{\$2,038.13} = -5.954 \%$$

As we stated in the CY 2025 HH PPS final rule (89 FR 88373), 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 2024 claims data, as shown in table 17, a permanent prospective adjustment of –5.954 percent to the CY 2026 30-day payment rate would be required to offset for such increases in estimated aggregate expenditures for CYs 2020 through 2024. We remind readers 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 CY 2026 proposed permanent adjustment, which would include estimated aggregate expenditures in CY 2024, by simply subtracting the –1.975 percent applied in CY 2025 from the total permanent

adjustment of –5.954 percent as shown in table 17.

Instead, we account for the permanent adjustment applied in CY 2025 of –1.975 percent when we calculate the CY 2026 permanent adjustment by solving the following equation $(1 - 0.01975) \times (1 \times -) = (1 - 0.05954)$. To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1 - 0.05954}{1 - 0.01975} \right)$$

$$x = 1 - 0.95941$$

$$x = 0.04059 \text{ (that is, 4.059 percent)}$$

Accounting for the previous permanent adjustments applied to the 30-day payment rate in CYs 2023, 2024, and 2025, we can simulate the permanent adjustment calculation with the simulated annual permanent adjustment percentage shown previously for CY 2026:

Annual Permanent Adjustments

Calculated:⁵

CY 2020 Claims = –6.52% (87 FR 66805)

CY 2021 Claims = –1.42% (87 FR 66806)

CY 2022 Claims = –1.767% (88 FR 77692)

CY 2023 Claims = –1.004% (89 FR 88366)

CY 2024 Claims = –2.087% (Table 16)

Permanent Adjustments Applied:

CY 2023 Rate = –3.925% (88 FR 66808)

CY 2024 Rate = –2.890% (88 FR 77697)

CY 2025 Rate = –1.975% (89 FR 88373)

Illustrative equation.

$$(1 - 0.0652)(1 - 0.0142)(1 - 0.01767)$$

$$(1 - 0.01004)(1 - 0.02087) =$$

$$(1 - 0.03925)(1 - 0.0289)$$

$$(1 - 0.01975)(1 - x)$$

Solving, $x = 4.059\%$.

In table 18, we provide the base payment rate for assumed behaviors (what CMS actually paid), the recalculated base payment rate for actual behaviors (what CMS should have paid), the total permanent adjustments calculated from the base payment rates (accounts for any adjustments taken prior), and the permanent adjustment applied.

**TABLE 18: SUMMARY OF PERMANENT ADJUSTMENTS
FOR CYs 2020 – 2026**

Claims Analysis Year	Base Payment Rate for Assumed Behaviors (Actual Amount Paid to HHAs in the Claims Analysis Year)	Base Payment Rate that Reflects Actual Behavior Changes (As Determined After Later Claims Analysis)	Total Permanent Adjustment Between Assumed and Actual Behavior Rates*	Permanent Adjustment CMS Finalized and Implemented in Rulemaking
CY 2020	\$1,864.03	\$1,742.52	-6.52%	n/a
CY 2021	\$1,901.12	\$1,751.90	-7.85%	-3.925% (88 FR 66808)
CY 2022	\$2,031.64	\$1,839.10	-5.78%	-2.890% (88 FR 77697)
CY 2023	\$2,010.69	\$1,873.17	-3.95%	-1.975% (89 FR 88373)
CY 2024	\$2,038.13	\$1,916.77	Proposed -4.059%	-4.059% proposed to be applied to CY 2026 rates
CY 2025	TBD	TBD	TBD	TBD
CY 2026	TBD	TBD	TBD	TBD

Note: With the prospective payment systems, the claims data analyzed differ from the rulemaking cycle. For example, CY 2020 claims are used in CY 2022 rulemaking.

*The total permanent adjustment accounts for prior adjustments that were finalized and implemented through rulemaking.

In the CY 2023, 2024, and 2025 HH PPS final rules (87 FR 66790, 88 FR 77696, 89 FR 88373), we acknowledged that the full permanent adjustment in a single year may be burdensome for some providers. As shown in table 18, we finalized only half of the permanent adjustment percentages in CYs 2023

through 2025 final rules. However, we explained in the CY 2023, 2024, and 2025 HH PPS final rules (87 FR 66808, 88 FR 77697, 89 FR 88373) that when we apply a reduced permanent adjustment, we may need to continue to implement a reduction in future years to satisfy the statutory requirements.

However, we recognize that only applying half of the calculated permanent adjustments in previous years has contributed to the significant growth of the temporary adjustment. Therefore, we believe it to be appropriate to propose the full permanent adjustment to help mitigate

⁵ The annual permanent adjustments are for illustrative purposes only and the annual (single

year) permanent adjustments cannot be combined

to calculate the total permanent adjustment proposed and finalized in rulemaking.

this continued accrual of the temporary adjustment. Therefore, we are proposing to apply the full permanent adjustment of –4.059 percent to the CY 2026 home health base payment rate, noting that we expect to make minor adjustments to this percentage in the final rule using more complete claims data. Proposing the full permanent adjustment would satisfy the statutory requirements at section 1895(b)(3)(D)(ii) of the Act to offset any increases or decreases on the impact of differences between assumed behavior and actual behavior changes on estimated aggregate expenditures, reduce the need for any future large permanent adjustments, and help slow

the accrual of the temporary payment adjustment amount.

As described previously in this proposed 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 2020 to 2026, we calculate one or more temporary prospective adjustments 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 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims, and section II.C.1.d. of this proposed rule for the analysis of CY 2024 claims. Table 19 provides a summary of the temporary adjustment dollar amount for CYs 2020 through 2026.

TABLE 19: 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	- \$971,431,113
CY 2024 – this proposed rule	- \$840,149,468
CY 2025	TBD
CY 2026	TBD
Total (through CY 2024)	-\$5,301,103,945

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed on the CCW July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on CCW July 15, 2023. CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on CCW July 11, 2024. CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on CCW March 13, 2025.

Note: The anticipated temporary adjustments of approximately \$5.3 billion (through CY 2024) 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.

Our analysis continues to show estimated aggregate expenditures are higher under the PDGM than if those same claims were paid under the prior 153-group system, though the data also show that the behavioral adjustment we implemented in CY 2023 and CY 2024 successfully brought estimated aggregate expenditures closer to the statutorily required budget neutrality. In the CY 2022 HH PPS proposed rule (86 FR 65884), the CY 2023 HH PPS proposed rule (87 FR 37608), the CY 2024 HH PPS proposed rule (88 FR 43664), the CY 2025 HH PPS proposed rule (89 FR 55320), and as shown in section II.B.1.b. of this proposed rule, our analysis has shown that the annual national standardized 30-day period payment rate has exceeded the average estimated

30-day period cost. In addition, MedPAC has continued to find that FFS Medicare’s payments for home health care are substantially in excess of costs.⁶

Given these facts, we believe that it is an appropriate time to begin recoupment of the temporary dollar amounts. Even though we have not yet calculated the temporary dollar amounts for CYs 2025 through 2026, we have done so for CYs 2020 through 2024, and the amounts are substantial. Beginning to adjust the base payment rate now to account for the calculated temporary dollar amount to date may help reduce the need for a larger reduction in future years. We estimate that collecting the

full temporary dollar amount of \$5,301,103,945 in a single year (as shown in table 19) would require an approximate 34 percent reduction to the CY 2026 base payment rate. And we anticipate that we would need to make additional adjustments for CYs 2025 and 2026, once data for those years are available.

We have stated in past rules that implementing both the permanent and temporary adjustments in the same year may be burdensome to HHAs; however, we propose only to implement a small temporary adjustment (rather than the estimated 34 percent) along with the permanent adjustment, which should lessen any hardship to HHAs, as well as reduce larger temporary adjustments in future years. Beginning to apply a

⁶ https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch7_MedPAC_Report_To_Congress_SEC.pdf.

temporary adjustment in CY 2026 balances the underlying statutory goal of budget neutrality against any hardship to HHAs.

Therefore, 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 2024. Specifically, we propose to implement a 5.0 percent reduction in CY 2026, that is equivalent to a 0.9500 temporary adjustment factor, to the CY 2026 national, standardized payment rate. Using historical trends, we estimated 7,723,632 number of 30-day periods would occur in CY 2026. Using this estimated utilization, a 5.0 percent reduction to the CY 2026 30-day payment rate would begin to collect approximately \$786 million of the total temporary adjustment dollar amount, equating to about 14.8 percent of the total \$5.3 billion shown in table 19. In doing so, however, we would need to account for the remaining temporary adjustment dollar amount for CYs 2020 through 2024, plus any possible adjustments for CY 2025 and 2026, in future years. It is important to note that the estimated \$786 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 2026. 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 2026 differ from what was estimated. In other words, CMS will calculate the actual amount collected from the temporary adjustment in CY 2026 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. We interpret this to mean we would not include the –5.0 percent temporary adjustment applied for CY 2026 when calculating the CY 2027 base payment rates. However, to continue recoupment of the retrospective overpayments we may propose additional temporary adjustments in future rulemaking and are not proposing that the –5.0 percent temporary adjustment would be applied each year after CY 2026. Rather, 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 refer

readers to section II.E.3.b. for the CY 2026 base payment rates with and without the temporary adjustment.

We solicit comments on the proposals to apply the permanent adjustment of –4.059 percent and the –5.0 percent temporary adjustment to the CY 2026 home health base payment rate.

D. Proposed CY 2026 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights

1. Proposed CY 2026 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain numerical minimum 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 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 would 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 would be made using the per-visit payment amounts as described in section II.E.3.c. of this proposed 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 would maintain the LUPA thresholds that were finalized and shown in table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. 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 public health emergency (PHE) will have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the 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 pre-PDGM data. Therefore, we finalized a policy to update the LUPA thresholds for CY 2024 using data from CY 2022.

For CY 2026, we are proposing to update the LUPA thresholds using CY 2024 home health claims utilization data (as of March 13, 2025), 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 2024 home health claims utilization data, we determined that LUPA visit patterns in 2024 were similar to visits in 2023 and a total of 15 case-mix groups have a decline in their LUPA threshold of a single visit and 4 case-mix groups have their LUPA threshold increase by a single visit. The proposed LUPA thresholds for the CY 2026 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in table 25.

We are soliciting public comments on the proposed updates to the LUPA thresholds for CY 2026. The proposed LUPA thresholds will be updated based on more complete CY 2024 claims data in the final rule.

2. Proposed CY 2026 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 2026, we are proposing to use CY 2024 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>, provides a more detailed explanation as to the construction of the functional impairment levels using the OASIS items. We are proposing to use the same methodology previously finalized to update the functional impairment levels for CY 2026. The proposed updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2026 are listed in tables 20 and 21, respectively.

BILLING CODE 4120–01–P

TABLE 20: PROPOSED OASIS POINTS TABLE FOR CY 2026

	Responses	CY 2026 Proposed Points	Percent of Periods with this Response Category*
M1800: Grooming	0 or 1	0	23.2%
	2 or 3	3	76.8%
M1810: Current Ability to Dress Upper Body	0 or 1	0	17.6%
	2 or 3	5	82.4%
M1820: Current Ability to Dress Lower Body	0 or 1	0	8.5%
	2	4	64.2%
	3	12	27.3%
M1830: Bathing	0 or 1	0	2.2%
	2	2	9.3%
	3 or 4	10	48.7%
	5 or 6	17	39.8%
M1840: Toilet Transferring	0 or 1	0	59.4%
	2, 3 or 4	6	40.6%
M1850: Transferring	0	0	1.0%
	1	1	17.2%
	2, 3, 4 or 5	4	81.8%
M1860: Ambulation/Locomotion	0 or 1	0	2.8%
	2	5	13.0%
	3	1	66.3%
	4, 5 or 6	20	17.8%
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	56.4%
	Four or more items marked (Excluding responses 8, 9 or 10)	12	43.6%

Source: Percent of periods in 2024 with this response category using CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on March 13, 2025.

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.

TABLE 21: PROPOSED THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, FOR CY 2026

Clinical Group	Level of Impairment	CY 2026 Proposed Points
MMTA – Other	Low	0-30
	Medium	31-45
	High	46+
Behavioral Health	Low	0-31
	Medium	32-46
	High	47+
Complex Nursing Interventions	Low	0-31
	Medium	32-54
	High	55+
Musculoskeletal Rehabilitation	Low	0-31
	Medium	32-45
	High	46+
Neuro Rehabilitation	Low	0-34
	Medium	35-52
	High	53+
Wound	Low	0-33
	Medium	34-52
	High	53+
MMTA - Surgical Aftercare	Low	0-30
	Medium	31-42
	High	43+
MMTA - Cardiac and Circulatory	Low	0-28
	Medium	29-43
	High	44+
MMTA - Endocrine	Low	0-27
	Medium	28-41
	High	42+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-34
	Medium	35-48
	High	49+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-32
	Medium	33-46
	High	47+
MMTA - Respiratory	Low	0-33
	Medium	34-46
	High	47+

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on March 13, 2025.

BILLING CODE 4120-01-C

We are soliciting public comments on the proposed updates to functional points and the functional impairment levels by clinical group.

3. Proposed CY 2026 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 2026, we are proposing to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2024 home health data with linked OASIS data (as of March 13, 2025).

For CY 2026, we are proposing to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups and 100 high comorbidity adjustment interaction subgroups. The proposed CY 2026 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity

adjustments are shown in tables 22 and 23. The proposed CY 2026 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/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center>.

We invite comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2026.

TABLE 22: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2026

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 10	Varicose Veins and Lymphedema
Circulatory 9	Other Venous Embolism and Thrombosis
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Gastrointestinal 2	Intestinal Obstruction and Ileus
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Heart 5	Atherosclerotic Heart Disease with Angina
Musculoskeletal 1	Lupus
Neoplasms 1	Malignant Neoplasms of Lip, Oral Cavity and Pharynx, includes Head and Neck Cancers
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
Neoplasms 6	Malignant neoplasms of trachea, bronchus, lung, and mediastinum
Neurological 10	Diabetes with neuropathy
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
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 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.

TABLE 23: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2026

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
1	Heart 12	Other Heart Diseases	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
2	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
3	Heart 11	Heart Failure	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
4	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Endocrine 1	Hypothyroidism
5	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
6	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Circulatory 9	Other Venous Embolism and Thrombosis
7	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Circulatory 10	Varicose Veins and Lymphedema
8	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
9	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
10	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
		Atherosclerosis and Stroke Sequelae		
11	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 12	Other Heart Diseases
12	Circulatory 9	Other Venous Embolism and Thrombosis	Musculoskeletal 4	Lumbar Spinal Stenosis
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure
14	Circulatory 9	Other Venous Embolism and Thrombosis	Heart 11	Heart Failure
15	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 10	Diabetes with neuropathy
16	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Infectious 1	C-diff, MRSA, E-coli
17	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
18	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
19	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Respiratory 2	Whooping cough
20	Circulatory 10	Varicose Veins and Lymphedema	Heart 9	Valve Disorders
21	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with neuropathy

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
22	Renal 1	Chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
23	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
24	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
25	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
26	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
27	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
28	Neurological 12	Nondiabetic neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
29	Heart 11	Heart Failure	Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
30	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
31	Endocrine 1	Hypothyroidism	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
32	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
33	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 10	Varicose Veins and Lymphedema	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
35	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Circulatory 10	Varicose Veins and Lymphedema
36	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
37	Circulatory 10	Varicose Veins and Lymphedema	Renal 1	Chronic kidney disease and ESRD
38	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
39	Heart 7	Chronic Ischemic Heart Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
40	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
41	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
42	Infectious 1	C-diff, MRSA, E-coli	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
43	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
44	Neurological 4	Alzheimer's disease and related dementias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
45	Heart 11	Heart Failure	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
46	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
48	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
49	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 4	Lumbar Spinal Stenosis

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
50	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease
51	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers
52	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
53	Infectious 1	C-diff, MRSA, E-coli	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
54	Circulatory 10	Varicose Veins and Lymphedema	Heart 8	Other Pulmonary Heart Diseases
55	Circulatory 10	Varicose Veins and Lymphedema	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
56	Circulatory 10	Varicose Veins and Lymphedema	Neurological 10	Diabetes with neuropathy
57	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
58	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
59	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
60	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers
61	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers
62	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of arteries, arterioles and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
63	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
64	Neurological 10	Diabetes with neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
65	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
66	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
67	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
68	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
69	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
70	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
71	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
72	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
73	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
74	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
75	Respiratory 9	Respiratory Failure and Atelectasis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
76	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
77	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
78	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
79	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
80	Circulatory 10	Varicose Veins and Lymphedema	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
81	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
82	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
83	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
84	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
85	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
86	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
87	Musculoskeletal 3	Joint Pain	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
88	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
89	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
90	Respiratory 2	Whooping cough	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
91	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
92	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
93	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
94	Heart 8	Other Pulmonary Heart Diseases	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
95	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
96	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
97	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
98	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
99	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
100	Circulatory 9	Other Venous Embolism and Thrombosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2024 Home Health Claims Data. Periods that end in CY 2024 accessed from the CCW March 13, 2025.

BILLING CODE 4120-01-C

4. Proposed CY 2026 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 2026 case-mix weights, we used CY 2024 home health claims data with linked OASIS data (as of March 13, 2025). These data are the most current and complete data available at the time of rulemaking. We believe that recalibrating the case-mix weights using data from CY 2024 would be reflective of PDGM utilization and patient resource use for CY 2026. The proposed recalibrated case-mix weights will be updated in the final rule based on more complete CY 2024 claims data.

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 20 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 2023 home health cost reports. We use 2023 home health cost report data because it is the most complete cost report data available at the time of rulemaking. Other variables in the regression model include the 30-day period's admission source, clinical

group, and 30-day period timing. We also include 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 24 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

BILLING CODE 4120-01-P

TABLE 24: 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	\$153.42	1.4%	0.0891
MMTA - Other - High Functional	\$324.11	1.2%	0.1882
MMTA - Surgical Aftercare - Low Functional	-\$12.86	1.2%	-0.0075
MMTA - Surgical Aftercare - Medium Functional	\$165.33	1.2%	0.0960
MMTA - Surgical Aftercare - High Functional	\$401.81	1.2%	0.2333
MMTA - Cardiac and Circulatory - Low Functional	-\$28.68	5.9%	-0.0167
MMTA - Cardiac and Circulatory - Medium Functional	\$140.40	5.7%	0.0815
MMTA - Cardiac and Circulatory - High Functional	\$325.38	5.9%	0.1890
MMTA - Endocrine - Low Functional	\$475.82	2.5%	0.2763
MMTA - Endocrine - Medium Functional	\$555.34	2.2%	0.3225
MMTA - Endocrine - High Functional	\$689.56	2.4%	0.4004
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-\$39.79	1.8%	-0.0231
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	\$144.40	1.6%	0.0839
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	\$328.62	1.7%	0.1908
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	\$2.03	1.6%	0.0012
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	\$156.15	1.7%	0.0907
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	\$414.03	1.4%	0.2404
MMTA - Respiratory - Low Functional	-\$14.23	2.5%	-0.0083
MMTA - Respiratory - Medium Functional	\$161.84	2.4%	0.0940
MMTA - Respiratory - High Functional	\$346.62	2.2%	0.2013
Behavioral Health - Low Functional	-\$74.73	0.7%	-0.0434
Behavioral Health - Medium Functional	\$149.33	0.8%	0.0867
Behavioral Health - High Functional	\$286.04	0.7%	0.1661
Complex - Low Functional	-\$33.61	0.9%	-0.0195
Complex - Medium Functional	\$212.24	0.9%	0.1233
Complex - High Functional	\$155.09	0.9%	0.0901
MS Rehab - Low Functional	\$42.96	7.3%	0.0250
MS Rehab - Medium Functional	\$192.90	7.2%	0.1120
MS Rehab - High Functional	\$423.58	6.8%	0.2460
Neuro - Low Functional	\$199.08	3.7%	0.1156
Neuro - Medium Functional	\$381.90	3.8%	0.2218
Neuro - High Functional	\$622.08	3.4%	0.3613
Wound - Low Functional	\$730.62	4.9%	0.4243
Wound - Medium Functional	\$870.17	4.5%	0.5053
Wound - High Functional	\$1,100.15	4.6%	0.6389
Admission Source with Timing (Community Early is excluded)			
Community - Late	-\$578.23	64.0%	-0.3358

Institutional – Early		\$355.47	18.6%	0.2064
Institutional – Late		\$234.11	6.1%	0.1359
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)				
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list		\$97.67	39.3%	0.0567
Comorbidity Adjustment - Has at least one interaction from interaction list		\$332.68	18.8%	0.1932
Constant		\$1,585.49		
Average Resource Use		\$1,722.00		
Number of 30-day Periods		7,430,908		
Adjusted R-Squared		0.3089		

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW March 13, 2025.

The proposed case-mix weights for CY 2026 are listed in table 25 and will also be posted on the HHA Center web

page⁷ upon display of this proposed rule.

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

TABLE 25: 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 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.0868	4
1FC21	Behavioral Health - High	Early - Community	1	1.1436	4
1FC31	Behavioral Health - High	Early - Community	2	1.2800	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.2933	4
2FC21	Behavioral Health - High	Early - Institutional	1	1.3500	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.4865	4
3FC11	Behavioral Health - High	Late - Community	0	0.7510	2
3FC21	Behavioral Health - High	Late - Community	1	0.8078	2
3FC31	Behavioral Health - High	Late - Community	2	0.9442	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.2228	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2795	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4160	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8773	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9340	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0705	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0838	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1405	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2769	2
3FA11	Behavioral Health - Low	Late - Community	0	0.5415	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5983	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7347	2
4FA11	Behavioral Health - Low	Late - Institutional	0	1.0133	3
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0700	3
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2065	2
1FB11	Behavioral Health - Medium	Early - Community	0	1.0074	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0642	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2006	4
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2139	3
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2706	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4071	4
3FB11	Behavioral Health - Medium	Late - Community	0	0.6717	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.7284	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3FB31	Behavioral Health - Medium	Late - Community	2	0.8649	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1434	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.2001	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3366	4
1DC11	Complex - High	Early - Community	0	1.0108	2
1DC21	Complex - High	Early - Community	1	1.0675	2
1DC31	Complex - High	Early - Community	2	1.2040	2
2DC11	Complex - High	Early - Institutional	0	1.2172	3
2DC21	Complex - High	Early - Institutional	1	1.2739	3
2DC31	Complex - High	Early - Institutional	2	1.4104	3
3DC11	Complex - High	Late - Community	0	0.6750	2
3DC21	Complex - High	Late - Community	1	0.7317	2
3DC31	Complex - High	Late - Community	2	0.8682	2
4DC11	Complex - High	Late - Institutional	0	1.1467	2
4DC21	Complex - High	Late - Institutional	1	1.2035	2
4DC31	Complex - High	Late - Institutional	2	1.3399	2
1DA11	Complex - Low	Early - Community	0	0.9012	2
1DA21	Complex - Low	Early - Community	1	0.9579	2
1DA31	Complex - Low	Early - Community	2	1.0944	2
2DA11	Complex - Low	Early - Institutional	0	1.1076	3
2DA21	Complex - Low	Early - Institutional	1	1.1644	3
2DA31	Complex - Low	Early - Institutional	2	1.3008	3
3DA11	Complex - Low	Late - Community	0	0.5654	2
3DA21	Complex - Low	Late - Community	1	0.6221	2
3DA31	Complex - Low	Late - Community	2	0.7586	2
4DA11	Complex - Low	Late - Institutional	0	1.0372	2
4DA21	Complex - Low	Late - Institutional	1	1.0939	2
4DA31	Complex - Low	Late - Institutional	2	1.2304	3
1DB11	Complex - Medium	Early - Community	0	1.0440	2
1DB21	Complex - Medium	Early - Community	1	1.1007	2
1DB31	Complex - Medium	Early - Community	2	1.2372	2
2DB11	Complex - Medium	Early - Institutional	0	1.2504	3
2DB21	Complex - Medium	Early - Institutional	1	1.3071	3
2DB31	Complex - Medium	Early - Institutional	2	1.4436	3
3DB11	Complex - Medium	Late - Community	0	0.7082	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3DB21	Complex - Medium	Late - Community	1	0.7649	2
3DB31	Complex - Medium	Late - Community	2	0.9014	2
4DB11	Complex - Medium	Late - Institutional	0	1.1799	3
4DB21	Complex - Medium	Late - Institutional	1	1.2366	3
4DB31	Complex - Medium	Late - Institutional	2	1.3731	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1097	4
1HC21	MMTA - Cardiac - High	Early - Community	1	1.1664	4
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3029	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3161	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3728	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5093	4
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7739	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8306	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9671	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2456	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3024	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4388	3
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9041	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9608	3
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.0973	4
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1105	4
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1672	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3037	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5683	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6250	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7615	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0400	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.0967	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2332	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.0023	4
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0590	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.1955	4
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2087	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.2654	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4019	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6665	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7232	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8597	2
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1382	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.1949	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3314	4
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3212	4
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3779	4
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5144	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5276	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.5843	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7208	4
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9854	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0421	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1786	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4571	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5138	4
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6503	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1970	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2538	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3902	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.4035	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4602	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.5967	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.8613	3
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.9180	3
3IA31	MMTA - Endocrine - Low	Late - Community	2	1.0544	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.3330	3
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3897	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.5262	3
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2432	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.2999	5
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4364	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4497	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5064	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6428	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.9074	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9642	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.1006	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3792	4
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4359	4
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.5724	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1116	3
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1683	3
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3048	2
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3180	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.3747	3
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5112	3
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7758	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8325	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9690	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2475	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.3042	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4407	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8976	2
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9543	2
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.0908	3
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1040	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1608	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.2972	3
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5618	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.6185	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7550	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0336	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0903	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2268	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0046	3
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0613	3
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.1978	3
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2110	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.2677	3
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4042	4
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6688	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7255	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8620	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1405	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.1972	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3337	3
1KC11	MMTA - Infectious - High	Early - Community	0	1.1612	2
1KC21	MMTA - Infectious - High	Early - Community	1	1.2179	2
1KC31	MMTA - Infectious - High	Early - Community	2	1.3544	2
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3676	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4243	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5608	3
3KC11	MMTA - Infectious - High	Late - Community	0	0.8254	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8821	2
3KC31	MMTA - Infectious - High	Late - Community	2	1.0186	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2971	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3538	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4903	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9219	2
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9786	2
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1151	2
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1283	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1851	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3215	3
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5861	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6428	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7793	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0579	3
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.1146	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2510	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0114	2
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.0681	2
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2046	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2178	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.2746	3
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4110	3
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6756	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7323	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8688	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1474	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2041	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3405	3
1AC11	MMTA - Other - High	Early - Community	0	1.1089	4
1AC21	MMTA - Other - High	Early - Community	1	1.1657	3
1AC31	MMTA - Other - High	Early - Community	2	1.3021	3
2AC11	MMTA - Other - High	Early - Institutional	0	1.3154	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.3721	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.5086	4
3AC11	MMTA - Other - High	Late - Community	0	0.7732	2
3AC21	MMTA - Other - High	Late - Community	1	0.8299	2
3AC31	MMTA - Other - High	Late - Community	2	0.9663	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2449	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.3016	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.4381	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9207	3
1AA21	MMTA - Other - Low	Early - Community	1	0.9774	3
1AA31	MMTA - Other - Low	Early - Community	2	1.1139	3
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1272	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.1839	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3203	3
3AA11	MMTA - Other - Low	Late - Community	0	0.5849	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6417	2
3AA31	MMTA - Other - Low	Late - Community	2	0.7781	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0567	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1134	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2499	3
1AB11	MMTA - Other - Medium	Early - Community	0	1.0098	4
1AB21	MMTA - Other - Medium	Early - Community	1	1.0665	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1AB31	MMTA - Other - Medium	Early - Community	2	1.2030	4
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2162	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.2730	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4094	4
3AB11	MMTA - Other - Medium	Late - Community	0	0.6740	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7308	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8672	2
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1458	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2025	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3390	3
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1220	3
1LC21	MMTA - Respiratory - High	Early - Community	1	1.1787	3
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3152	3
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3284	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.3852	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5216	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7862	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8429	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9794	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2580	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3147	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4512	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9125	3
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9692	3
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1057	3
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1189	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1756	3
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3121	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5767	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6334	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7699	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0484	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.1051	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2416	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0147	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0714	3
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2079	3
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2211	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.2779	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4143	4
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6789	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7356	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8721	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1507	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2074	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3439	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.1541	3
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2108	3
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3473	2
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3605	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4172	4
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5537	4
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.8183	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8750	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0115	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2900	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3467	3
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4832	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.9133	3
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9700	2
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1065	2
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1197	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1764	3
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3129	3
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.5775	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.6342	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7707	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0492	3
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.1059	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2424	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0167	3
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.0735	3
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2099	3
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2232	3
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2799	4
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4164	4
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6809	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7377	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8741	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1527	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2094	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3459	4
1EC11	MS Rehab - High	Early - Community	0	1.1667	5
1EC21	MS Rehab - High	Early - Community	1	1.2234	4
1EC31	MS Rehab - High	Early - Community	2	1.3599	4
2EC11	MS Rehab - High	Early - Institutional	0	1.3731	5
2EC21	MS Rehab - High	Early - Institutional	1	1.4299	5
2EC31	MS Rehab - High	Early - Institutional	2	1.5663	5
3EC11	MS Rehab - High	Late - Community	0	0.8309	2
3EC21	MS Rehab - High	Late - Community	1	0.8876	2
3EC31	MS Rehab - High	Late - Community	2	1.0241	3
4EC11	MS Rehab - High	Late - Institutional	0	1.3027	4
4EC21	MS Rehab - High	Late - Institutional	1	1.3594	4
4EC31	MS Rehab - High	Late - Institutional	2	1.4959	4
1EA11	MS Rehab - Low	Early - Community	0	0.9457	4
1EA21	MS Rehab - Low	Early - Community	1	1.0024	4
1EA31	MS Rehab - Low	Early - Community	2	1.1389	4
2EA11	MS Rehab - Low	Early - Institutional	0	1.1521	4
2EA21	MS Rehab - Low	Early - Institutional	1	1.2088	5
2EA31	MS Rehab - Low	Early - Institutional	2	1.3453	5
3EA11	MS Rehab - Low	Late - Community	0	0.6099	2
3EA21	MS Rehab - Low	Late - Community	1	0.6666	2
3EA31	MS Rehab - Low	Late - Community	2	0.8031	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.0816	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.1383	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4EA31	MS Rehab - Low	Late - Institutional	2	1.2748	4
1EB11	MS Rehab - Medium	Early - Community	0	1.0327	5
1EB21	MS Rehab - Medium	Early - Community	1	1.0895	4
1EB31	MS Rehab - Medium	Early - Community	2	1.2259	4
2EB11	MS Rehab - Medium	Early - Institutional	0	1.2392	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.2959	5
2EB31	MS Rehab - Medium	Early - Institutional	2	1.4324	5
3EB11	MS Rehab - Medium	Late - Community	0	0.6970	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7537	2
3EB31	MS Rehab - Medium	Late - Community	2	0.8902	2
4EB11	MS Rehab - Medium	Late - Institutional	0	1.1687	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2254	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.3619	4
1BC11	Neuro - High	Early - Community	0	1.2820	4
1BC21	Neuro - High	Early - Community	1	1.3387	4
1BC31	Neuro - High	Early - Community	2	1.4752	4
2BC11	Neuro - High	Early - Institutional	0	1.4884	5
2BC21	Neuro - High	Early - Institutional	1	1.5451	4
2BC31	Neuro - High	Early - Institutional	2	1.6816	4
3BC11	Neuro - High	Late - Community	0	0.9462	2
3BC21	Neuro - High	Late - Community	1	1.0029	3
3BC31	Neuro - High	Late - Community	2	1.1394	3
4BC11	Neuro - High	Late - Institutional	0	1.4179	4
4BC21	Neuro - High	Late - Institutional	1	1.4746	4
4BC31	Neuro - High	Late - Institutional	2	1.6111	4
1BA11	Neuro - Low	Early - Community	0	1.0363	4
1BA21	Neuro - Low	Early - Community	1	1.0931	4
1BA31	Neuro - Low	Early - Community	2	1.2295	4
2BA11	Neuro - Low	Early - Institutional	0	1.2428	4
2BA21	Neuro - Low	Early - Institutional	1	1.2995	4
2BA31	Neuro - Low	Early - Institutional	2	1.4360	4
3BA11	Neuro - Low	Late - Community	0	0.7005	2
3BA21	Neuro - Low	Late - Community	1	0.7573	2
3BA31	Neuro - Low	Late - Community	2	0.8937	2
4BA11	Neuro - Low	Late - Institutional	0	1.1723	4

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4BA21	Neuro - Low	Late - Institutional	1	1.2290	3
4BA31	Neuro - Low	Late - Institutional	2	1.3655	3
1BB11	Neuro - Medium	Early - Community	0	1.1425	4
1BB21	Neuro - Medium	Early - Community	1	1.1992	4
1BB31	Neuro - Medium	Early - Community	2	1.3357	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3489	5
2BB21	Neuro - Medium	Early - Institutional	1	1.4057	5
2BB31	Neuro - Medium	Early - Institutional	2	1.5421	5
3BB11	Neuro - Medium	Late - Community	0	0.8067	2
3BB21	Neuro - Medium	Late - Community	1	0.8634	2
3BB31	Neuro - Medium	Late - Community	2	0.9999	2
4BB11	Neuro - Medium	Late - Institutional	0	1.2785	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3352	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4716	4
1CC11	Wound - High	Early - Community	0	1.5596	4
1CC21	Wound - High	Early - Community	1	1.6163	4
1CC31	Wound - High	Early - Community	2	1.7528	4
2CC11	Wound - High	Early - Institutional	0	1.7660	5
2CC21	Wound - High	Early - Institutional	1	1.8228	4
2CC31	Wound - High	Early - Institutional	2	1.9592	4
3CC11	Wound - High	Late - Community	0	1.2238	3
3CC21	Wound - High	Late - Community	1	1.2805	3
3CC31	Wound - High	Late - Community	2	1.4170	3
4CC11	Wound - High	Late - Institutional	0	1.6956	4
4CC21	Wound - High	Late - Institutional	1	1.7523	4
4CC31	Wound - High	Late - Institutional	2	1.8887	4
1CA11	Wound - Low	Early - Community	0	1.3450	4
1CA21	Wound - Low	Early - Community	1	1.4017	4
1CA31	Wound - Low	Early - Community	2	1.5382	4
2CA11	Wound - Low	Early - Institutional	0	1.5514	4
2CA21	Wound - Low	Early - Institutional	1	1.6082	4
2CA31	Wound - Low	Early - Institutional	2	1.7446	4
3CA11	Wound - Low	Late - Community	0	1.0092	3
3CA21	Wound - Low	Late - Community	1	1.0659	3
3CA31	Wound - Low	Late - Community	2	1.2024	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4CA11	Wound - Low	Late - Institutional	0	1.4810	4
4CA21	Wound - Low	Late - Institutional	1	1.5377	4
4CA31	Wound - Low	Late - Institutional	2	1.6742	4
1CB11	Wound - Medium	Early - Community	0	1.4260	4
1CB21	Wound - Medium	Early - Community	1	1.4828	4
1CB31	Wound - Medium	Early - Community	2	1.6192	4
2CB11	Wound - Medium	Early - Institutional	0	1.6325	4
2CB21	Wound - Medium	Early - Institutional	1	1.6892	5
2CB31	Wound - Medium	Early - Institutional	2	1.8257	4
3CB11	Wound - Medium	Late - Community	0	1.0903	3
3CB21	Wound - Medium	Late - Community	1	1.1470	3
3CB31	Wound - Medium	Late - Community	2	1.2835	3
4CB11	Wound - Medium	Late - Institutional	0	1.5620	4
4CB21	Wound - Medium	Late - Institutional	1	1.6187	4
4CB31	Wound - Medium	Late - Institutional	2	1.7552	4

Source: CY 2024 Home Health Claims Data. Periods that end in CY 2024 accessed on the CCW March 13, 2025.

period payment rate by a case-mix budget neutrality factor. Typically, the case-mix weight recalibration neutrality factor is also calculated using the most recent, complete home health claims data available. For CY 2026, we would continue the practice of using the most recent complete home health claims data at the time of rulemaking, which is CY 2024 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 2026 PDGM case-mix weights (developed using CY 2024 home health claims data) are applied to CY 2024 utilization (claims) data are equal to total payments when CY 2025 PDGM case-mix weights (developed using CY 2023 home health claims data) are applied to CY 2024 utilization data. This produces a case-mix budget neutrality factor for CY 2026 of 1.0051.

We invite public comments on the CY 2026 proposed case-mix weights and proposed case-mix weight budget neutrality factor.

E. Proposed CY 2026 Home Health Payment Rate Updates

1. Proposed CY 2026 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 will be 74.9 percent, and the non-labor-related share will be 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 multifactor 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)), 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. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term “multifactor productivity” with “total factor productivity” (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as “private nonfarm business total factor productivity”. We refer readers to <https://www.bls.gov> 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 2026 is based on the estimated home health market basket percentage increase, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.2 percent (based on IHS Global Inc.’s first quarter 2025 forecast with historical data through fourth quarter 2024). The estimated CY 2026 proposed home health market basket percentage increase of 3.2 percent would then be reduced by a productivity adjustment, in accordance with section 1895(b)(3)(B)(vi) of the Act. Based on IGI’s first quarter 2025 forecast, the proposed productivity adjustment is currently estimated to be 0.8 percentage point for CY 2026. Therefore, the proposed productivity-adjusted CY 2026 home health market basket update is 2.4 percent (3.2 percent market basket percentage increase, reduced by a 0.8 percentage point productivity adjustment). Furthermore, we are proposing that if more recent data become 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 2026 market basket percentage increase and productivity adjustment in the final rule.

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 2026, the proposed home health payment update percentage is 0.4 percent (2.4 percent minus 2 percentage points).

We invite public comments on the proposed CY 2026 home health market basket percentage increase and productivity adjustment.

2. Proposed CY 2026 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 are proposing to continue this practice for CY 2026, 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 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.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-metropolitan-statistical-areas.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). According to OMB, the delineations 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). A copy of OMB Bulletin No. 23–01 is available online at <https://www.bls.gov/bls/omb-bulletin-23-01-revised-delineations-of-metropolitan-statistical-areas.pdf>.

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.

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 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 2026, 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 will continue to use the same transition code for CY 2026, other counties that required a transition code in CY 2025 will no longer require a transition code in CY 2026. In the counties that will no longer require a transition code beginning in CY 2026 wage index, the CY 2026 wage index of the CBSA or rural area that the county was redesignated into has a wage index value higher than 95 percent of the county’s CY 2025 wage index. Therefore, 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. Proposed CY 2026 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 2026, we are proposing to base the HH PPS wage index on the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022 (FY 2022 cost report data). The proposed CY 2026 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 2026 HH PPS wage index, we are proposing 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 2026, 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 are proposing the CY 2026 wage index value for Hinesville, GA, would be 0.8800.

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 are proposing that the CY 2026 HH PPS wage index for rural North Dakota would be 0.8346.

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 CY 2025 final unadjusted wage index value for rural Puerto Rico was 0.2510. However, because 0.2510 is more than a 5 percent decline in the area’s CY 2024 wage index, the 5 percent cap was applied and the final CY 2025 5 percent cap adjusted wage index for rural Puerto Rico was set equal to 95 percent of the CY 2024 wage index, which resulted in a final wage index value of 0.3845.

The unadjusted CY 2026 proposed wage index for rural Puerto Rico is 0.2452. However, because 0.2452 is more than a 5 percent decline in the CY 2025 wage index, we are proposing that the CY 2026 5 percent cap adjusted wage index for rural Puerto Rico be set equal to 95 percent of the CY 2025 wage index, which would result in a proposed wage index value of 0.3653.

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 are proposing that the CY 2026 wage index for rural Delaware would be 1.0133.

Finally, the Northern Mariana Islands and American Samoa are rural areas with no hospital data from which a wage index can be calculated. Consistent with our established methodology, we compute an appropriate wage index for rural areas with no hospital using the average wage index values from contiguous CBSAs, to represent a reasonable proxy. Therefore, we are proposing that 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 proposed HH PPS wage index file applicable for CY 2026 (January 1, 2026, through December 31, 2026) is available on the CMS website at <https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center>.

3. Proposed CY 2026 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, 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 will be 74.9 percent, and the non-labor-related share will be 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 2026:

- 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. Proposed CY 2026 National, Standardized 30-Day Period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget-neutral manner. To determine the CY 2026 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 2024 claims data for CY 2026 payment rate updates. We apply a permanent adjustment factor, 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 2026 payment rate. As discussed in section II.C.1. of this proposed rule, we are proposing the implementation of a permanent adjustment of – 4.059 percent to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been under the 153-group payment system as required by law. The proposed permanent adjustment factor is 0.95941. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we apply a case-mix weight budget neutrality factor to the CY 2026 national, standardized 30-day period payment rate. The proposed case-mix weight budget neutrality factor for CY 2026 is 1.0051.

Additionally, we apply 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 2026 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 2025 wage index (with the 5 percent cap) and the CY 2025 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 2026 wage index with the 5 percent cap on wage index decreases) by the payment rate for non-LUPA 30-day periods using the CY 2025 wage index (with the 5 percent cap on wage index decreases), we obtain a wage index budget neutrality factor of 1.0019. We then apply the wage index budget neutrality factor of 1.0019 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the proposed CY 2026 home health payment update percentage of 2.4 percent. As discussed in section II.C.1. of this proposed rule, we are also proposing the implementation of a temporary 5.0 percent reduction to the CY 2026 base payment rate. The proposed temporary adjustment factor is 0.95000. 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 should not be included in the starting payment rate for CY 2027. Therefore, we have calculated the CY 2026 national, standardized 30-day period payment with and without the temporary adjustment factor. The CY 2026 national standardized 30-day period payment rate without a temporary adjustment is only for illustrative purposes. The actual CY 2026 national standardized 30-day period payment rate includes the proposed temporary adjustment and is calculated in table 26.

TABLE 26: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2025 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
\$2,057.35	0.95941	1.0051	1.0019	1.024	\$2,035.38	0.95000	\$1,933.61

The CY 2026 national standardized 30-day period payment rate for an HHA that does not submit the required

quality data would be updated by 0.4 percent (the proposed CY 2026 home health payment update percentage of 2.4

percent minus 2 percentage points) and is shown in table 27.

TABLE 27: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2025 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor Minus 2 Percentage Points	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
\$2,057.35	0.95941	1.0051	1.0019	1.004	\$1,995.63	0.95000	\$1,895.85

c. Proposed CY 2026 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 proposed CY 2026 national per-visit rates, we started with the CY 2025 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 2026 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 2025 wage index with the 5 percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2026 wage index by the total payments for LUPA 30-day periods of care using the CY 2025 wage index, we obtained a wage index budget neutrality factor of 1.0004. 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 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 proposed CY 2026 home health payment update percentage of 2.4 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 proposed CY 2026 national per-visit rates for HHAs that submit the required quality data are updated by the proposed CY 2026 home health payment update percentage of 2.4 percent and are shown in table 28.

TABLE 28: CY 2026 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2025 Per-Visit Payment Amount	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor	CY 2026 Per-Visit Payment Amount
Home Health Aide	\$78.20	1.0004	1.024	\$80.11
Medical Social Services	\$276.85	1.0004	1.024	\$283.61
Occupational Therapy	\$190.08	1.0004	1.024	\$194.72
Physical Therapy	\$188.79	1.0004	1.024	\$193.40
Skilled Nursing	\$172.73	1.0004	1.024	\$176.95
Speech-Language Pathology	\$205.22	1.0004	1.024	\$210.23

The CY 2026 per-visit payment rates for HHAs that do not submit the required quality data would be updated

by 0.4 percent, which is the proposed CY 2026 home health payment update percentage of 2.4 percent minus 2

percentage points and are shown in table 29.

TABLE 29: CY 2026 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2025 Per-Visit Payment Amount	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor Minus 2 Percentage Points	CY 2026 Per-Visit Payment Amount
Home Health Aide	\$78.20	1.0004	1.004	\$78.54
Medical Social Services	\$276.85	1.0004	1.004	\$278.07
Occupational Therapy	\$190.08	1.0004	1.004	\$190.92
Physical Therapy	\$188.79	1.0004	1.004	\$189.62
Skilled Nursing	\$172.73	1.0004	1.004	\$173.49
Speech-Language Pathology	\$205.22	1.0004	1.004	\$206.12

We are soliciting comments on the proposed CY 2026 30-day home health payment rates and the per-visit payment rates.

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 the proposal to use the same methodology to establish the LUPA add-on amount for CY 2014, using updated claims data.

Specifically, 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 a proposal to discontinue use of the PT LUPA add-on factor as a proxy and established a definitive LUPA add-on factor for occupational therapy. 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.

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 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 2025 HH PPS final rule (89 FR 88354), using CY 2023 claims data (as of July 11, 2024), we finalized the FDL ratio of 0.35 for CY 2025.

b. Proposed FDL Ratio for CY 2026

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

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

Using CY 2024 claims data (as of March 13, 2025) 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 proposing an FDL ratio of 0.46 for CY 2026. CMS would update the FDL, if needed, in the final rule once we have more complete CY 2024 claims data.

F. Proposed Regulation Change to Face-to-Face Encounter

As a condition for payment, section 6407(a) of the Affordable Care Act (Pub. L. 111–148, March 23, 2010) requires that prior to certifying a patient's eligibility for the home health benefit, the physician must document that the physician himself or herself or a non-physician practitioner (NPP) has had a face-to-face encounter with the patient. In the Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices final rule (75 FR 70427) (hereinafter referred to as the CY 2011 HH PPS final rule), we established that the certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs performed the face-to-face encounter. Sections 6407(a)(1)(B) and 6407(a)(2)(B) of the Affordable Care

Act further describes NPPs who may perform this face-to-face patient encounter.

In the Medicare Program, Home Health Prospective Payment System Rate Update for Calendar Year 2012 final rule (hereinafter referred to as the CY 2012 HH PPS final rule), we stated that the Medicare home health benefit relies on the patient's physician to determine eligibility for home health services (76 FR 68596), noting that this type of physician involvement is critical from both a quality of care and program integrity perspective. Prior to enactment of section 6407(a) of the Affordable Care Act regarding the home health face-to-face encounter provision, the patient's physician often relied on information provided by an HHA when making decisions about patient care. In the CY 2012 HH PPS final rule (76 FR 68597), we stated that, in addition to the certifying physician and allowed NPPs, the physician who cared for the patient in an acute or post-acute care facility, and who had privileges in such facility, could also perform the face-to-face encounter and inform the certifying physician, who would document the encounter as part of the certification of eligibility, and that encounter supported the patient's homebound status and need for skilled services. During the CY 2012 HH PPS rulemaking comment period, stakeholders requested that CMS allow any physician to complete the face-to-face encounter, rather than limiting it to the certifying physician or allowed NPP; however, CMS referred commenters to the CY 2011 HH PPS final rule where we stated we did not believe that we had the statutory authority to allow for this additional flexibility (76 FR 68596). The Affordable Care Act established the requirement for a physician face-to-face encounter prior to certifying a patient's eligibility for home health services, along with other program integrity provisions, to address concerns surrounding ineligible patients receiving home health services and concerns that physicians who had no firsthand knowledge of the patient's clinical condition were certifying the patient's eligibility for home health. In the CY 2011 HH PPS final rule, we described research that showed fewer re-hospitalizations when the home health patient had a recent encounter with the physician responsible for the home health care plan. As such, 42 CFR 424.22(a)(1)(v)(A) requires that a face-to-face encounter be performed by the certifying physician; the certifying allowed practitioner (for example, nurse practitioner, clinical nurse specialist, physician assistant); or a certified nurse

midwife. Additionally, 42 CFR 424.22(a)(1)(v)(C) requires that a face-to-face encounter be performed by the certifying physician or allowed practitioner unless the encounter is performed by a certified nurse midwife or a physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

Section 3708 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, March 27, 2020) amended sections 1814(a) and 1835(a) of the Act to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) (as those terms are defined in section 1861(aa) of the Act), to order and certify patients for eligibility under the Medicare home health benefit and establish a plan of care. Since its implementation in the March 31, 2020 COVID–19 interim final rule with comment period (85 FR 27550), CMS has received requests from stakeholders to change the current face-to-face encounter policy to allow any practitioner to perform the face-to-face encounter and not limit this regulation to the certifying practitioner, a permitted NPP, or a physician or allowed practitioner with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health, as set out at § 424.22(a)(1)(v)(C). Commenters have stated that the CARES Act language allows this additional flexibility. Additionally, commenters have stated, and CMS agrees, that the current regulation text at § 424.22(a)(1)(v)(A)(1) through(4) can be read to allow NPs, CNSs, and PAs to perform the face-to-face encounter regardless of whether they certify the patient for home health services, but limits the provision of the face-to-face encounter to the certifying physician or a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health. Therefore, stakeholders have requested that any physician, in addition to NPs, CNSs, and PAs, be allowed to perform the face-to-face encounter regardless of whether they are the certifying practitioner or whether they cared for the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner. Some commenters have

referenced situations in which a patient sees a physician in the same practice as the patient's primary care physician (PCP), but where the patient's PCP was unavailable to see the patient on a particular date.

We agree that it would be reasonable for the patient's PCP to certify eligibility under the Medicare home health benefit and establish the plan of care even though a different physician or allowed practitioner in the same practice conducted the face-to-face encounter. However, we note that it would not be appropriate for a practitioner who specializes in optometry to certify a patient for home health services that are needed due to orthopedic reasons. These are only a couple of examples of circumstances that could occur, and we do not plan to enumerate in this rulemaking all situations in which the certifying provider may be different than the provider who conducted the face-to-face encounter.

Regarding our original concern in limiting the face-to-face encounter to the certifying provider (or the provider who cared for the patient in the inpatient facility), we still believe physician or allowed practitioner involvement is critical from both a quality of care and program integrity perspective. However, we note that additional program integrity protections exist currently in the certification policies. To be eligible for Medicare home health services, in accordance with § 424.22(a)(1)(iv) a patient must be under the care of a physician or an allowed practitioner. Additionally, in accordance with § 424.22(a)(1)(v), the face-to-face encounter documentation must be related to the primary reason the patient requires home health services, occur in the required time frame by an allowed provider type, and the certifying practitioner must include a signature and the date of the encounter as part of the certification. Furthermore, our subregulatory guidance in the Medicare General Information, Eligibility and Entitlement Manual (Pub. 100–01, chapter 4, section 30.1) provides that physicians and allowed practitioners should complete the certification when the plan of care is established, or as soon as possible thereafter, and that it is not acceptable to wait until the end of the required time frame to complete the requirements. As such, the certification also cannot be completed after a patient is discharged from home health services.

Additionally, our subregulatory guidance in the Medicare General Information, Eligibility and Entitlement Manual (Pub. 100–01, chapter 4, section 30.1), the Medicare Benefit Policy

Manual (Pub. 100–02, chapter 7, section 30.5), and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6 section 6.2.1 and 6.2.3) also supports our program integrity and quality goals. Specifically, the subregulatory guidance provides additional details on requirements that include the following: specific signature and date requirements; a requirement for an actual clinical note from the certifying practitioners for the face-to-face encounter visit; specific information that must be present in face-to-face encounter documentation; a requirement that a new face-to-face encounter is required if the patient's condition has changed; a requirement that home health eligibility must be supported by other medical entries in the certifying provider's medical record for the patient and this documentation must be available for medical reviews as needed; and a requirement that documentation of the face-to-face encounter can only be from physicians or allowed NPPs who do not have a financial relationship with the HHA.

We believe the regulations at 42 CFR 424.22(a)(1), in conjunction with the Medicare home health eligibility requirements at 42 CFR 424.22(c), finalized in the CY 2019 final rule (83 FR 56627), provide sufficient preservation of our original intent of ensuring that the home health benefit relies on the patient's physician (or subsequently, the allowed practitioner) to determine eligibility for home health services, and that the physician or NPP performing the face-to-face encounter should be a practitioner who is most knowledgeable and has firsthand information of the patient's current clinical condition when certifying the patient's eligibility for home health services and establishing a patient's plan of care.

As such, we propose to revise § 424.22(a)(1)(v)(A) to state that the face-to-face encounter must be performed by one of the following: a physician, a nurse practitioner, a clinical nurse specialist, or a physician assistant as defined at 42 CFR 484.2; or a certified nurse-midwife as defined in section 1861(gg) of the Act as authorized by State law. We also propose to remove § 424.22(a)(1)(v)(C), which limits the face-to-face encounter to the certifying physician or allowed practitioner unless the encounter is performed by either of the following:

- A certified nurse midwife as described in paragraph (a)(1)(v)(A)(4) of this section.
- A physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for

the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

The proposed additional flexibility should decrease ambiguity regarding which providers are able to complete the face-to-face encounter and potentially improve access to home health services by increasing the number of providers allowed to perform the face-to-face encounter. These proposed revisions would also address concerns that the current regulations do not align with the CARES Act language. We solicit comments on these proposed revisions to 42 CFR 424.22(a)(1)(v).

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 Provisions of This Proposed Rule

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are proposing the following policies and requests for information:

We are proposing to remove the “COVID–19 Vaccine: Percent of Patients Who Are Up to Date” measure and the item related to the measure and corresponding data element. CMS is proposing the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. We are also proposing to revise the policy to allow for providers that fail to provide complete, timely data to CMS to submit a request for reconsideration if they can demonstrate full compliance. In very limited circumstances, we would permit the HHA to request an extension to file a reconsideration request if the HHA was affected by an

extraordinary circumstance beyond the control of the HHA (that is, a natural disaster such as a hurricane tornado or earthquake) during the 30-day reconsideration period. CMS is also proposing to implement a revised HHCAHPS Survey beginning with the April 2026 sample month. This rule also includes a proposal to update regulatory text to account for all-payer data submission of OASIS data. We are seeking feedback on a potential change to the final data submission deadline from 4.5 months to 45 days after the close of the period. We are also seeking feedback on the digital quality measurement (DQM) transition for HHAs. We aim to solicit feedback from the public on the current adoption of health information technology (IT) and standards including Fast Healthcare Interoperability Resources (FHIR), what related challenges or barriers HHAs are

facing. Finally, we are seeking input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

For a detailed discussion of the considerations, we historically use 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 19 measures for the CY 2026 program year, as described in table 30.

BILLING CODE 4120–01–P

TABLE 30: MEASURES CURRENTLY ADOPTED FOR THE CY 2026 HH QRP

Short Name	Measure Name & Data Source
QM Name	OASIS-based
Ambulation	Improvement in Ambulation/Locomotion (CBE #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674).
Bathing	Improvement in Bathing (CBE #0174).
Bed Transferring	Improvement in Bed Transferring (CBE # 0175).
Patient COVID-19 Vaccination	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
DC Function	Discharge Function Score
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (CBE #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation of Care (CBE #0526).
TOH-Provider	Transfer of Health Information to Provider-Post-Acute Care ¹
TOH-Patient	Transfer of Health Information to Patient-Post-Acute Care ¹
QM Name	Claims-based
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (CBE #3477)
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
PPH	Home Health Within Stay Potentially Preventable Hospitalization
QM Name	HHCAPHS-based
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (CBE #0517) ² - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

¹ Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider.

² The HHCAPHS has five components that together are used to represent one CBE-endorsed measure.

BILLING CODE 4120-01-C

D. Proposed Removal of the “COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date” (Patient/Resident COVID-19 Vaccine Measure) Beginning With the CY 2026 HH QRP

We refer readers to the CY 2024 HH PPS final rule, where we adopted the “COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date” (“Patient/Resident COVID-19 Vaccine measure”) into the HH QRP (88 FR 77762 through 77764). For the HH QRP, we propose to remove the Patient/Resident COVID-19 Vaccine measure beginning with the CY 2026 HH QRP under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (§ 484.245(b)(3)(viii)). The estimated burden of collecting this information annually across all 11,904 active HHAs is 47,168 hours at a cost of \$4,326,249. We refer readers to section VII of this proposed rule for more details on the estimated burden reduction related to this proposal.

When we adopted the Patient/Resident COVID-19 Vaccine measure, COVID-19 continued to be a major challenge for HHAs, with older adults at a significantly higher risk of mortality, severe disease, and death following infection (88 FR 77762). HHAs have expressed concerns about data collection challenges and increased provider burden in collecting patient immunization data.⁸ Providers were required to integrate the required Patient/Resident COVID-19 Vaccine OASIS item into their assessment instrument and ensure accurate assessment for all their patients. While preventing the spread of COVID-19 remains a public health goal, the number of COVID-19 cases and deaths⁹ is declining, and we believe the continued costs and burden to providers of reporting this measure outweigh the benefit of continued information collection on COVID-19 vaccination coverage among patients in HHAs. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of \$4,326,249 or \$363 (\$4,326,249/11,904) for each of the 11,904 active HHAs. We refer readers to

section VII.A.3. of this proposed rule for more details on this estimated burden reduction.

We propose that, effective with assessments completed on or after the date of publication of the CY 2026 HH PPS final rule, the data from the “Patient/Resident COVID-19 Vaccination is Up to Date” OASIS item (O0350) would no longer be used in the calculation of the Patient/Resident COVID-19 Vaccine measure, and the measure itself would be withdrawn pursuant to measure removal factor eight (set out at 42 CFR

484.245(b)(3)(viii)). We propose to remove the Patient/Resident COVID-19 Vaccination is Up to Date item (O0350) from the OASIS effective April 1, 2026, since it is not technically feasible to remove this item earlier. However, under our proposal, until this item could be removed from the OASIS, HHAs may submit any valid response (0—No, 1—Yes or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications. Note that the item must be completed with one of these three valid responses (must not be left blank) in order for the submitted assessment to not be rejected by the iQIES under existing submission specification edits.

We invite public comment on our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the HH QRP beginning with the CY 2026 HH QRP.

E. Proposed Removal of Four Standardized Patient Assessment Data Elements Beginning With the CY 2026 HH QRP

We refer readers to the CY 2025 HH PPS final rule (88 FR 88433 through 88439) where we finalized the adoption of four items as standardized patient assessment data elements under the social determinants of health (SDOH) category: one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330). As finalized in the CY 2025 HH PPS final rule, HHAs would be required to report these data elements using the OASIS beginning with patients discharged in the CY 2027 HH QRP and each program year after (89 FR 88433 through 88439).

In this proposed rule, we are proposing to remove these four standardized patient assessment data elements under the SDOH category as we acknowledge the burden associated with these items at this time. We continuously look for ways to balance the need for data collections regarding

quality care and the burden of data collection on health care providers. CMS has a goal to facilitate improved health care delivery by requiring different systems and software applications to communicate and exchange data. Therefore, we would like to work towards the workflow for these specific data elements being part of a low burden interoperable electronic system. The focus would turn towards how these data and associated recommendations exchanged can improve care coordination, efficiency, reduction in errors and patient experience.

As health information technology (HIT) advances and interoperability of data becomes more standardized, the burden to collect and share clinical data on these and other relevant patient information would become less burdensome allowing for better outcomes for HH patients and their families. The objectives of the HH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement, while not imposing undue burden on essential health providers. HHAs and providers across the industry play a vital role in improving the health of all patients, including those who may be experiencing unstable housing, food insecurity or challenges paying utilities. At the same time, we recognize the burden that the collection of these additional data would impose on already overextended staff. We also acknowledge the additional cost and resources HHAs would bear for training HH staff and altering their workflows if they were required to collect and submit these items. The objectives of the HH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement. The estimated savings from not collecting this information annually across all 11,904 HHAs is 158,835 hours, with total savings of \$13,484,033 (or \$1,132 per HH). We refer readers to section VII.A.3. of this proposed rule for more details on this estimated burden reduction.

Under our proposal, HHAs would no longer be required to collect and submit Living Situation (R0310), Food (R0320A and R0320B), and Utilities (R0330) beginning with patients discharged on or after April 1, 2026. Under our proposal, these items would not be required to meet HH QRP requirements beginning with the CY 2026 HH QRP.

We invite public comment on our proposal to remove four standardized patient assessment data elements collected under the SDOH category from

⁸ Standing Technical Expert Panel for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets Summary Report December 15, 2023. <https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf>.

⁹ Provisional COVID-19 Deaths, by Week, in The United States, Reported to CDC. Accessed on March 18, 2025, via https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.

the HH QRP beginning with the CY 2026 HH QRP.

F. Amending the Data Non-Compliance Reconsideration Request Policy and Process Beginning With the CY 2026 HH QRP

1. Background

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096). At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be non-compliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2-percentage point reduction to its market basket percentage update for that calendar year. In the CY 2018 HH PPS final rule (82 FR 52738 through 51740), CMS finalized a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters beginning with the CY 2019 HH QRP when there are certain extraordinary circumstances outside the control of the HHA. When an exception or extension is granted, we finalized that we would not reduce the HHA's PPS payment for failure to comply with the requirements of the HH QRP.

In that rule, we finalized a policy that, in very limited circumstances, CMS could grant a request by an HHA to extend the proposed deadline for their reconsideration requests (82 FR 52738 through 51740). We stated that, to extend the deadline, HHAs would have to request an extension and demonstrate that "extenuating circumstances" existed which prevented the filing of the reconsideration request by the proposed 30-day deadline (82 FR 52738 through 51740).

In the CY 2018 HH PPS final rule (82 FR 51752), we codified the reconsideration policy and process for HHAs at § 484.250. As codified, our regulation at § 484.250 addressed how we send our written notification of non-compliance to an HHA, the process for an HHA to request reconsideration, what information an HHA must include with its reconsideration request (for example, documentation that demonstrates the HHA's compliance HH QRP requirements), and how we would notify the HHA of our final decision regarding its reconsideration request. In 2019, we moved the regulatory text to § 484.245 and updated and clarified the regulatory text in the CY 2020 HH PPS final rule (84 FR 60645).

We have become aware that there are inconsistencies in our preamble and regulation text regarding HHA requests for reconsideration. On this basis, in this proposed rule, we seek to address these inconsistencies.

2. HH QRP Reconsideration Policy: Proposal To Amend and Codify Requirements Related to Requests for Extension To File Reconsideration Request Beginning With the CY 2027 HH QRP

As noted previously, in the CY 2018 HH PPS final rule (82 FR 51738 through 51740), we provided that, in very limited circumstances, we may grant a request by an HHA to extend the deadline to submit its reconsideration request, so long as the HHA requested the extension and demonstrated that extenuating circumstances existed that prevented it from filing a reconsideration request by the 30-day deadline (82 FR 51738 through 51740). However, we did not codify this policy—permitting HHAs to request an extension to file their reconsideration request—in our regulation text at § 484.245(d).

In implementing this finalized policy, we have noted an area where further clarity would be beneficial to HHAs. Specifically, we have noted that HHAs may benefit from clearly demarcated deadlines. Although we believe an HHA would have an interest in asking for an extension to file a reconsideration request prior to the deadline, our policy currently does not specify a deadline for an HHA to submit its request for such an extension (82 FR 51738 through 51740). Our policy also provides that, to support such request, the HHA must demonstrate that extenuating circumstances existed that prevented filing the reconsideration request by the 30-day deadline (82 FR 51738 through 51740). However, we have not specified a deadline from when the extenuating circumstances occurred. We believe HHAs may benefit from further specificity by setting a deadline for submitting a request to extend the deadline to file a reconsideration request.

On this basis, we propose to amend our reconsideration policy as codified at § 484.245(d) to permit a HHA to request, and CMS to grant, an extension to file a request for reconsideration of a non-compliance determination if, during the period to request a reconsideration as set forth in § 484.245(d), the HHA was affected by an extraordinary circumstance beyond the control of the HHA (for example, a natural or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake). We

propose that the HHA submit its request for an extension to file a reconsideration request to CMS via email no later than 30 calendar days from the date of the written notification of non-compliance. We propose that the HHA's extension request, submitted to CMS, must contain all of the following information: (1) the CCN for the HHA; (2) the business name of the HHA; (3) the business address of the HHA; (4) certain contact information for the HHA's chief executive officer or designated personnel; (5) a statement of the reason for the request for the extension; and (6) evidence of the impact of the extraordinary circumstances, including, for example, photographs, newspaper articles, and other media. We propose to codify this process at § 484.245(d)(5).

We further propose that CMS would notify the HHA in writing of its final decision regarding its request for an extension to file a reconsideration of non-compliance request via an email from CMS. We propose to notify the HHA in writing via email because this would allow for more expedient correspondence with the HHA, given the 30-day reconsideration timeframe. We propose to codify this process at § 484.245(d)(6).

We note that we are considering proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invite comment on these proposals to amend the HH QRP Reconsideration policy to permit HHAs to request an extension to file a reconsideration request beginning with the CY 2027 HH QRP and to codify this proposed policy and process at § 412.634(d)(5) and (d)(6).

3. Proposal To Codify the Bases on Which CMS Can Grant a Reconsideration Request

As discussed previously, in CY 2013 HH PPS final rule, we stated that, after we review an HHA request for reconsideration, we may reverse our initial finding of non-compliance if: (1) the HHA provides proof of compliance with all requirements during the reporting period; or (2) the HHA provides adequate proof of a valid or justifiable excuse for non-compliance if the HHA was not able to comply with requirements during the reporting period (77 FR 67096). We also stated that we will uphold an initial finding of non-compliance if the HHA cannot show any justification for non-compliance (77 FR 67096).

As previously discussed, we codified our reconsideration policy at § 484.245(d) in the CY 2013 HH PPS

final rule (77 FR 67096). Our regulation at § 484.245(d)(3) requires that an HHA's request for reconsideration include accompanying documentation that demonstrates the HHA's compliance with the HH QRP requirements. Then, we will notify the HHA in writing regarding our final decision on its reconsideration request (§ 412.634(d)(4)).

We believe it would be beneficial for HHAs if we codify our specific bases for granting a reconsideration request in our regulation at § 484.245(d). These have not been previously outlined in regulatory text and CMS has outlined these details for clarity for any HHA seeking an extension in the reconsideration process.

On these bases, we propose to modify our reconsideration policy to provide that we will grant a timely request for reconsideration and reverse an initial finding of non-compliance, only if CMS determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year. We would consider full compliance with the HH QRP requirements to include CMS granting an exception or extension to HH QRP reporting requirements under our extraordinary circumstance exception and extension (ECE) policy at § 484.245(c). However, to demonstrate full compliance with our ECE policy, the HHA would need to comply with our ECE policy's requirements, including the specific scope of the exception or extension as granted by CMS.

We propose to modify § 484.245(d)(4) to codify this modified policy in our regulation. We note that we are considering proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invite comment on these proposals to amend the bases by which we grant a reconsideration request under the HH QRP reconsideration policy and to codify this proposed policy at § 484.245(d)(5).

G. Updates to Requirements for OASIS All-Payer Data Submission

1. Statutory Authority and Background

Section 1891(d) of the Act, cross-referencing section 1891(c)(2)(C)(i)(I) of the Act (section 4021(b) of Pub. L. 100–203 (December 22, 1987)) requires the Secretary to develop a comprehensive assessment for Medicare-participating HHAs. In 1993, CMS (then known as HCFA) developed an assessment instrument that identified each patient's

need for home care and the patient's medical, nursing, rehabilitative, social and discharge planning needs. As part of this assessment, Medicare-certified HHAs were required to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS). As part of the home health assessment, the statute requires a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care provided by the HHA. OASIS is the designated assessment instrument for use by an HHA in complying with the requirement and HHAs must submit the data collected by the OASIS assessment to CMS as an HHA condition of participation (42 CFR part 484.45).

Section 704 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 12, 2003) “suspended” the legal authority of the Secretary to require HHAs to report non-Medicare and non-Medicaid patient data to CMS until at least two months after the Secretary published final regulations on CMS's collection and use of OASIS data following the submission of a report to Congress on the study required under section 704(c) of the MMA. Subsequently, CMS conducted the study from 2004 to 2005 and submitted a report¹⁰ to Congress in 2006 titled “The OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients—Report to Congress.” While the 2006 report recommended that the suspension continue, the passage of the Improving Medicare Post-Act Care Transformation (IMPACT) Act (Pub. L. 113–115) in 2014 required CMS to create a uniform quality measurement system that allows CMS to compare outcomes across post-acute care (PAC) providers.

The final rule¹¹ titled, “Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements” finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period (example

July 1, 2025–June 30, 2026) (87 FR 66862). With the CY 2025 HH PPS final rule, CMS established that start of care (SOC) is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory period. CMS would use the M0090 “Date Assessment Completed” date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments in the phase-in and mandatory periods (89 FR 88439 through 88441). This ended the suspension of the OASIS data collection on non-Medicare and non-Medicaid HHA patients. As discussed in the final rule, the most accurate representation of the quality of care furnished by HHAs is best captured by calculating the assessment-based measures rates using OASIS data submitted on all HHA patients receiving skilled care, regardless of payer.

2. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))

Section 484.45(a) of the HHA CoPs currently requires an HHA to encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. To align with the transition to OASIS all-payer submission requirements as outlined in the CY 2023 Home Health PPS final rule, we are proposing at § 484.45(a) to remove the term “beneficiary” and replace it with the term “patient.” Thus, § 484.45(a) would read, if finalized as proposed, “An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each patient with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the patient.”

Patients must receive, and an HHA must provide, a comprehensive assessment no later than five calendar days after the start of care. The comprehensive assessment not only examines patients' current health, psychosocial, functional, and cognitive status, but also must incorporate the most current version of the OASIS data items. This includes clinical record items, patient history, supportive assistance, etc. Currently, the comprehensive assessment, including administration of OASIS, must be

¹⁰ <https://www.cms.gov/files/document/cms-oasis-study-all-payer-data-submission-2006.pdf>.

¹¹ <https://www.federalregister.gov/documents/2022/11/04/2022-23722/medicare-program-calendar-year-cy-2023-home-health-prospective-payment-system-rate-update-home>.

updated and revised as frequently as the patient's condition warrants, but not less frequently than the last five days of every 60 days beginning with the start-date of care. Language at § 484.55(d)(1)(i) references a "beneficiary elected transfer" in reference to one scenario in which an OASIS assessment would be updated. To support the transition to OASIS all-payer submission requirements, we are also proposing to remove the term "beneficiary" at § 484.55(d)(1)(i).

These technical changes to update terminology would further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language in the CoPs with the requirements finalized in the CY 2023 and CY 2025 Home Health PPS final rules. We note that this policy does not change current patient exemptions for OASIS, which are as follows: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.

H. Proposed HHCAHPS Survey Updates

a. Survey and Measure Changes

Based on feedback from patients and interested parties, CMS launched an effort to update and shorten the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey. CMS conducted a mode experiment with 100 HHAs in 2022. The experiment tested a web-mail mode and a revised survey instrument. The revised survey is shorter than the current survey and includes new

questions on topics suggested by interested parties. Specifically, changes to the survey and the quality measures derived from testing include the following:

- Addition of three new questions to assess new topics of importance to patients:
 - ++ Whether the care provided helped the patient take care of their health.
 - ++ Whether the patient's family/friends were given sufficient information and instructions.
 - ++ Whether the patient felt the staff cared about them "as a person."
- Removal of questions or topics of less importance to patients (that is, six questions about medications were reduced to two questions).
- The following 4 questions were removed:
 - ++ Whether someone asked to see all the prescription and over-the-counter medicines the patient was taking.
 - ++ Whether the patient is taking any new prescription medicines or whether the patient's medicines have changed.
 - ++ Whether home health providers talked to the patient about the purpose for taking new or changed prescription medicines.
 - ++ Whether home health providers talked to the patient about when to take the medicines.
- Removal of questions not currently used in public reporting composites (that is, three questions on which type of staff served the patient—nurse, physical or occupational therapist, and home care aide).
- Removal of one question which did not perform well in testing to stand alone or fit into one of the revised composite measures:

- Whether the patient got information about what care and services they would get when they first started getting home health care.

- Minor text changes to selected existing questions to help clarify the question or response options, based on feedback from patients.

The revised HHCAHPS Survey, including the revised Care of Patients and Communications between Providers and Patients measures, and the three stand-alone measures that remain from the current Specific Care Issues measure were reviewed as part of the 2025 Measures Under Consideration list (MUC2024–054, –055, –061, –062, & –063) through the Pre-Rulemaking Measure Review (PRMR) Post-Acute Care/Long-Term Care (PAC/LTC) Committee. The PRMR PAC/LTC Committee recommended four out of the five measures without any conditions and one of the measures with conditions, such as stratifying the survey data for analysis and including greater detail about the types of medications. For more information, please see <https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf>. Due to the very favorable recommendations from the PRMR, we are proposing to move forward with the five measures. CMS is proposing to implement the revised HHCAHPS Survey beginning with the April 2026 sample month. Table 31 provides a comparison of the current and proposed HHCAHPS Survey measures.

BILLING CODE 4120–01–P

TABLE 31: CURRENT AND PROPOSED CHANGES TO HHCAHPS SURVEY MEASURES

Measure	Item(s) in Current Measure	Item(s) in Proposed Revised or New Measure
Care of Patients	In the last 2 months of care, how often did home health providers from this agency seem informed and up to date about all the care or treatment you got at home? (Q9)	In the last 2 months of care, how often did home health staff from this agency seem to be aware of all the care or treatment you were getting at home? (Q6)
	In the last 2 months of care, how often did home health providers from this agency treat you as gently as possible? (Q16)	In the last 2 months of care, how often did home health staff from this agency treat you with care – for example, when moving you around or changing a bandage? (Q7)
	In the last 2 months of care, how often did home health providers from this agency treat you with courtesy and respect? (Q19)	In the last 2 months of care, how often did home health staff from this agency treat you with courtesy and respect? (Q10)
	N/A (not on current survey)	In the last 2 months of care, how often did you feel that home health staff from the agency cared about you as a person? (Q11)
	N/A (not on current survey)	In the last 2 months of care, how often have the services you received from this agency helped you take care of your health? (Q13)
	In the last 2 months of care, did you have any problems with the care you got through this agency? (Q24)	N/A (removed from revised survey)
Communications between Providers and Patients	When you first started getting home health care from this agency, did someone from the agency tell you what care and services you would get? (Q2)	N/A (removed from revised survey)
	In the last 2 months of care, how often did home health providers from this agency keep you informed about when they would arrive at your home? (Q15)	In the last 2 months of care, how often did home health staff from this agency keep you informed about when they would arrive at your home? (Q5)
	In the last 2 months of care, how often did home health providers from this agency explain things in a way that was easy to understand? (Q17)	In the last 2 months of care, how often did home health staff from this agency explain things in a way that was easy to understand? (Q8)
	In the last 2 months of care, how often did home health providers from this agency listen carefully to you? (Q18)	In the last 2 months of care, how often did home health staff from this agency listen carefully to you? (Q9)
	N/A (not on current survey)	In the last 2 months of care, did home health staff from this agency provide your family or friends with information or instructions about your care as much as you wanted? (Q12)
	In the last 2 months of care, when you contacted this agency's office did you get the help or advice you needed? (Q22)	When you contacted this agency's office, did you get the help or advice you needed? (Q16)

Measure	Item(s) in Current Measure	Item(s) in Proposed Revised or New Measure
	When you contacted this agency's office, how long did it take for you to get the help or advice you needed? (Q23)	N/A (removed from revised survey)
Specific care issues	When you first started getting home health care from this agency, did someone from the agency talk with you about how to set up your home so you can move around safely? (Q3)	- When you first started getting home health care from this agency, did someone from the agency talk about ways to help make your home safer? For example, they may have suggested adding grab bars in the shower or removing tripping hazards. (Q2) - Removed composite; reporting as standalone item
	When you started getting home health care from this agency, did someone from the agency talk with you about all the prescription and over-the-counter medicines you were taking? (Q4)	- Has someone from the agency ever reviewed the prescribed and over-the-counter medicines you were taking? For example, they might have asked you to show them your medicines and talked with you about how and when to take each one. (Q3) - Removing composite; reporting as standalone item
	When you started getting home health care from this agency, did someone from the agency ask to see all the prescription and over-the-counter medicines you were taking? (Q5)	N/A (removed from revised survey)
	In the last 2 months of care, did home health providers from this agency talk with you about the side effects of these medicines? (Q14)	- In the last 2 months of care, did home health staff from this agency talk with you about any side effects of your medicines? (Q4) - Removing composite; reporting as standalone item
	In the last 2 months of care, did you and a home health provider from this agency talk about pain? (Q10)	N/A (removed from revised survey)
	In the last 2 months of care, did home health providers from this agency talk with you about the purpose for taking your new or changed prescription medicines? (Q12)	N/A (removed from revised survey)
	In the last 2 months of care, did home health providers from this agency talk with you about when to take these medicines? (Q13)	N/A (removed from revised survey)
Overall rating	We want to know your rating of your care from this agency's home health providers. Using any number from 0 to 10, where 0 is the worst home health care possible and 10 is the best home health care possible, what number would you use to rate your care from this agency's home health providers? (Q20)	We want to know your rating of your care from this agency's home health staff. Using any number from 0 to 10, where 0 is the worst home health care possible and 10 is the best home health care possible, what number would you use to rate your care from this agency's home health staff? (Q14)
Willingness to recommend	Would you recommend this agency to your family or friends if they needed home health care? (Q25)	Would you recommend this agency to your family or friends if they needed home health care? (Q17)

BILLING CODE 4120-01-C

b. Impact on Public Reporting and Star Ratings

HHCAHPS Survey measure scores are calculated across four rolling quarters and are published quarterly for all HHAs over the reporting period. The Summary Star Rating is currently based on the Overall Rating of Care and the three composite measures that are equally weighted. We are proposing to calculate the Summary Rating based on the Overall Rating of Care, the two modified composite measures (Care of Patients and Communications between Providers and Patients), and the three new stand-alone measures related to talking about home safety, reviewing prescribed and over-the-counter medicines, and talking about medicine side effects. In the calculation of the Summary Star Rating, we are proposing that the Overall Rating of Care and two modified composite measures would each have a weight of 1 and each of the three new stand-alone measures would have a weight of one-third. The Summary Star Ratings would continue to be calculated using four rolling quarters and would be publicly reported for all HHAs with 40 or more completed surveys over the reporting period. Star Ratings are updated every quarter. To determine what impact the changes to the survey measures would have on public reporting, CMS considered the nature of the measure change. As Talk About Home Safety, Review Medicines, and Talk About Medicine Side Effects are new measures for the HHCAHPS Survey, since they would be reported individually, we would have to wait to introduce public reporting until we have four quarters of data. Although the revised Care of Patients measure is conceptually similar to the current Care of Patients measure, we believe the change (adding two new questions and dropping one question) is substantive and the revised measure should be treated as new for purposes of public reporting and Star Ratings. Similarly, the revised Communications Between Providers and Patients measure is also conceptually similar to the current Communications Between Providers and Patients measure; however, the change (dropping two questions and adding one new question) is substantive and the revised measure should be treated as new for purposes of public reporting and Star Ratings. As such, we propose waiting to publicly report the new versions of Care of Patients and Communications Between Providers and Patients until we have four quarters of data. We anticipate that the first Care Compare refresh in which publicly

reported measures scores would be updated to include the new measures would be October 2027, with scores calculated using data from Q2 2026 through Q1 2027. In the interim period, measure scores would be made available to HHAs confidentially via their Provider Preview reports on the HHCAHPS Survey website after two full quarters of data are submitted.

We believe the change to the Overall Rating measure (minor wording change from “provider” to “staff”) is non-substantive (*i.e.*, does not meaningfully change the measure) and along with the unchanged Willingness to Recommend the Agency measure, both measures can continue to be publicly reported in the transition period between the current and new surveys. During the transition period, scores and Star Ratings for the Overall Rating and Willingness to Recommend measures would be calculated by combining scores from quarters using the current and new survey and continue to be reported.

c. Survey Administration Changes

No survey administration changes are proposed with the new survey.

d. Case-Mix and Mode Adjustments

Prior to public reporting, HHAs’ HHCAHPS Survey scores are adjusted for the effects of case mix. Case mix refers to characteristics of the patient that are not under control of the HHA that may affect reports of home health experiences. Case-mix adjustment is performed within each quarter of data after data cleaning. The current case-mix adjustment model includes the following variables: patient age, patient education, self-reported overall health, self-reported mental health, diagnosis of schizophrenia or dementia, whether the patient lives alone, whether the patient or a proxy answered the survey, and language in which the survey was completed. The model used and adjustments are updated quarterly and are available on the HHCAHPS website at this link: <https://homehealthcahps.org/General-Information/Archived-Publicly-Reported-Data> Based on testing the revised survey in a 2022 Mode Experiment, CMS reviewed the variables included in the case-mix adjustment models currently in use for the HHCAHPS Survey to determine if any changes needed to be introduced along with the revised survey. We found that while no case-mix variables need to be added, the diagnosis adjustments were no longer significant. As such, CMS proposes to drop the adjustment for diagnoses of schizophrenia or dementia with the revised survey.

Using data from the 2022 Mode Experiment, CMS also tested for whether there were impacts in how someone responds to the survey based on the mode of survey administration. Mode effects were observed with the 2022 Mode Experiment, so CMS is proposing to add a mode adjustment in addition to the case-mix adjustment, with the revised survey. Case-mix adjustment would be performed within each quarter of data after data cleaning and before mode adjustment. When we make mode adjustments, it is necessary to choose one mode as a reference mode. One can then interpret all adjusted responses from all modes as if they had been surveyed in the reference mode. CMS would use mail-only as the reference mode for the HHCAHPS Survey, because it is the most used mode for HHCAHPS. The choice of mail mode as the reference mode does not indicate that mail mode is preferable to other approved modes in any way. In the 2022 HHCAHPS Survey mode experiment, telephone-only respondents were more negative in their evaluations of care relative to mail-only respondents across the HHCAHPS measures. The mode adjustments are generally small—most are around 2 percentage points.

Please see the HHCAHPS Revised Survey Mode Adjustments on <https://homehealthcahps.org> for the mode adjustments if these measures are finalized through rulemaking.

We invite public comment on the HHCAHPS Survey proposals.

1. HH QRP Quality Measure Concepts Under Consideration for Future Years—Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the quality measure concepts under consideration listed in Table 32 for future years of the HH QRP. In the CY 2024 HH PPS proposed rule (88 FR 43738 through 43740), we included a request for information (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 are seeking input on four concepts for future measures for the HH QRP.

1. Interoperability

We are seeking input on the quality measure concept of interoperability, focusing on information technology (IT) systems’ readiness and capabilities in the HH setting. Title XXX of the Public

Health Service Act defines “interoperability” in part, and with respect to health IT, as health IT that enables the secure exchange of electronic health information with, and use of electronic health information from, other health IT without requiring special efforts by the user.¹² The definition further states that interoperability of health IT allows for complete, including by providers and patients, access, exchange, and use of electronically accessible health information for authorized uses under applicable State or Federal law.¹³ We request input and comment on approaches to assessing interoperability in the HH setting, for instance, measures that address or evaluate the level of readiness for interoperable data exchange, or measures that evaluate the ability of data systems to securely share information across the spectrum of care.

2. Cognitive Function

Illnesses associated with limitations in cognitive function, which may include stroke, traumatic brain injuries, dementia, and Alzheimer’s disease, affect an individual’s ability to think, reason, remember, problem-solve, and make decisions. The IMPACT Act identifies cognitive function as a key quality measure domain, and an area for inclusion as a standardized assessment data element.

Two sources of information on cognitive function currently collected in HHAs are the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM®).¹⁴ Both the BIMS and CAM have been incorporated into the OASIS. Scored by providers via direct observation, the BIMS is used to

determine orientation and the ability to register and recall new information. The CAM assesses the presence of inattention, disorganized thinking, and level of consciousness.

The BIMS and CAM include items representing different aspects of cognitive function, from which quality measures may be constructed. Although these instruments have been subjected to feasibility, reliability, and validity testing, additional development and testing would be required prior to transforming the concepts reflected in the BIMS and CAM (example temporal orientation, recall) into fully specified measures for implementation in the HH QRP.

This RFI is requesting input on cognitive functioning measures that may be available for immediate use, or that may be adapted or developed for use in the HH QRP, using the BIMS or the CAM. In addition to comment on specific measures and instruments, CMS seeks input on the feasibility of measuring improvement in cognitive functioning during a HH stay, which typically averages 56 days;¹⁵ the cognitive skills (example executive functions) that are more likely to improve during an HHA stay; conditions for which measures of maintenance—rather than improvement in cognitive functioning—are more practical; and the types of intervention that have been demonstrated to assist in improving or maintaining cognitive functioning.

3. Well-Being

We are seeking input on a quality measure concept of well-being. Well-being is a comprehensive approach to

disease prevention and health promotion, as it integrates mental, social, and physical health while emphasizing preventative care to proactively address potential health issues.¹⁶ This comprehensive approach emphasizes person-centered care by promoting well-being of patients and their family members. We are seeking comments on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, fulfillment, and self-care.

4. Nutrition

Finally, we are seeking input on a quality measure concept of nutrition. Assessment for nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. This also includes aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventable care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual’s health and nutritional needs. We are seeking feedback on tools and frameworks that promote healthy eating habits, exercise, nutrition, or physical activity for optimal health, well-being, and best care for all.

TABLE 33: MEASURE CONCEPTS UNDER CONSIDERATION FOR FUTURE YEARS OF THE HH QRP

Quality Measure Concepts
Interoperability
Cognitive Function
Well-being
Nutrition

¹² 21st Century Cures Act, 42 U.S.C. 300jj(9) (2016).

¹³ 21st Century Cures Act, 42 U.S.C. 300jj(9) (2016).

¹⁴ Centers for Medicare & Medicaid Services. Long-Term Care Hospital Continuity Assessment

Record and Evaluation (CARE) Data Set Version 5.0. Effective October 1, 2022. <https://www.cms.gov/files/document/lth-care-data-set-version-50-planned-discharge-final.pdf>.

¹⁵ Based on home health episodes ending in CY2021 (the most recent year for which complete data are available).

¹⁶ Well-Being Concepts. CDC Archives. *WHPL_Canon_WB_Well-Being_Concepts_HRQOL_CDC_2017.pdf*.

We intend to use this input to inform our future measure development efforts.

J. Potential Revision of the Final Data Submission Deadline Period From 4.5 Months to 45 Days—Request for Information (RFI)

Section 1895(b)(3)(B)(v)(I) of the Act states that for 2007 and each subsequent year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points if a home health agency does not submit quality data to the Secretary in accordance with subclause (II) for such a year. 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 is not 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.

In the process of implementing the public reporting programs, CMS has become concerned that the time between when data are collected and when the measures are reported from

those data may be too long to get the desired results in a public reporting program. Public reporting programs are designed to provide patients and their families with the most current information so they can make quality-informed decisions about where to receive their care. Currently, the largest contributing factor to the 9-month lag between end of the data collection and when measures are publicly reported is the current 4.5-month timeframe for data submission. If the timeframe for data submission was reduced from 4.5 months to 45 days, the lag time between collection and reporting could be reduced by up to 3 months. This would result in more timely public reporting that would be more valuable for patients and families as they make decisions about where they can receive the best care.

An important consideration in reducing the data submission timeframe is the potential burden it may place on providers, which could lead to lower quality data. CMS conducted analysis to evaluate the potential impact of reducing the timeframe by determining how many charts are being submitted by 60 days currently. Using 2022 data, CMS found that only 1.3 percent of all OASIS assessments were submitted after the 60-day timeframe. Of those submissions, only three-quarters (or 0.9 percent of the total) were submitted between 60 days and 4.5 months and hence have potential to be impacted. Because assessments are tied to payment, providers are likely to submit assessments close to the date of service and to close out medical records once the patient is discharged from service. Therefore, we believe that by reducing this deadline from 135 days to 45 days, we can reduce the time between data collection and public reporting resulting in the improvement in timeliness with limited change in burden to providers.

We are requesting feedback on this potential future reduction of the HH QRP data submission deadline from 4.5 months to 45 days. Specifically, we are requesting comment on the following:

- How this potential change could improve the timeliness and actionability of HH QRP quality measures.
- How this potential change could improve public display of quality information.
- How this potential change could impact HHA workflows or require updates to Systems.

We intend to use this input to inform our program improvement efforts.

K. Advancing Digital Quality Measurement in the HH QRP—Request for Information

As part of our effort to advance the digital quality measurement (dQM) transition, we are issuing this request for information (RFI) to gather broad public input on the dQM transition in HHAs.

1. Background

We are committed to improving healthcare quality through measurement, transparency, and public reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health information technology (IT) that enables information exchange using Fast Healthcare Interoperability Resources® (FHIR®) standards. Proposing to require the use of such technology within the HH QRP in the future could potentially enable greater care coordination and information sharing, which is essential for delivering high-quality, efficient care and better outcomes at a lower cost. In the CYs 2022 and 2023 HH PPS proposed rules,¹⁷ we outlined several HHS initiatives aimed at promoting the adoption of interoperable health IT and facilitating nationwide health information exchange. Further, to inform our digital strategy, in the CY 2022 HH PPS proposed rule (86 FR 35980) we shared and sought feedback on the following:

- Our intent to explore the use of FHIR®-based standards to exchange clinical information through application programming interfaces (APIs).
- Enabling quality data submission to CMS through our internet Quality Improvement and Evaluation System (QIES).
- To work with healthcare standards organizations to ensure their standards support our assessment tools.

We are considering opportunities to advance FHIR®-based reporting of patient assessment data for the submission of the OASIS. Our objective is to explore how HHAs typically integrate technologies with varying complexity into existing systems and how this affects HH workflows. In this RFI, we seek to identify the challenges and/or opportunities that may arise during this integration, and determine the support needed to complete and submit quality data in ways that protect and enhance care delivery.

We are also seeking input on future measures under consideration including applicability of interoperability as a

¹⁷ “Advancing Health Information Exchange” in the CY 2022 HH PPS proposed rule (86 FR 35979) and CY 2023 HH PPS proposed rule (87 FR 37602).

future measure concept in post-acute care settings. We refer readers to section III.H.1. of this proposed rule for more information.

Any updates specific to the HH QRP program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

2. Solicitation of Comment

We seek feedback on the current state of health IT use, including electronic health records (EHRs), in HHAs:

- To what extent does your HHA use health IT systems to maintain and exchange patient records?
- If your agency has transitioned to using electronic records, in part or in whole, what types of health IT does your HHA use to maintain patient records? Are these health IT systems certified under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program? If your agency uses health IT products or systems that are not certified under the ONC Health IT Certification Program, please specify. Does your agency use EHRs or other health IT products or systems that are not certified under the ONC Health IT Certification Program? If no, what is the reason for not doing so? Do these other systems exchange data using standards and implementation specifications adopted by HHS? Does your agency maintain any patient records outside of these electronic systems? If so, are the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems and providers?
- Does your HHA submit patient assessment data to CMS through your current health IT system? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your agency currently exchange health information with other healthcare providers or systems, specifically between HHAs and other provider types? What about health information exchange with other entities, such as public health agencies? What challenges do you face with electronic exchange of health information?
- Are there any challenges with your current electronic devices (for example, tablets, smartphones, computers) that hinder your ability to achieve interoperability, such as collecting, storing, sharing, or submitting data? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other

healthcare providers, including community-based care services, or your ability to submit patient assessment data to CMS? Please specify.

- What steps does your HHA take with respect to the implementation of health IT systems to ensure compliance with security and patient privacy requirements such as HIPAA?
- Does your HHA refer to the Safety Assurance Factors for EHR Resilience (SAFER) Guides (see newly revised versions published in January 2025 at <https://www.healthit.gov/topic/safety/safer-guides>) to self-assess EHR safety practices?
- What challenges or barriers does your agency encounter when submitting quality measure data to CMS as part of the HH QRP? What opportunities or factors could improve your agency's successful data submission to CMS?
- What types of technical support, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR®-based technology in your agency for the submission of the OASIS to CMS? What strategies can CMS, HHS, or other Federal partners take to ensure that technical assistance is both comprehensive and user-friendly? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?
- Is your agency using technology that utilizes APIs based on the FHIR® standard to enable electronic data sharing? If so, with whom are you sharing data using the FHIR® standard and for what purpose(s)? For example, have you used FHIR® APIs to share data with public health agencies? Does your agency use any Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR® applications? If so, are the SMART on FHIR®¹⁸ applications integrated with your EHR or other health IT?
- How do you anticipate the adoption of technology using FHIR®-based APIs to facilitate the reporting of patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?
- Does your facility have any experience using technology that shares electronic health information using one or more versions of the United States Core Data for Interoperability (USCDI) standard?¹⁹
- Would your HHA and/or vendors be interested in participating in testing

to explore options for transmission of assessments, for example testing the transmission of a FHIR®-based assessment to CMS?

- The Trusted Exchange Framework and Common Agreement™ (TEFCA™) framework supports nationwide health information exchange by connecting health information networks (HINs) across the country.²⁰ Additionally, TEFCA™ facilitates FHIR exchange by requiring Qualified HINs (QHINs) to perform patient discovery for those querying for data and providing data holders with FHIR endpoints to enable point-to-point exchange via FHIR APIs. How could the TEFCA™ support CMS quality programs' adoption of FHIR®-based assessment submissions consistent with the FHIR® Roadmap (available here: <https://rce.sequoia-project.org/three-year-fhir-roadmap-for-tefca/>)? How might patient assessment data hold secondary uses for treatment or other TEFCA™ exchange purposes?
- What other information should we consider that could facilitate successful adoption and integration of FHIR®-based technologies and standardized data for patient assessment instruments like the OASIS? We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

While we would not be responding to specific comments in response to this RFI in the CY 2026 HH PPS final rule, we invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies and would use this input to inform our future dQM transition efforts.

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

We are not proposing any new policies regarding Form, Manner, and Timing of Data Submission Under the HH QRP in this proposed rule.

M. Policies Regarding Public Display of Measure Data for the HH QRP

1. Proposal To End the Public Display of Patient/Resident COVID-19 Measure

In the CY 2024 HH PPS final rule (88 FR 77762 through 77764), we finalized our proposal to begin publicly displaying data for the Patient/Resident COVID-19 measure beginning with the January 2026 Care Compare refresh. In section III.C.2, we are proposing to remove the Patient/Resident COVID-19 Measure beginning with the CY 2026

¹⁸ <https://smarthealthit.org/>.

¹⁹ For more information about USCDI see <https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi>.

²⁰ For more information about TEFCA™, see <https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca>.

HH QRP. However, if finalized as proposed, effective with assessments completed on or after the date of publication of the CY 2026 HH final rule, the data from O0350 Patient's COVID-19 Vaccination is Up to Date may be submitted using any of the three valid responses (0—No, 1—Yes, or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications.

We propose that the Patient/Resident COVID-19 measure rates would be publicly reported for the last time with the January 2026 Care Compare refresh on Medicare.gov, based on data from Q1 of 2025. We invite public comments on our proposal to end the public display of Patient/Resident COVID-19 Measure data after the January 2026 Care Compare refresh on Medicare.gov.

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

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), 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.

The original Model resulted in an average 4.6 percent improvement in HHAs' total performance scores (TPS) and an average annual savings of \$141 million to Medicare without evidence of adverse risks.²¹ The evaluation of the original Model also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) stays, resulting in reductions in inpatient and SNF spending. The U.S. Secretary of Health and Human Services (the Secretary) determined that expansion of the original Model will further reduce Medicare spending and improve the quality of care. In October 2020, the CMS Chief Actuary certified that

expansion of the HHVBP Model will produce Medicare savings if expanded to all states.²²

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.²³ 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. The first payment year is CY 2025 based on the first performance year which was CY 2023. 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.

In the CY 2024 HH PPS final rule (88 FR 77676), we finalized proposals to codify in the Code of Federal Regulations (CFR) the measure removal factors finalized in the CY 2022 HH PPS final rule; to replace the two Total Normalized Composite Measures (for Self-Care and Mobility) with the Discharge Function Score measure effective January 1, 2025; to replace the OASIS-based Discharge to Community (DTC) measure with the claims-based Discharge to Community-Post Acute Care (PAC) Measure for Home Health Agencies, effective January 1, 2025; to replace the claims-based Acute Care Hospitalization During the First 60 Days of Home Health Use and the Emergency Department Use without Hospitalization During the First 60 Days of Home Health measures with the claims-based Potentially Preventable Hospitalization measure effective January 1, 2025; to change the weights of individual measures due to the change in the total number of measures; and to update the Model baseline year to CY 2023 for all applicable measures in the finalized measure set beginning with performance year CY 2025.

B. Proposed Changes to HHVBP Measure Removal Factors

In the CY 2023 HH PPS final rule (88 FR 77776), CMS finalized the codification of specific factors that CMS considers for measure removal. Currently, there are eight measure removal factors that CMS considers when determining whether to remove measures from the expanded HHVBP

Model's applicable measure set. We are proposing to add and codify an additional measure removal factor at § 484.358, Factor 9: It is not feasible to implement the measure specifications.

This proposed new measure removal factor will enable CMS to address situations in which it is no longer feasible to continue implementing a quality measure, such as when a data collection instrument is revised in a way that no longer collects the information required for the quality measure specifications.

We invite public comments on this proposal.

C. Proposed Changes to the Expanded HHVBP Model's Applicable Measure Set

We are proposing to remove three measures from the current applicable measure set and add four measures starting in CY 2026. The removal of the three measures is necessary due to revisions to the HHCAHPS Survey that are proposed beginning with the April 2026 sample. These proposed survey revisions prevent the three HHCAHPS Survey-based measures from being calculated as currently specified. These measures will only be removed if the proposed changes to the HHCAHPS Survey are finalized.

1. Proposed Removal of Three HHCAHPS Survey-Based Measures From the Expanded HHVBP Model Applicable Measure Set

The Home Health Consumer Assessment of Healthcare Providers and System® (HHCAHPS) Survey, a nationally standardized and publicly reported survey, is designed to measure the experiences of people receiving home health care from Medicare-certified home health agencies. It is conducted for home health agencies by approved HHCAHPS Survey vendors. Currently, the expanded HHVBP Model includes five HHCAHPS Survey-based measures:

- Care of Patients
- Communications between Providers and Patients
- Specific Care Issues
- Overall Rating of Home Health Care
- Willingness to Recommend the Agency

The Care of Patients, Communications between Providers and Patients, and Specific Care Issues measures are based on multiple items from the HHCAHPS Survey while Overall Rating of Home Health Care and Willingness to Recommend the Agency are single-item measures.

Elsewhere in this proposed rule, the Center for Medicare (CM) is proposing

²¹ <https://innovation.cms.gov/data-and-reports/2020/hhvp-thirdann-rpt>.

²² <https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvp-model.pdf>.

²³ <https://www.cms.gov/newsroom/press-releases/cms-takes-action-improve-home-health-care-seniors-announces-intent-expand-home-health-value-based>.

changes to the HHCAHPS survey. These proposed changes will affect the survey questions used to calculate three measures that are used in the expanded HHVBP Model. CM plans to make changes to the questions used for two of the multi-item measures (Care of Patients and Communication between Providers and Patients). In addition, the Specific Care Issues measure will no longer exist as four of the seven items used for that measure will be removed from the survey. These changes are described in section III.H. of this proposed rule, and if finalized, will become effective in beginning with the April 2026 sample month.

Given these proposed changes, we propose to remove the following HHCAHPS Survey-based measures from the HHVBP applicable measure set starting with CY 2026:

- Care of Patients
- Communications between Providers and Patients
- Specific Care Issues

We propose to remove these three HHCAHPS Survey-based measures using the proposed Removal Factor 9: It is not feasible to implement the measure specifications. This proposed measure removal factor is described in more detail above. The proposed removal of these measures will be necessary if the proposed changes to the HHCAHPS Survey instrument are finalized, as the current measure specifications cannot be calculated using the proposed survey revisions. If the proposed changes to the HHCAHPS Survey instrument are finalized, several of the survey questions used to calculate the Care of Patients and Communication Between Providers and Patients measures will be changed and will no longer match the measure specifications. Also, four of the seven survey items used to calculate the Specific Care Issues measure would be removed if the survey changes are finalized, making it impossible to calculate the measure as currently specified.

While CMS could revise the HHCAHPS measures to use the proposed HHCAHPS Survey instrument changes, a full year of data with the revised HHCAHPS measures will not be available until CY 2027. Data from multiple quarters will be needed to establish benchmarks and achievement thresholds for the revised HHCAHPS Survey-based measures. Removing these three measures as part of this rulemaking cycle will give CMS the time needed to collect the required data and potentially develop updated benchmarks and achievement thresholds for revised or new measures.

If CMS decides to propose the addition of the new versions of the Care of Patients and Communications between Providers and Patients measures and individual item measures to replace the Specific Care Issues measure, CMS will do so through future rulemaking.

2. Proposed Addition of Medicare Spending Per Beneficiary Post-Acute Care (MSPB–PAC) to the Expanded HHVBP Model Applicable Measure Set

We propose to add the claims-based MSPB–PAC measure to the HHVBP applicable measure set starting in CY 2026. This cross-setting 2-year measure was required by the Improving Post-Acute Care Transformation Act of 2014 (IMPACT Act) and was added to the Home Health Quality Reporting Program on January 1, 2017.

Public comments on the CY 2025 HH PPS proposed rule (89 FR 88354) in support of adding this measure to the expanded HHVBP Model suggested that the MSPB–PAC measure could help to identify the costs associated with the delivery of high-quality home health services, which could identify areas for improved efficiencies in resource usage.

The MSPB–PAC measure is intended to incentivize providers to redesign care systems to provide coordinated, high-quality, and cost-efficient care. It holds HHAs accountable for Medicare payments for an episode of care that includes the period during which a patient is directly under HHA care, as well as a defined period after the end of HHA treatment, which may be reflective of and influenced by the services provided by the HHA. Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. In conjunction with the other performance measures used in the expanded HHVBP Model, explicit measurement of costs of care will allow recognition of HHAs that provide high quality care at a lower cost.

We anticipate that adding the MSPB–PAC measure will create incentives for greater care coordination to deliver high-quality care at a lower cost to Medicare and incentivize providers to find efficient ways to address patients' care needs. Incentivizing efficient resource utilization aligns with the pay-for-performance approach used in the expanded HHVBP Model. The MSPB–PAC measure would ensure that HHVBP payment adjustments consider not only patient outcomes but also HHA's ability to produce those outcomes at a lower cost.

The MSPB–PAC measure is a claims-based measure that includes price-standardized payments for Part A and Part B services. It measures Medicare spending during an episode of care relative to the Medicare spending for other home health agencies. The Medicare spending measure is payment standardized and risk adjusted. The MSPB–PAC measure captures Medicare spending for most Part A and B services during the episode of care, excluding services that are clinically unrelated to post-acute care treatment or services over which home health agencies may have limited to no influence (for example, routine management of certain preexisting chronic conditions). The episode of care window consists of a treatment period and an associated services period (from the admission to the home health services up to 30 days after the end of the home health treatment period). The episode includes the period a patient is directly under HHA care, as well as a defined period after the end of the HHA's treatment which may be reflective of and influenced by the services rendered by the HHA.²⁴

If this measure is finalized as proposed, we anticipate reporting preliminary benchmarks, achievement thresholds, and improvement thresholds for the MSPB–PAC measure in the October 2025 Interim Performance Reports (IPR). The MSPB–PAC measure will use 2 years of data covering CY 2022 and CY 2023 as baseline data. Because the MSPB–PAC measure is a two-year measure, CY 2026 performance for the measure will be calculated based on 2 years of performance data (CY 2025/2026). The MSPB–PAC measure was designed as a 2-year measure to optimize reliability. In addition, each performance year will consist of 1 year of data that does not overlap with data from the prior performance year, which provides sufficient opportunity to capture quality improvement over time.

Adding the MSPB–PAC and function measures described below will increase the number of HHAs that have sufficient data for at least five measures, the minimum required to have a payment adjustment for the expanded HHVBP Model. Increasing the number of HHAs that receive payment adjustments will allow the Model to better incentivize high-quality home health care across the country.

²⁴ See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/2016_07_20_mspb_pac_ltr_inf_snf_measure_specs.pdf for more details on the specifications for the MSPB–PAC measure.

3. Proposed Addition of OASIS-Based Function Measures to the Expanded HHVBP Model Applicable Measure Set

We propose adding three OASIS-based function measures to the HHVBP applicable measure set beginning with CY 2026:

- Improvement in Bathing (based on OASIS item M1830)
- Improvement in Upper Body Dressing (based on OASIS item M1810)
- Improvement in Lower Body Dressing (based on OASIS item M1820)

These measures are intended to complement the Discharge (DC) Function Score measure added to the HHVBP applicable measure set starting with CY 2025 to provide a more holistic picture of patients' functional status. The DC Function Score measure uses a cross-setting function item set which does not include items related to bathing or dressing.

These three measures have already been tested, validated, and implemented for other purposes within CMS models and programs. Improvement in Bathing is used in the Home Health Quality Reporting Program, the Home Health Quality of Patient Star Rating system, and reported on Care Compare. All three of the OASIS items underlying these measures were also used in the Total Normalized Change (TNC) in Self-Care measure that were part of the CY 2023 and CY 2024 expanded HHVBP Model applicable measure set. Additionally, the underlying OASIS M1800 items are used in the Home Health Patient-Driven Groupings Model that is used for Medicare home health payments. Therefore, adding these measures to the expanded HHVBP Model would align with existing quality measurement and payment practices. Adding these measures would not create additional burden to HHAs, as the data for these measures is already collected on OASIS assessments.

In the CY 2024 HH PPS final rule (88 FR 77676), CMS finalized the decision to add the DC Function Score measure to replace the previous OASIS-based TNC measures (TNC Self-Care and TNC Mobility). That change aligned the expanded HHVBP Model with other PAC quality programs. The DC Function Score measure is an OASIS-based measure that is used in the HH QRP and the expanded HHVBP Model starting in CY 2025. This measure reports the percentage of patients who meet or exceed an expected discharge function score during the reporting period. The DC Function Score measure considers two dimensions of patient function—

self-care and mobility activities—using 13 OASIS items.²⁵

The Model's Technical Expert Panel (TEP) has raised concerns that the DC Function Score measure does not consider bathing or dressing abilities, as these items are not available across all PAC settings covered by this cross-setting measure. TEP members identified the ability to bathe and dress as being critically important for home health patients. Many patients who receive home health care are recovering from an injury or illness and may have difficulty performing the tasks of bathing and dressing, requiring help from another person or special equipment to accomplish these activities. Improving patients' ability to bathe themselves contributes to patient comfort and quality of life and is often a rehabilitative goal for home health patients. These metrics also promote safer discharges from home care. Improvement in both upper and lower body dressing are important indicators of usefulness and improvement for patients, as well as indicators of being able to stay home, care for themselves, and be independent.

In 2024, TEP members supported CMS moving ahead as quickly as possible to add bathing and dressing function measures to the Model's applicable measure set to complement the DC Function measure. The TEP recommended using existing measures based on the OASIS M1800 items, which could be added sooner than future measures based on Section GG items.²⁶

The baseline data for these three measures will cover CY 2023, which was specified as the Model baseline year in the CY 2024 HH PPS final rule. This baseline data will be used to calculate benchmarks and achievement thresholds for the proposed OASIS-based function measures. If these three measures are finalized as proposed, we anticipate providing HHAs with the benchmarks, achievement thresholds, and improvement thresholds for the OASIS-based function measures in the October 2025 IPRs.

²⁵ These OASIS items and activities include GG0130 Self-Care, GG0130A Eating, GG0130B Oral hygiene, GG0130C Toileting hygiene, GG0170 Mobility, GG0170A Roll left and right, GG0170C Lying to sitting on side of bed, GG0170D Sit to stand, GG0170E Bed-to-chair transfer, GG0170F Toilet transfer, GG0170I Walk 10 feet, GG0170J Walk 50 feet with two turns, GG0170R Wheel 50 feet with two turns.

²⁶ The Section GG items were added to patient assessment tools for home health, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals to support alignment of measurement of functional abilities and goals across post-acute care assessment instrument.

Adding these three measures would increase the number of OASIS-based measures used in the Model, allowing for more robust measurement of HHA performance. The change will also allow more HHAs to have sufficient data for at least five measures, the minimum required to calculate a payment adjustment. HHAs that receive payment adjustments will have greater incentives to improve or maintain quality of care.

4. Updates to Individual Measure Weights and Category Weights

Along with the proposed revisions to the current HHVBP applicable measure set, we propose to revise the weights of the individual measures starting with the CY 2026 performance year as well as to the measure category weights. Table 34 has current and proposed individual measure weights and category weights.

Changes to the measure weights are necessary given the proposed changes to the expanded HHVBP Model applicable measure set. Reflecting the reduction in the number of HHCAHPS Survey-based measures, the proposed weights include a lower total weight for the HHCAHPS Survey-based measures and a higher weight for the OASIS-based and claims-based measures. In addition, some of the weight for the current claims-based measures is shifted to the MSPB-PAC measure and some weight for the OASIS-based measures is shifted to the additional function measures. As with the current measure weights, higher weight is given to claims-based measures because they may have a greater impact on reducing Medicare expenditures. For example, HHAs with better performance scores on the claims-based PPH measure have lower rates of potentially preventable hospitalizations for their patients, reducing Medicare expenditures.

Currently, the OASIS-based, claims-based, and HHCAHPS Survey-based measures contribute 35 percent, 35 percent, and 30 percent, respectively, to the Total Performance Score (TPS) for HHAs in the larger-volume cohort. We propose adjusting the measure category weights for the larger-volume cohort such that the OASIS-based and claims-based measure categories each contribute 40 percent, and the HHCAHPS Survey-based measure category contributes 20 percent to the TPS due to the reduction in the number of individual HHCAHPS Survey-based measures. For HHAs in the smaller-volume cohort, the OASIS-based and claims-based measures both contribute 50 percent to the TPS. We do not propose changing the measure category weights for the smaller-volume cohort

as the HHCAHPS measures are not used for the smaller-volume cohort.

As proposed, changes to the applicable measure set would increase the number of OASIS-based measures from three measures to six and increase

the number of claims-based measures from two to three. The number of individual measures for the HHCAHPS Survey-based measures would decrease from five to two. Note that we have changed weights for measures and

measure categories in the past due to changes to the applicable measure set (for example, replacing the two TNC measures with the DC Function Score measure).

TABLE 34--CY 2025 AND PROPOSED INDIVIDUAL MEASURE WEIGHTS AND CATEGORY WEIGHTS FOR THE EXPANDED HHVBP MODEL

Measure	CY 2025 Measure Weights		Proposed Measure Weights	
	Larger-Volume Cohort	Smaller-Volume Cohort	Larger-Volume Cohort	Smaller-Volume Cohort
Improvement in Dyspnea	6.00%	8.57%	7.00%	8.75%
Improvement in Management of Oral Medications	9.00%	12.86%	11.00%	13.75%
Discharge Function Score (DC Function)	20.00%	28.57%	15.00%	18.75%
Improvement in Bathing	-	-	3.50%	4.38%
Improvement in Upper Body Dressing	-	-	1.75%	2.19%
Improvement in Lower Body Dressing	-	-	1.75%	2.19%
Sum of OASIS-based Measures	35.00%	50.00%	40.00%	50.00%
Home Health within-stay Potentially Preventable Hospitalization (PPH)	26.00%	37.14%	15.00%	18.75%
Discharge to Community – Post Acute Care (DTC-PAC)	9.00%	12.86%	15.00%	18.75%
Medicare Spending Per Beneficiary- Post-Acute Care (MSPB-PAC)	-	-	10.00%	12.50%
Sum of Claims-based measures	35.00%	50.00%	40.00%	50.00%
Care of Patients	6.00%	0.00%	-	-
Communication Between Providers and Patients	6.00%	0.00%	-	-
Specific Care Issues	6.00%	0.00%	-	-
Overall Rating of Home Health Care	6.00%	0.00%	10.00%	0.00%
Willingness to Recommend the Agency	6.00%	0.00%	10.00%	0.00%
Sum of HHCAHPS Survey-based measures	30.00%	0.00%	20.00%	0.00%
Sum of All Measures	100.00%	100.00%	100.00%	100.00%

5. Alternatives Considered

We considered two alternative options for revising the HHVBP measure weights prior to choosing the previously discussed proposals. Table 35 describes these alternative options for HHAs in the larger-volume cohort, including

maintaining measure category weights consistent with current measure set weights and adjusting within-category measure weights (Option 1), reducing the HHCAHPS-based measure category weight to 20 percent (Option 2), and maintaining HHCAHPS-based measure weights consistent with current measure

set weights, adjusting measure category weights accordingly (Option 3). We also considered these options for the smaller-volume cohort and came to the same conclusions. Therefore, we only provided a table with measure weighting alternatives for the larger-volume cohort.

TABLE 35 - ALTERNATIVE INDIVIDUAL MEASURE WEIGHTS AND CATEGORY WEIGHTS CONSIDERED FOR THE EXPANDED HHVBP MODEL

Measure	Option 1	Option 2	Option 3
	Maintain Category Weights	Reduce HHCAHPS Category Weight	Maintain Individual HHCAHPS Measure Weights
Improvement in Dyspnea	6.13%	7.00%	7.70%
Improvement in Management of Oral Medications	9.63%	11.00%	12.10%
Discharge Function Score (DC Function)	13.13%	15.00%	16.50%
Improvement in Bathing	3.06%	3.50%	3.85%
Improvement in Upper Body Dressing	1.53%	1.75%	1.93%
Improvement in Lower Body Dressing	1.53%	1.75%	1.93%
Sum of OASIS-based Measures	35.00%	40.00%	44.00%
Home Health within-stay Potentially Preventable Hospitalization (PPH)	18.00%	20.00%	16.50%
Discharge to Community – Post Acute Care (DTC-PAC)	8.50%	10.00%	16.50%
Medicare Spending Per Beneficiary- Post-Acute Care (MSPB-PAC)	8.50%	10.00%	11.00%
Sum of Claims-based measures	35.00%	40.00%	44.00%
Overall Rating of Home Health Care	15.00%	10.00%	6.00%
Willingness to Recommend the Agency	15.00%	10.00%	6.00%
Sum of HHCAHPS Survey-based measures	30.00%	20.00%	12.00%
Sum of All Measures	100.00%	100.00%	100.00%

We determined that these alternatives would be less consistent with previous decisions about applying differential weights to measures, and therefore these alternatives were not proposed.

We seek comments on these proposals.

D. HHVBP Quality Measure Concepts Under Consideration for Future Years—Request for Information

The expanded HHVBP Model provides an opportunity to examine a broad array of quality measures that address critical gaps in care. A comprehensive review of the Value-Based Purchasing (VBP) experience, conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), identified several objectives for HHVBP measures.²⁷ The recommended objectives emphasize measuring patient outcomes and functional status; appropriateness of care; and incentives for providers to build infrastructure to facilitate measurement within the quality framework. The study identified the following seven objectives which served as guiding principles for the development of performance measures used in the original Model:

- Use a broad measure set that captures the complexity of the HHA service provided.

- Incorporate the flexibility to include Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 measures that are cross-cutting amongst post-acute care settings.

- Develop second-generation measures of patient outcomes, health and functional status, shared decision making, and patient activation.
- Include a balance of process, outcome, and patient experience measures.
- Advance the ability to measure cost and value.
- Add measures for appropriateness or overuse.
- Promote infrastructure investments.

A central driver of the process used to select measures for the original Model was incorporating innovative thinking from the field while simultaneously drawing on evidence-based literature and documented best practices. Broadly, measures were selected based on their impact on care delivery and to support the goal of improving health outcomes, quality, safety, efficiency, and experience of care for patients.

As we continue to leverage our value-based purchasing initiatives to improve the quality of care furnished across healthcare settings, we are interested in considering new performance measures for inclusion in the expanded HHVBP Model. We specifically request public comments on one specific performance measure as well as general comments on other potential future model concepts that may be considered for inclusion in the expanded HHVBP Model. We encourage stakeholders to consider how

to reduce burden on HHVBP Model participants without compromising the quality of care when responding to the Deregulation RFI in the **SUPPLEMENTARY INFORMATION** section of this proposed rule.

1. Falls With Major Injury Measure (OASIS-Based and Claims-Based)

Within the home health population, approximately one third of individuals over the age of 65 experience one or more falls each year^{28 29}). Since 2022, CMS has reported rates for the Falls with Major Injury (FMI) measure on Care Compare. This measure is based on OASIS data.

A recent study³⁰ found that more than half of falls with a major injury (identified using Medicare claims data) were not reported on OASIS assessments. OIG observed that a low fall rate reported on Care Compare may

²⁸ Avin KG, Hanke TA, Kirk-Sanchez N, McDonough CM, Shubert TE, Hardage J, Hartley G; Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Management of falls in community-dwelling older adults: clinical guidance statement from the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. *Phys Ther.* 2015 Jun;95(6):815–34. doi: 10.2522/ptj.20140415. Epub 2015 Jan 8. PMID: 25573760; PMCID: PMC4757637.

²⁹ Carande-Kulis V, Stevens JA, Florence CS, Beattie BL, Arias I. A cost-benefit analysis of three older adult fall prevention interventions. *J Safety Res.* 2015 Feb;52:65–70. doi: 10.1016/j.jsr.2014.12.007. Epub 2015 Jan 6. PMID: 25662884; PMCID: PMC6604798.

³⁰ <https://oig.hhs.gov/reports/all/2023/home-health-agencies-failed-to-report-over-half-of-falls-with-major-injury-and-hospitalization-among-their-medicare-patients/>.

²⁷ U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2014). *Measuring Success in Health Care Value-Based Purchasing Programs*. Cheryl L. Damberg et al. on behalf of RAND Health.

reflect a provider's lack of falls reporting, rather than a low incidence of falls among its patients. OIG further observed that HHAs with low falls with major injury rates on Care Compare were more likely than other HHAs not to report falls among patients enrolled in Medicare. These findings raised concerns about the accuracy of this measure. In response to this OIG study, CMS is currently working on a respecified version of the FMI measure that uses fee-for-service claims, encounter data, and OASIS data. Using multiple data sources will produce a more robust and complete data set, allowing the respecified FMI measure to be more accurate and include more providers. Members of the Post-Acute Care (PAC) and Home Health Cross-Setting TEP also broadly agreed that data accuracy is vitally important for the measure's aim of making cross-provider comparisons.

In addition, the respecified FMI measure includes other injuries not explicitly covered in the OASIS-based FMI measure, which uses a specific measure of falls with major injury that includes only bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematomas.

We request comments related to the potential addition of the respecified FMI measure to the measure set for the expanded HHVBP Model.

2. Potential Future Changes to HHCAHPS Scoring Rules and Applicable Measure Set

We seek public comments regarding two potential changes to the HHCAHPS Survey-based measures scoring rules and applicable measure set as they relate to the expanded HHVBP Model:

a. Measuring HHA Performance on Forthcoming HHCAHPS Items Based Only on HHA Achievement

As discussed previously within this proposed rule, CMS anticipates proposing new HHCAHPS Survey-based measures to replace the Care of Patients, Communication Between Providers and Patients, and Specific Care Issues measures through future rulemaking. These revised HHCAHPS Survey-based measures will be based on data collected from the revised HHCAHPS Survey instrument. Data for these revised measures will be required to establish benchmarks and achievement thresholds. CMS will require 1 year of data to establish appropriate benchmarks and achievement thresholds for measuring HHAs' level of performance. By contrast, CMS will require 2 years of data to measure

improvement over time and establish improvement thresholds.

Therefore, CMS seeks public comments on the possibility of initially measuring HHA performance on the future HHCAHPS Survey-based measures based solely on achievement, rather than both achievement and improvement. This would allow CMS to potentially begin using the revised HHCAHPS measures in the expanded HHVBP Model starting with the CY 2028 performance year. If CMS proposes adding the achievement-based HHCAHPS Survey-based measures to the expanded HHVBP Model starting with the 2028 performance year, then benchmarks and achievement thresholds would be published in 2027, using data from 2026.

After sufficient data are available to develop appropriate improvement thresholds, CMS anticipates measuring HHA performance on these HHCAHPS Survey-based measures based on both achievement and improvement. This change would be proposed through future rulemaking.

b. Adding to the Applicable Measure Set for the Expanded HHVBP Model the Three Remaining Items in the Specific Care Issues Measure as Single Item Measures

As discussed previously, CM proposes to modify the HHCAHPS Survey instrument. Among other changes, this proposal would remove several items used in the multi-item Specific Care Issues measure. Three of the items used in the Specific Care Issues measure will remain in the HHCAHPS Survey instrument. The three items from the Specific Care Issues measure included in the revised HHCAHPS Survey instrument are as follows:

- When you first started getting home health care from this agency, did someone from the agency talk about ways to help make your home safer? For example, they may have suggested adding grab bars in the shower or removing tripping hazards.
- Has someone from the agency ever reviewed the prescribed and over-the-counter medicines you were taking? For example, they might have asked you to show them your medicines and talked with you about how and when to take each one.
- In the last 2 months of care, did home health staff from this agency talk with you about any side effects of your medicines?

CMS seeks public comments on the possibility of adding these three remaining HHCAHPS Survey items to the expanded HHVBP Model as single-

item measures. We also seek public comments on the possibility of giving each of these single item measures a weight of one third the weight of the other HHCAHPS items, thus maintaining the same relative weight of the Specific Care Issues measure.

V. Updates to the Home Health Agency Conditions of Participation (CoPs) To Align With the OASIS All-Payer Submission Requirements

A. Statutory Authority and Background

Section 1891(d) of the Act, cross-referencing section 1891(c)(2)(C)(i)(I) of the Act (section 4021(b) of Pub. L. 100–203 (December 22, 1987)) required the Secretary to develop a comprehensive assessment for Medicare-participating HHAs. In 1993, CMS (then known as Health Care Financing Administration (HCFA)) developed an assessment instrument that identified each patient's need for home care and the patient's medical, nursing, rehabilitative, social and discharge planning needs. As part of this assessment, Medicare-certified HHAs were required to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS). As part of the home health assessment, the statute requires a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care provided by the HHA. OASIS is the designated assessment instrument for use by an HHA in complying with the requirement and HHAs must submit the data collected by the OASIS assessment to CMS as an HHA CoP (42 CFR part 484.45).

Section 704 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 12, 2003) “suspended” the legal authority of the Secretary to require HHAs to report non-Medicare and non-Medicaid patient data to CMS until at least two months after the Secretary published final regulations on CMS's collection and use of OASIS data following the submission of a report to Congress on the study required under section 704(c) of the MMA. Subsequently, CMS conducted the study from 2004 to 2005 and submitted a report to Congress in 2006 titled “The OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients—Report to Congress.” While the 2006 report recommended that the suspension continue, the passage of the Improving Medicare Post-Act Care Transformation

(IMPACT) Act (Pub. L. 113–115) in 2014 required CMS to create a uniform quality measurement system that allows CMS to compare outcomes across post-acute care (PAC) providers.

The final rule titled, “Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements” finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period (for example, July 1, 2025–June 30, 2026) (87 FR 66862). With the CY 2025 HH PPS final rule, CMS established that start of care (SOC) is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory period. CMS will use the M0090 “Date Assessment Completed” date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments in the phase-in and mandatory periods (89 FR 88439 through 88441). This ended the suspension of the OASIS data collection on non-Medicare and non-Medicaid HHA patients. As discussed in the CY 2025 HH PPS final rule (89 FR 88439–88441), the most accurate representation of the quality of care furnished by HHAs is best captured by calculating the assessment-based measures rates using OASIS data submitted on all HHA patients receiving skilled care, regardless of payer.

B. Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))

Section 484.45(a) of the HHA CoPs currently requires an HHA to encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. To align with the transition to OASIS all-payer submission requirements as outlined in the CY 2023 HH PPS final rule (87 FR 66790), we are proposing at § 484.45(a) to remove the term “beneficiary” and replace it with the term “patient.” Thus, § 484.45(a) would state, if finalized as proposed, that an HHA must encode and electronically transmit each completed OASIS assessment to the

CMS system, regarding each patient with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the patient.

All patients must receive, and an HHA must provide, a comprehensive assessment no later than 5 calendar days after the start of care. The comprehensive assessment not only examines patients’ current health, psychosocial, functional, and cognitive status, but also must incorporate the most current version of the OASIS data items. This includes clinical record items, patient history, supportive assistance, etc. Currently, the comprehensive assessment, including administration of OASIS, must be updated and revised as frequently as the patient’s condition warrants, but not less frequently than the last 5 days of every 60 days beginning with the start-date of care. Language at § 484.55(d)(1)(i) describes a “beneficiary elected transfer” in reference to one scenario in which an OASIS assessment would be updated. To support the transition to OASIS all-payer submission requirements, we are also proposing to remove the term “beneficiary” at § 484.55(d)(1)(i).

These technical changes to update terminology would further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language in the CoPs with the requirements finalized in the CY 2023 and CY 2025 HH PPS final rules. These updates to the CoPs do not propose any revisions to the specific requirements for submitting data to OASIS and does not have any bearing on the change to expand the data collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). We note that this policy does not change current patient exemptions for OASIS, which are as follows: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.

VI. Provider Enrollment, Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation Policies, and DMEPOS Prior Authorization

A. Provider Enrollment

1. Medicare Enrollment

a. Background

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 (for example, the Form CMS–855A (OMB control number 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 includes, but is not limited to, general identifying information (for instance, legal business name), licensure and/or certification data, and practice locations. The application is used for a variety of provider enrollment transactions, including all of 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 by keeping unqualified providers out of the Medicare program.

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 with this, and as we discuss in this section VI.A.1.c of this proposed rule, we propose several changes to our existing Medicare provider enrollment regulations.

(We note that section VI.A.2 of this proposed rule addresses a proposed change to one of our Medicaid provider enrollment provisions.)

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. Medicare Provider Enrollment Provisions

(1) Revocation and Denial Reasons and Revisions to Other Revocation Policies

(a) Revocations and Denials

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 instance, the provider's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS Office of Inspector General (OIG); (iii)

felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing; and (v) termination by another Federal health care program. A revocation is designed to safeguard the Medicare program, the Trust Funds, and beneficiaries by removing (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. The length of this "reenrollment bar" is determined based upon the severity of the basis of the revocation.

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, felony conviction, termination by another federal health care program). 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 new revocation and denial reasons to subpart P to address particular program integrity vulnerabilities and types of provider conduct. We have also used rulemaking to refine other policies regarding revocations, such as the effective dates of certain revocations. Given our continuing obligation to establish effective payment safeguards, we believe that several additions and revisions to our revocation and denial policies in subpart P are needed at this time.

(i) False or Misleading Information Revocation and Denial Ground (§§ 424.535(a)(4) and 424.530(a)(4))

Existing §§ 424.535(a)(4) and 424.530(a)(4) permit revocation or denial, respectively, if the provider or supplier certified as "true" misleading or false information on the enrollment application to be enrolled or maintain enrollment in Medicare. We propose to update § 424.510, which addresses certain general enrollment requirements, by adding new paragraph (d)(10). It would emphasize that all providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application. We have encountered situations where a provider has another individual complete an enrollment application on the provider's behalf (for example, officer manager). The

individual furnishes false or misleading information, and the provider (or, if applicable, the provider's authorized official) signs the application. The provider then later states it was not responsible for the submitted false data because the other person, not the provider, had furnished it. Such an assertion is incorrect. Our proposed revision would reiterate longstanding CMS policy that the enrolling provider bears ultimate legal responsibility for the accuracy and thoroughness of all data on the application. The provider cannot transfer this responsibility to another party even if the latter completed the application. To illustrate, the certification statement on the Form CMS-855I enrollment application (Medicare Enrollment Application—Physicians and Non-Physician Practitioners (NPP) (OMB control number 0938-1355)) requires the enrolling physician or NPP to attest and certify, under penalty of perjury, to meeting a number of Medicare requirements. These include, but are not limited to, that the physician or NPP—

- Has read the contents of the application, and that the information contained therein is true, correct, and complete;
- Has read and understands the Penalties for Falsifying Information, as printed in the application, and also understands that any omission, misrepresentation, or falsification of any information contained in the application or contained in any communication supplying information to Medicare may be punishable by criminal, civil, or administrative penalties; and
- Is indeed the physician or NPP applying for Medicare billing privileges and that the signature on the application is the physician's or NPP's.

Nothing in these attestations, nor anything in the enrollment applications or subpart P, indicates that a party other than the provider is responsible for the data in the application. It is, in the end, the provider's information, and the provider is certifying to its correctness, hence the reason for our proposed clarification.

(ii) Authority To Prescribe Drugs (§§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii))

Sections 424.535(a)(13)(ii) and 424.530(a)(11)(ii) permit CMS to revoke or deny a physician's or eligible professional's enrollment if the licensing or administrative body for any state where the individual practices suspends or revokes the person's ability to prescribe drugs. We have received questions regarding the term "prescribe

drugs”—specifically, whether the state’s prohibition: (1) must be for all drugs for § 424.535(a)(13)(ii) or § 424.530(a)(11)(ii) to potentially apply; or (2) need only apply to one drug. Our position has long been the latter, and we accordingly propose to revise §§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii) to change “prescribe drugs” to “prescribe one or more drugs.” Considering the seriousness of any state suspension or revocation action regarding an individual’s prescribing authority, we believe a prohibition involving even one drug is sufficient to warrant revocation or denial if we deem it necessary to protect beneficiaries and the Trust Funds.

(iii) Pattern or Practice of Prescribing (§ 424.535(a)(14))

We currently may revoke a physician’s or practitioner’s enrollment under § 424.535(a)(14) if the individual has a pattern or practice of prescribing Part B or D drugs that is abusive, threatens the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. The purpose of this authority is to protect Medicare beneficiaries and the Trust Funds against harmful and non-compliant prescribing practices, and since the provision’s inception we have revoked the enrollments of a number of practitioners who have engaged in such conduct.

Drugs associated with services covered under Part A presently do not fall within the purview of § 424.535(a)(14). This is of increasing concern to us. Although Part A does not cover many drugs that beneficiaries take at home or in outpatient facilities, it can cover drugs administered as part of an inpatient covered stay, such as at a hospital or a skilled nursing facility. We do not believe the important protections that § 424.535(a)(14) affords must be dependent on the setting in which the drugs were furnished. That is, it is the abusive or non-compliant prescribing itself, rather than the beneficiary’s location or inpatient or outpatient status, that is most critical for purposes of program integrity. Beneficiaries can be endangered by such prescribing during inpatient stays no less than in other environments. For these reasons, we believe that only by expanding § 424.535(a)(14) to include drugs associated with Part A services can we be better able to address all instances of abusive Medicare prescribing—irrespective of the type of Medicare coverage or setting involved—to help shield beneficiaries and taxpayer monies from such conduct. We accordingly propose to revise

§ 424.535(a)(14) to change “Part B or D drugs” to “Medicare-covered drugs” to encompass Medicare Parts B, D, and now A.

(iv) Certain Modifications to Provider Enrollment Paragraph References (§§ 424.535(a)(23) and 424.530(a)(18)) and Enrollment Provisions (§ 424.205))

Sections 424.535(a)(23) and 424.530(a)(18) allow CMS to revoke or deny, respectively, a provider’s or supplier’s enrollment if the provider or supplier violates certain conditions and standards pertaining to its provider or supplier type. One such supplier type is Medicare Diabetes Prevention Programs (MDPP). Aforementioned paragraphs (a)(23) and (a)(18) state, in part, that revocation or denial is permissible if an MDPP violates an enrollment condition or standard in § 424.205(b) or (d), respectively. Although paragraphs (a)(23) and (a)(18) only apply to enrollment conditions and standards, § 424.205 (which was established in 2017) contains several other enrollment-related provisions, such as grounds for revocation. Yet we have not updated the enrollment requirements in § 424.205 post-2017, since which time: (1) paragraphs (a)(23) and (a)(18) were promulgated (in 2023); and (2) there have been revisions to the organizational structure of § 424.205. To ensure that (a)(23), (a)(18), and § 424.205 accurately reflect current policy and paragraph designations, we propose changes to all three.

First, the MDPP enrollment standards are now in § 424.205(c) rather than § 424.205(d). We accordingly propose that references to paragraph (d) would be changed to paragraph (c) in the following regulatory provisions:

- § 424.535(a)(23)(v).
- § 424.530(a)(18)(v).
- Definition of “Coach eligibility end date” in § 424.205(a) (reference to (d)(5) would change to (c)(5)).
- § 424.205(b)(4) (reference to (d)(5) would change to (c)(5)).
- § 424.205(b)(6).
- § 424.205(c)(3) (reference to (d)(5) would change to (c)(5)).
- § 424.205(c)(6) (reference to (d)(4) would change to (c)(4)).
- § 424.205(c)(8) (reference to (d)(8)(i) would change to (c)(8)(i)).
- § 424.205(c)(8)(ii) (references to (d)(8)(i)(B) and (d)(8)(i)(C) would change to (c)(8)(i)(B) and (c)(8)(i)(C), respectively).
- § 424.205(c)(10) (reference to (d)(8) would change to (c)(8)).
- § 424.205(c)(11)(iii).
- § 424.205(d)(2) (reference to (d)(5) would change to (c)(5)).
- § 424.205(g)(1)(ii).

- § 424.205(g)(1)(v)(A) (reference to (d)(3) would change to (c)(3)).

Second, the following references in § 424.205 would be revised to reflect that section’s present structure.

- In paragraph (c)(3), (e)(1) would change to (d)(1).
- In paragraph (c)(12), (g) would change to (f).
- In paragraph (c)(15), (g) would change to (f).
- In paragraph (d)(2), (e)(1) would change to (d)(1).
- In paragraphs (g)(1)(i)(A) and (B), (h)(1)(i) would change to (g)(1)(i).
- In paragraphs (g)(1)(ii)(A) and (B), (h)(1)(ii) would change to (g)(1)(ii).
- In paragraphs (g)(1)(v)(B) and (B)(2), (h)(1)(v) would change to (g)(1)(v).

Third, current § 424.205(g)(1)(i)(A) and (B) state that the MDPP supplier’s failure to meet the conditions in paragraph (b) is considered an enrollment denial or revocation, respectively, under §§ 424.530(a)(1) or 424.535(a)(1). Likewise, § 424.205(g)(1)(ii)(A) and (B) state that a failure to meet the standards in paragraph (d) is considered a denial or revocation, respectively, under §§ 424.530(a)(1) or 424.535(a)(1). We propose to add “or § 424.530(a)(18)” after paragraph references to § 424.530(a)(1) and “or § 424.535(a)(23)” after references to § 424.535(a)(1). This is because we can deny or revoke under either (a)(1) or (a)(18)/(23) in such situations. Our authority is not limited to (a)(1).

(v) Abuse of Billing Privileges (§ 424.535(a)(8)(i))

Section 424.535(a)(8) permits revocation based on the provider’s abuse of billing privileges. The latter term includes either of the following as outlined respectively in paragraphs (a)(8)(i) and (ii):

- The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service; and
- CMS determines that the provider has a pattern or practice of submitting claims that fail to meet Medicare requirements.

Paragraph (a)(8)(i) states that situations falling within its purview include but are limited to (and are enumerated as paragraphs (a)(8)(i)(A) through (C)):

- The beneficiary is deceased.
- The directing physician or beneficiary is not in the state or country when services were furnished.
- When the equipment necessary for testing is not present where the testing is stated to have occurred.

We propose to add new paragraph (i)(D) to § 424.535(a)(8) to include

another potential paragraph (a)(8) situation: specifically, the beneficiary attests that the item(s) or service(s) identified on the provider's or supplier's claim or claims was not or were not rendered or furnished. We have recently seen cases where providers have submitted claims for payment involving services or items that the beneficiary states were never provided. Although paragraph (a)(8)(i) has a "but are not limited to" caveat, meaning paragraphs (a)(8)(i)(A) through (C) are not exclusive, we believe the seriousness of the attestation cases we have seen and the potential fraud, waste, and abuse that has resulted therefrom warrant a specific mention of this situation in new paragraph (a)(8)(i)(D). This would make clear that § 424.535(a)(8)(i) applies to such cases.

(b) Retroactive Revocations Bases

Section 424.535(g) addresses revocation effective dates. 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. That is, the revocation effective date is prospective. However, paragraph (2) lists a number of situations where the revocation effective date is retroactive, meaning, generally, that the revocation becomes effective back to the date on which the provider's non-compliance with Medicare requirements commenced. To illustrate, paragraphs (g)(2)(ii) and (iii) outline the following retroactive revocation grounds and their corresponding effective dates:

- For revocations based on a felony conviction, the date of the felony conviction.
- For revocations based on a state license suspension or revocation, the date of the license suspension or revocation.

The aim of these and other exceptions in paragraph (g)(2) is to prevent payment to a provider while it is non-compliant. Assume a provider's license is revoked by the state on September 1. CMS learns of this and sends a revocation notice to the provider on September 15. If we applied paragraph (g)(1)'s prospective "30 days after mailing" timeframe, the provider could bill and be paid for services furnished between September 1 and October 15 while unlicensed, resulting in potentially thousands of dollars in improper Medicare payments. Preventing improper payments is a cornerstone of provider enrollment, and we believe that retroactive revocation effective dates are crucial means of ensuring that taxpayer monies are paid

only to legitimate, compliant providers. Indeed, it is for this reason that we added several new grounds for retroactive revocations (current paragraphs (g)(2)(v) through (viii)) in the Calendar Year (CY) 2024 Physician Fee Schedule (PFS) final rule (88 FR 78818).³¹ Yet because of our continuing serious concerns about improper payments to non-adherent providers and our responsibility to protect the Trust Funds, we propose to further expand the bases for which we can apply a retroactive revocation effective date. Our new grounds and effective dates, which would be designated as paragraphs (g)(2)(viii) through (xiv) (the requirement in current paragraph (g)(2)(viii) would be removed, as later explained), would respectively be as follows:

- For revocations based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6), the date the insurance lapsed.
- For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application's certification statement was signed.
- For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, the day after the date by which the provider or supplier was required to report the change, addition, or deletion.
- For revocations based on the surrender of the provider's or supplier's Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.
- For revocations based on the State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs, the date of the suspension or revocation.
- For revocations of any of the provider's or supplier's other enrollments under § 424.535(i), the effective date of the revocation that triggered the revocation(s) of the other enrollment(s).
- For revocations based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c), respectively, the date on which the non-compliance began.

In the foregoing situations, the provider or supplier has engaged in action or inaction resulting in non-compliance and/or otherwise concerning conduct. Regarding proposed paragraph (g)(2)(viii), lapsed IDTF liability insurance could have eliminated financial protection for beneficiaries negligently harmed by a test the IDTF performed. We believe such an insurance lapse and the risk it could have posed to patients warrants a retroactive revocation effective date. Moreover, because IDTF liability insurance is required per § 410.33(g)(6), failure to maintain it means the IDTF is non-compliant with enrollment requirements; the supplier must therefore not receive payments for services furnished on or after the date the non-compliance commenced. Providing false or misleading data on the enrollment application, meanwhile, in our view reflects dishonest behavior that could have resulted in improper payments to the provider. To illustrate, assume an enrolled provider had failed to report one of its practice locations on its application, knowing that it was not a valid site. If the provider furnished services from that site, it could have received payments to which it was not entitled due to the location's non-compliance. We believe the severity of such conduct justifies a retroactive revocation.

The same concerns about potential improper payments are behind proposed new paragraph (g)(2)(x). As an example, if a provider moves its practice location without notifying CMS and the new location does not meet the definition of "operational" in § 424.502, Medicare might have been paying for services while the provider was non-compliant with enrollment requirements. Accordingly, we believe this warrants application of the revocation retroactively to the date the non-compliance began as described in proposed paragraph (g)(2)(x). As for new paragraphs (g)(2)(xi) and (xii), meeting all applicable federal and state requirements is necessary for enrollment. If an individual is prescribing or dispensing drugs while non-compliant, we believe the risk this presented to beneficiaries after the loss of DEA or state authority justifies a revocation back to the date said loss occurred. With respect to proposed paragraph (g)(2)(xiii), we believe it would be inconsistent to apply one effective date to the triggering revocation and a different, later one to others, for the same individual or provider organization is involved in all these enrollments. Proposed paragraph

³¹ "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".

(g)(2)(xiv), in our view, is appropriate because the supplier's non-compliance may have resulted in payments (on or after the date of non-compliance) to which the supplier was not entitled.

We previously noted our authority under § 424.535(a)(8) to revoke a provider for the abusive billing situations described in paragraphs (a)(8)(i) and (ii). These situations are especially disconcerting with regard to the question of improper payments. If a provider is engaging in abusive billing, this, in our view, constitutes a direct threat to the Medicare program. To allow a provider that was revoked for submitting claims for unfurnished services to continue billing Medicare for another 30 days would run entirely counter to our role as steward of the Trust Funds. Consequently, we propose to include revocation bases in § 424.535(a)(8) as grounds for retroactive applicability.

New paragraph (a)(8)(iii) would state that the revocation effective date in paragraph (a)(8)(i) would be the earliest date of service on the claim or claims that are triggering the revocation. For instance, suppose CMS revokes the provider for submitting three claims for non-furnished services; the claims' service dates were June 1, June 5, and June 10. The revocation date would be the earliest of them, or June 1. Considering the serious program integrity risks associated with such claims, we do not believe the effective date must be the last claimed service date, for the risk commenced with the first claim's submission. The revocation effective date under paragraph (a)(8)(ii), meanwhile, would be the last date of service on the claims in question; using our prior example, this means the revocation effective date would be June 10. The reason for the different effective dates is that while paragraph (a)(8)(i) requires only one claim submission, paragraph (a)(8)(ii) requires a pattern or practice. . The last claim establishes the pattern or practice, hence the need to use the date thereon as the effective date.

To further accommodate new paragraph (a)(8)(iii), we would add reference to it in the previously noted opening clause of § 424.535(g)(1) as being excluded from application under paragraph (g)(1).

There are several other technical changes involving retroactive revocations we believe are necessary.

First, § 405.800(b)(2) states that a revocation is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, the only exceptions being the revocations referenced in current

§ 424.535(g)(2)(i) through (iv), which are retroactive. Given our significant changes to § 424.535(g)(2) since promulgation of § 405.800(b)(2), we propose to replace the current language in the latter provision with a statement that the effective date of a revocation is as specified in § 424.535 (which would include § 424.535(a)(8)(iii) and (g)).

Second, § 424.57(e)(1) states that except as otherwise provided in § 424.57, a DMEPOS supplier's revocation for violating § 424.57(b) or (c) is effective 30 days after the entity is sent notice of the revocation, as specified in § 405.874. Similar to our proposed revision to § 405.800(b)(2), we propose to modify § 424.57(e)(1) to state that the revocation effective date would be as specified in § 424.535.

Third, current § 424.535(g)(2)(viii) outlines effective dates for revocations under § 424.535(a)(23). Paragraphs § 424.535(g)(2)(viii)(A) through (C) identify three situations where a retroactive effective date applies. Section 424.535(g)(2)(viii)(D), meanwhile, states that for all standard violations not addressed in paragraphs (A) through (C), the prospective effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not. We propose two changes involving § 424.535(g)(2)(viii). One is that—given proposed new § 424.535(g)(2)(viii) through (xiv)—we propose to redesignate existing § 424.535(g)(2)(viii) as new § 424.535(g)(2)(xv). The other change would involve replacing the reference to “paragraphs (A) and (C)” in current § 424.535(g)(2)(viii)(D) (proposed new § 424.535(g)(2)(xv)(D)) with “paragraph (g)(2)”. This is because we are proposing to add certain standard violations to (g)(2) in paragraphs other than current (g)(2)(viii)(A), (B), and (C) (for example, including DMEPOS supplier standard violations in new § 424.535(g)(2)(xiv)).

(2) New Deactivation Authority

Regulatory policies regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or “reactivated”) upon the submission of information required under § 424.540. While a deactivated provider or supplier is not revoked from Medicare, the provider's or supplier's ability to bill the program is halted pending its reactivation.

There are currently eight reasons under § 424.540(a) for which CMS can deactivate a provider or supplier, one of which is that the provider or supplier has not submitted any Medicare claims

for 6 consecutive months. In an April 25, 2003, proposed rule titled “Medicare Program; Requirements for Establishing and Maintaining Medicare Billing Privileges” (68 FR 22064) that proposed this non-billing deactivation ground, we outlined our program integrity concerns related to inactive billing numbers. We noted our desire to prevent dishonest parties from: (1) deliberately obtaining multiple numbers so they could keep one ‘in reserve’ [for future use] if their active billing number is subject to a payment suspension; and (2) obtaining information about discontinued providers or suppliers and then, for example, using the Medicare billing number of a deceased physician.³² Although we established a 12-month (rather than a 6-month) non-billing period in the subsequent final rule published in the **Federal Register** on April 21, 2006,³³ the need to shut down inactive billing numbers for the reasons noted previously persisted.

In the CY 2024 HH PPS final rule that appeared in the November 13, 2023, **Federal Register** (88 FR 77676)), we reduced this 12-month period to 6 months.³⁴ We detailed our rationale for this change in the CY 2024 HH PPS proposed rule³⁵ by expounding upon the concerns we expressed in the aforementioned April 25, 2003, proposed rule. We cited an increasingly common example of a fraudulent, “whack-a-mole”-type scheme whereby a provider: (1) establishes multiple enrollments with multiple billing numbers; (2) abusively or inappropriately bills under one billing number; (3) receives an overpayment demand letter or becomes the subject of investigation; (4) voluntarily terminates the billing number in question; and then (5) begins to bill via another of its

³² Ibid. (68 FR 22072).

³³ “Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment” (71 FR 20754).

³⁴ “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”.

³⁵ “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 43654 (July 10, 2023)).

billing numbers that is dormant (for example, 6 consecutive months without billing) but nonetheless active, repeating the same improper conduct as before. We also further outlined the program integrity risks of extended non-billing periods, noting that in some cases the provider may have ceased operations without notifying CMS. Deactivating the provider's billing number enables CMS to not only prevent it from being accessed by other parties but also confirm via the deactivation process whether the provider or supplier is in fact operational—specifically, whether the provider responds with a reactivation application. In other words, action under § 424.540(a)(1) helps protect the Medicare program by deactivating the number while enabling verification as to whether the provider remains in existence; if it does, and it subsequently submits a reactivation application, CMS can validate the data thereon to ensure the provider's continued credentials and compliance with Medicare requirements.

We recognize that the deactivation concept has only applied to Medicare billing privileges rather than the ordering, certifying, and referring (OCR) of Medicare services and items. Yet this does not mean improper OCR poses a significantly less risk to the Medicare program and its beneficiaries than billing for Medicare services. To the contrary, we have established a number of provider enrollment requirements to prevent inappropriate OCR. Several examples follow.

First, under § 424.507(a) and (b), physicians and practitioners who wish to order or certify certain Medicare services and items must either opt-out of Medicare (pursuant to 42 CFR part 405, subpart D) or enroll in Medicare. Even if the individual does not seek to bill Medicare and only wants to order or certify the services and items addressed in § 424.507, the person must still enroll in Medicare by submitting a Form CMS–855O application (Medicare Enrollment Application—Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners (OMB control number. 0938–1135)). Though a shorter, more abbreviated form than other CMS–855 applications, the Form CMS–855O requires the individual to furnish important information regarding, for instance, licensure and final adverse actions. This enables CMS to screen the person to ensure that all Medicare requirements are met, hence reducing the payment safeguard risk that an unvetted physician or practitioner intent on fraudulent or abusive conduct can order or certify such services or items.

Second, pursuant to § 424.535(a)(21) we may revoke a physician's or eligible professional's enrollment if the individual has a pattern or practice of ordering, certifying, or referring Medicare Part A or B services or items that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. This provision was established in response to instances of fraudulent or unnecessary ordering, certifying, and referring of Medicare services and items, which resulted in: (1) Medicare payment for services or items that beneficiaries did not require; and (2) potential harm to beneficiaries from these unnecessary services or items. We also believed the potential for revocation would deter physicians and other eligible professionals from engaging in such activity, thus reducing fraud and waste and enhancing beneficiary safety.

Third, under § 424.542(a) a physician or other eligible professional who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests Medicare and its beneficiaries may not order, refer, or certify Medicare services or items. As with § 424.535(a)(21), the aim of § 424.542(a) is to prevent fraud, abuse, and beneficiary harm.

All the foregoing signifies that CMS takes improper and abusive ordering, referring, and certifying no less seriously than improper and abusive billing. The former can be just as harmful to Medicare and its beneficiaries as the latter. For this reason, we do not believe that important program integrity safeguards such as deactivation must be limited to billing situations. A Form CMS–855O-enrolled physician or practitioner's unused ordering, certifying, or referring number (which CMS assigns to the individual upon enrollment) can be accessed by nefarious parties to the same extent as an unused billing number. Our obligation to protect beneficiaries and the Trust Funds, in our view, requires us to prevent such improper access, and we accordingly propose to do so in new § 424.547.

In § 424.547(a)(1)(i) and (ii), respectively, we propose that CMS may deactivate a physician's or non-physician practitioner's ability to order, certify, or refer the Medicare services or items described in § 424.507(a) and (b) if the individual:

- Is enrolled via the Form CMS–855O application solely to order, certify, or refer Medicare services or items; and
- Has not been listed as the ordering, certifying, or referring individual on a

Medicare Part A or B claim received in the previous 12 consecutive months.

We are comfortable with initially establishing a 12-month period. This would be consistent with the 12-month timeframe we originally established in 2006 for § 424.540. Should we determine after implementation that a shorter timeframe is warranted, we may consider future rulemaking.

To distinguish deactivations of billing privileges from those of ordering, referring, or certifying capabilities, we propose in new § 424.547(a)(2) that for purposes of § 424.547 only, the term “deactivate” means that the physician's or non-physician practitioner's ability to order, certify, or refer Medicare services or items has been stopped but can be restored upon the submission of updated information. In a similar vein, because the current definition of deactivation in § 424.502 is limited to billing privileges, we propose to add the following language to the beginning of this definition: “Except in the situations described in § 424.547”. We also believe that some of the deactivation and reactivation procedures and impacts in § 424.540 must be included within new § 424.547. These have existed for numerous years and help us obtain updated information on non-billing providers to ensure the latter are still active and have not, for instance, ceased operations. We thus propose the following, which would mirror, respectively, current § 424.540(b)(1), (b)(2), (d)(2), and (e):

- In § 424.547(b)(1), we would state that for a deactivated physician or practitioner to reactivate their ability to order, certify, or refer Medicare services and items, the individual must recertify that their enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in Title 42.

- In § 424.547(b)(2), we would state that notwithstanding § 424.547(b)(1), CMS may, for any reason, require a deactivated physician or practitioner to, as a prerequisite for reactivating the ability to order, certify, or refer, submit a complete Form CMS–855O application.

- In § 424.547(c), we would state that the effective date of a reactivation of the ability to order, certify, or refer Medicare services and items under § 424.547 is the date on which the Medicare contractor received the individual's reactivation submission that was processed to approval.

- In § 424.547(d), we would clarify that a physician or practitioner may not order, certify, or refer the Medicare

services or items referenced in § 424.507(a) and (b) while deactivated under § 424.547.

(c) Revisions to Stay of Enrollment Authority (§ 424.541)

As already noted, revocations and deactivations are two important vehicles CMS uses to prevent Medicare fraud, waste, and abuse as well as improper payments. In the CY 2024 PFS final rule, we promulgated a third vehicle labeled a stay of enrollment, which is addressed in § 424.541. Under § 424.541(a)(1) and (2), we can impose a stay of enrollment against a provider if the latter:

- Is non-compliant with at least one enrollment requirement in Title 42; and
- Can remedy the non-compliance by submitting, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application.

We established the stay of enrollment concept based largely on our concern that there were instances of provider non-compliance that did not necessarily warrant a measure as significant as a deactivation, much less a revocation. We believed that a more moderate CMS approach in addressing such cases would ease the burden on such providers without hindering our obligation to protect the Trust Funds. In further explaining our rationale for the stay of enrollment, we outlined in the CY 2024 PFS final rule several critical differences between this new action and revocations and deactivations.

The first involves the length of the action. We previously noted that a revoked provider is subject to a reenrollment bar typically lasting between 1 to 10 years. Deactivations last until the provider has reactivated its billing privileges under § 424.540; if no reactivation occurs, the deactivation remains effective indefinitely. A stay of enrollment, however, lasts a maximum of 60 calendar days, during which period the provider remains enrolled in Medicare, unlike with a revocation. Described otherwise, a stay of enrollment represents a comparatively brief “pause” in the provider’s enrollment that permits the provider to quickly resume compliance without the greater burdens associated with deactivations and revocations.

The second pertains to payments. Section 424.541(a)(2)(ii)(A) states that claims submitted by the provider with dates of service within the stay period will be rejected. However, there is a critical caveat. Under § 424.541(a)(2)(ii)(B), claims submitted by the aforementioned provider in this situation are, in fact, eligible for

payment (and may be resubmitted by the provider within applicable timeframes specified in Title 42) if—

- CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and
- The stay ends on or before the 60th day of the stay period.

This means that whereas revocations and deactivations prohibit payment for services or items furnished during the revocation or deactivation period with no possibility of retroactive payments, a stay of enrollment permits the latter if the requirements of § 424.541(a)(2)(ii)(B) are met.

A third involves the timing and mechanism for how the provider can resume compliance. A revoked or deactivated provider cannot, respectively, re-enroll in Medicare (after the reenrollment bar expires) or reactivate its billing privileges until the applicable provider enrollment application process is complete, which can take considerable time. Under § 424.541(a)(5), a stay of enrollment can end on the date on which CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42. However, for purposes of § 424.541(a)(5) only, we have interpreted the term “has resumed compliance” as meaning the provider has submitted the required application referenced § 424.541(a)(1)(ii) (for example, Form CMS-855 change of information). With this, a stay could end within a few days, allowing the provider to rapidly resume billing.

Considering the burden-reducing aspects of the stay concept, we believe its scope must be expanded to cover other situations. While this proposed rule has focused largely on preventing improper payments, we also believe that providers must not be excessively or unfairly penalized for minor instances of non-compliance that, in general, do not pose or potentially pose significant threats to the Medicare program. One such situation is where a provider submits a revalidation or change of information application that is rejected under § 424.525(a)(1) or (2). Per these provisions, rejection is permissible if the provider does not furnish complete information on the application (or required supporting documentation under (a)(2)) within 30 calendar days of the date the Medicare contractor requested the missing or incomplete data or documentation. A deactivation often follows the rejection. Unlike cases where the provider did not submit the required revalidation or change of

information at all, the provider in § 424.525(a)(1) cases did submit the application, albeit incompletely. Accordingly, we do not believe the latter situations must be treated more harshly via a deactivation than the former. It would be inconsistent to allow the more concerning action of application non-submission to be subject to a stay and not situations where the provider actually submitted the form. To this end, and to further the goal of reducing provider burden, we propose to expand § 424.541(a)(1)(i) to include instances where the provider’s change of information or revalidation application is rejected under § 424.525(a)(1) or (2)).

In addition, current § 424.541(a)(3) states that a stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay. We believe two changes to this section are necessary.

First, we propose to delete existing § 424.541(a)(3) and, in new § 424.541(a)(3)(i), state that the effective date of a stay is, as applicable: (1) the date on which the provider’s or supplier’s non-compliance began; or (2) the date on which the provider’s or supplier’s change of information or revalidation application was rejected under § 424.525. In light of our concerns about payments to providers when they are non-compliant, we no longer believe commencing the stay period upon the notification letter’s postmark date is appropriate. As an illustration, assume a provider became non-compliant on June 1 and the stay notice was postmarked on June 6. This means that the provider’s claims for a 5-day period (June 1 to 6) can be paid even though the provider is non-compliant. With our proposed change, however, these claims would be rejected due to the stay’s June 1 effective date. We believe the latter is a better approach for preventing payments to non-compliant providers.

Second, we propose in new § 424.541(a)(3)(ii) that CMS may establish a stay of enrollment for any period up to a maximum of 60 days. This is consistent with current CMS policy, but we wish to make clearer that the CMS-assigned stay period need not be 60 days but can be any timeframe up to that point.

We previously noted the reference in § 424.541(a)(2)(ii)(B) regarding claim submission eligibility, with § 424.541(a)(2)(ii)(B)(2) referencing the end of the stay on or before the 60th day. We propose to revise paragraph (a)(2)(ii)(B)(2) to replace the 60-day reference therein with the requirement that the stay must end on or before the

expiration of the originally designated stay period. This would further clarify that the stay period can be less than 60 days. Meanwhile, § 424.541(a)(5) states that a stay of enrollment ends on the date on which CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first. Since the stay period CMS has assigned may be less than 60 days, we propose to change “60-day period” to “CMS-assigned stay period”.

(d) Submission of Documentation

One of the many critical functions of MACs is to validate the accuracy of the information the provider furnishes on its enrollment application. If submitted data is incorrect, the potential exists for improper payments based thereon. Consider the following: (1) an individual practitioner indicates on the application that all licensure and certification requirements have been met; and (2) a provider lists a particular address as its practice location. If these providers’ respective applications were approved without verifying these data elements and it turns out the individual did not, in fact, meet licensure and certification requirements or had an invalid practice location, many thousands of dollars could be inappropriately paid to providers that did not meet Medicare requirements. Although MACs can validate certain data via electronic means, verifying documentation from the provider is sometimes needed. Sections 424.510(d)(2)(ii), (iii)(A), and (iii)(B) therefore state that each submitted provider enrollment application must include the following:

- Documentation to identify the provider, such as proof of the legal business name, practice location, social security number, tax identification number (TIN), National Provider Identifier, and the business’ owners.
- All applicable Federal and State licenses and certifications including, but not limited to, Federal Aviation Administration; and
- Documentation associated with regulatory and statutory requirements needed to establish a provider’s eligibility to furnish Medicare covered items or services.

Some of this documentation is also identified on the Form CMS–855 enrollment applications as materials the provider must submit with its application. These include, for example, proof of licensure, sales agreements for ownership changes, and Internal

Revenue Service documentation of the provider’s TIN.

Notwithstanding existing § 424.510 and the documents that providers must currently submit, we remain concerned about the MACs’ ability to verify all information on the applications they receive. This is especially true regarding the provider’s ownership and management. Consistent with sections 1124 and 1124A of the Act, providers must report this data on their enrollment applications. Inaccurate ownership and managerial information, like other reported data, could result in improper payments. To illustrate, suppose a provider has five owners it must report but only discloses four. The fifth one was not listed because that owner is excluded by the OIG. If this provider is subsequently enrolled because of an inability to verify (1) the provider’s current ownership and that (2) all owners are reported, we would be paying a provider with an excluded owner in violation of federal law.

To therefore strengthen our ability to validate ownership and managerial data—as well as other information that CMS or the MAC may be unable to verify through current means—we propose in new § 424.510(d)(2)(iii)(C) that CMS may require the submission of any other documentation needed to verify and confirm the information furnished on the enrollment application; this includes, but is not limited to, documentation regarding the provider’s or supplier’s ownership or management. We emphasize that our proposal does not necessarily mean that the amount of documentation providers must currently submit will greatly increase. It only means CMS reserves the right to request validating documents if needed to ensure the accuracy of the provider’s information.

(e) Reassignment Effective Dates

In the provider enrollment context, and consistent with 42 CFR 424.80, reassignment of benefits refers to the scenario in which an individual physician or non-physician practitioner has granted another Medicare-enrolled provider or supplier the right to receive payment for the physician’s or non-physician practitioner’s services. Existing § 424.522(a) states that a reassignment is effective beginning 30 days before the Form CMS–855R (OMB control number 0938–1179) is submitted if all applicable requirements during that period were otherwise met. The CMS–855R (Medicare Enrollment Application for Reassignment of Medicare Benefits) was long used by physicians and practitioners to reassign their right to Medicare payment to

another party and for the latter to accept such reassignment. However, with the Form CMS–855R now obsolete and the collection of reassignment information currently facilitated via the Form CMS–855I (OMB control number 0938–1355) and Form CMS–855B (OMB control number 0938–1377) applications, we must revise § 424.522(a) to reflect both the elimination of the Form CMS–855R and the need to establish a new reassignment effective date.

Under current § 424.520(d)(1)(i) and (ii), the effective date of billing privileges for physicians and non-physician practitioners is the later of—

- The date of filing of a Medicare enrollment application that a MAC subsequently approved; or
- The date the individual first began furnishing services at a new practice location.

Notwithstanding § 424.520(d)(1), physicians and non-physician practitioners under § 424.521(a)(1) may retroactively bill for services when they have met all program requirements and services were provided at the practice location for up to—

- 30 days before their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days before their effective date if a Presidentially declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of furnishing services to Medicare beneficiaries.

Because reassignments are often initiated at the same time a physician or practitioner enrolls in Medicare via the Form CMS–855I, we believe the effective dates of the two (that is, the initial enrollment and the reassignment) should be determined in the same manner, especially since, as noted, reassignments are now captured via the Form CMS–855I. In our view, it would be confusing to physicians, practitioners, and other stakeholders to have different regulatory effective dates for two separate transactions reported on the same form. Therefore, we propose to modify § 424.522(a) such that the reassignment’s effective date and the ability to retroactively bill for services mirror the provisions in § 424.520(d)(1) and 424.521(a)(1). Specifically, new § 424.522(a)(1) would state that the reassignment’s effective date is the later of the two dates identified in § 424.520(d)(1)(i) and (ii). New § 424.522(a)(2) would state that retrospective billing pursuant to a reassignment is permissible if the circumstances in § 424.521(a)(1) apply.

(f) DMEPOS Liability Insurance

Section 424.57(c) outlines a number of standards that DMEPOS suppliers must meet to become or remained enrolled in Medicare. One such standard, codified in § 424.57(c)(10), requires the supplier to have a comprehensive liability insurance policy of at least \$300,000 that covers the supplier's place of business, customers, and employees. We have seen instances where the insurance policy is signed by a supplier employee who did not appear to have the authority to act on the supplier's behalf. Considering the importance of the liability insurance requirement, we must ensure that the supplier, through its signature on the policy, is bound by its terms. Accordingly, we propose to modify § 424.57(c)(10) such that an "authorized official" of the supplier (as that term is defined in § 424.502) must sign the liability insurance policy.

(g) Deactivation Reason Clarification

Section 424.550(b) addresses "change(s) in majority ownership" (CIMO) (as that term is defined in § 424.502) involving home health agencies (HHA) and hospices. Unless an exception applies, an HHA or hospice undergoing a CIMO must enroll in Medicare as a new HHA or hospice and undergo a state survey or accreditation. Since, in this situation, the seller will be departing the Medicare program, § 424.540(a)(8) permits CMS to deactivate the seller's billing privileges. However, § 424.540(a)(8) currently only references sellers in an HHA CIMO and not those in a hospice CIMO. As a technical clarification, we thus propose to include the latter within the scope of § 424.540(a)(8).

(h) Adverse Legal Actions

Consistent with § 424.516(b) through (d), certain provider and supplier types—such as physicians, non-physician practitioners, DMEPOS suppliers, and independent diagnostic testing facilities—must report any adverse actions (for example, felony convictions, misdemeanor conviction related to health care, medical license revocation) imposed against them, their owners, managing employees or organizations, or corporate directors or officers within 30 calendar days of the action. Other provider and supplier types, however, have 90 days to report this information. Existing § 424.516(e)(1) states that for all provider and supplier types other than those in § 424.516(b) through (d) (as well as MDPPs), changes of ownership or control and practice location changes,

additions, and deletions must be reported within 30 days. We propose to include adverse legal actions within § 424.516(e)(1), meaning all providers and suppliers, regardless of type, would have 30 days, rather than 90 in some instances, to disclose this data. We believe this would establish more consistent reporting timeframes. More importantly, a 30-day requirement would alert us much sooner when the provider or an associated party poses a risk of fraud, waste, or abuse or and better allow us to take corresponding measures to protect the Medicare Trust Funds and Medicare beneficiaries.

2. Medicaid and CHIP Enrollment and Termination

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program that (as of October 2024) covers more than 72 million low-income individuals. States have considerable flexibility when administering their Medicaid programs within a broad Federal framework, and programs vary from State to State. The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that (as of October 2024) provides health care coverage to over 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll in order to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.³⁶ States may also establish their own provider enrollment requirements which must be met in addition to the applicable Federal provider enrollment requirements. Similar to Medicare provider enrollment, the purpose of the Medicaid and CHIP provider enrollment processes is to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different States may have different provider enrollment processes in operating their Medicaid and CHIP programs. However, all States must comply with Federal Medicaid and

CHIP provider enrollment statutory and regulatory requirements, including those in part 455, subparts B and E.³⁷ One such requirement, outlined in section 1902(a)(39) of the Act and which will be the subject of this section VI.A.2. of this proposed rule, is that the State must deny or terminate a provider's Medicaid or CHIP enrollment if the provider is—

- Terminated under the Medicare program, or the Medicaid program or CHIP of any other State; and
- Currently included in the termination database under § 455.417.

CMS established this termination database pursuant to sections 1902(kk)(8) and 1902(ll) of the Act. These two sections are summarized as follows:

- Require the State to report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination. However, this reporting requirement is limited to terminations for reasons specified in § 455.101, which, in turn, are restricted to terminations "for cause" (including, but not limited to, terminations for reasons relating to fraud, integrity, or quality);

- Provide that within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary must review such termination and, if the Secretary determines appropriate, include such termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.

CMS has developed and currently operates such a database. It contains information on Medicaid and CHIP terminations and Medicare revocations. It enables a State to: (1) review Medicaid and CHIP terminations in other States, as well as Medicare revocations; and (2) to deny enrollment under § 455.416(c) or take its own termination action against a provider if the latter is also enrolled in the State.

The previously referenced provisions of section 1902(a)(39) of the Act are currently incorporated in § 455.416(c), though with one inadvertent exception. Rather than stating that the provider—along with being in the termination database—must be terminated under the Medicare program or the Medicaid program or CHIP of any other State, § 455.416(c) states that the provider's termination must be from Medicare and the Medicaid or CHIP program of any state. That is, the word "and" is between the references to Medicare and

³⁶ Section 1902(kk)(7) of the Act also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

³⁷ All of subpart E, and 42 CFR 455.107 in Subpart B, are applicable to CHIP in accordance with § 457.990.

Medicaid when the word “or” should be there instead, consistent with the statutory language. To correct this issue and to ensure compliance with section 1902(a)(39) of the Act, we proposing to change the aforementioned “and” reference to “or.”

B. DMEPOS Supplier Accreditation Process

1. Introduction

a. Overview of DMEPOS Accreditation

(1) DMEPOS Suppliers

(A) Background

Among the types of providers and suppliers that must enroll in Medicare to bill the Medicare program are DMEPOS suppliers. Such suppliers include, but are not limited to, the following:

- Medical supply companies that exclusively furnish DME like wheelchairs, walkers, and canes.
- Physicians and non-physician practitioners who provide DMEPOS to their own patients.
- Home health agencies (HHAs) and hospitals that provide DMEPOS to their own patients
- Oxygen and oxygen equipment suppliers.
- Prosthetists and orthotists.
- Pharmacies.

DMEPOS suppliers enroll in Medicare via the Form CMS–855S application (Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); OMB Control No. 0938–1056). Per 42 CFR 424.57(b)(1)—and excluding locations it utilizes solely as warehouses or repair facilities—the supplier must separately enroll each physical location it uses to furnish Medicare-covered DMEPOS.

DMEPOS suppliers have long presented to the Medicare program an elevated risk of fraud, waste, and abuse. In recognizing this threat, CMS over the years has established particularly stringent requirements that DMEPOS suppliers must meet to enroll and maintain enrollment in Medicare. For example, DMEPOS suppliers under 42 CFR 424.518(c) are one of only six provider and supplier types that are subject to the highest and strictest level of screening during the enrollment process. (They were also one of only two types (the other being HHAs) that were originally assigned to the “high-risk” screening category when § 424.518(c) was promulgated in 2011.) This screening includes: (1) a site visit; and (2) submission of fingerprints of the supplier’s 5 percent or greater owners for a Federal Bureau of Investigation

(FBI) criminal background check. There also are other regulatory provisions besides the basic provider enrollment requirements in subpart P of 42 CFR part 424 (§§ 424.500 through 424.575) that DMEPOS suppliers must meet. With certain exceptions based on the type of DMEPOS supplier involved, these requirements include, but are not limited, to the following:

- Compliance with the DMEPOS supplier standards outlined in § 424.57(c).
 - Acquisition and maintenance of a surety bond consistent with § 424.57(d).
 - Compliance with DMEPOS quality standards.
 - Accreditation by a CMS-approved DMEPOS accrediting organization.
- Such has been our longstanding concerns about DMEPOS program integrity that DMEPOS suppliers are also one of two only Medicare provider or supplier types (the other being Medicare Diabetes Prevention Programs) with an enrollment application (Form CMS–855S) devoted exclusively to a single provider/supplier type.

(B) Continued Program Integrity Concerns With DMEPOS Suppliers

Despite these and other DMEPOS program integrity efforts we have undertaken, serious concerns remain. Indeed, numerous Office of Inspector General (OIG) reports since 1998 have noted such payment safeguard issues associated with DMEPOS suppliers. Two recent OIG reports are illustrative.

In May 2024, the OIG issued a report titled “Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees” (A–09–21–03019). The report noted that prior OIG reviews identified vulnerabilities associated with orthotic braces, such as: (1) questionable DMEPOS supplier billing practices; (2) improper payments made for braces that were not medically necessary or were not documented; and (3) fraud related to off-the shelf (OTS) braces.³⁸ The May 2024 report also cited issues related to Medicare’s oversight of OTS braces, including the following:

- Medicare paid for OTS braces that were—
 - ++ Ordered by suppliers that did not have treating relationships with beneficiaries.
 - ++ Marketed to beneficiaries by telemarketers using prohibited direct solicitation.

³⁸ <https://oig.hhs.gov/reports/all/2024/medicare-remains-vulnerable-to-fraud-waste-and-abuse-related-to-off-the-shelf-orthotic-braces-which-may-result-in-improper-payments-and-impact-the-health-of-enrollees/#:-:>

- Payments to suppliers for fraudulently billed OTS braces have cost Medicare millions of dollars.³⁹

Given these issues, the OIG recommended that, among other things, CMS analyze DMEPOS supplier billing patterns, identify emerging fraud schemes related to OTS braces, and use CMS’s authority to prevent further losses to the Medicare program.⁴⁰

Another OIG report titled “Medicare Improperly Paid Suppliers for Intermittent Urinary Catheters” (A–09–22–03019) was released in February 2025. Citing the ongoing risk of improper payments, the OIG performed a nationwide audit to determine whether Medicare paid suppliers for catheters consistent with Medicare requirements for catheters furnished to beneficiaries between July 2021 through June 2022.⁴¹ The OIG found that payments for 15 sample items did not comply with Medicare requirements, in some cases because suppliers were non-compliant with requirements for catheter refills, proof of delivery, or a standard written order.⁴² This resulted in approximately \$35.1 million in improper payments.⁴³ Even before this report, however, CMS in early 2023 had identified a concerning rise in urinary catheter billings attributed to a fraud scheme involving 15 DMEPOS companies that had recently changed ownership. CMS’ own investigation of this matter determined that: (1) Medicare beneficiaries did not receive catheters from these DMEPOS companies and were not billed directly; (2) physicians did not order these supplies; and (3) the supplies were not needed.⁴⁴ Although CMS took prompt action to address this matter, including stopping payments from being made to these suppliers and revoking the Medicare enrollments of all 15 suppliers, both the OIG report and our investigation underscored the program integrity issues in the DMEPOS arena.⁴⁵

Yet these issues go far beyond the aforementioned OIG and CMS reviews. There have been a considerable number of criminal convictions and other findings over the years involving DMEPOS suppliers. Below is a non-exhaustive list of several recent cases:

³⁹ *Ibid.* pp. 7–12.

⁴⁰ *Ibid.*, p. 13.

⁴¹ <https://oig.hhs.gov/reports/all/2025/medicare-improperly-paid-suppliers-for-intermittent-urinary-catheters/>.

⁴² *Ibid.*

⁴³ *Ibid.*

⁴⁴ <https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf>. See also <https://oig.hhs.gov/fraud/consumer-alerts/consumer-alert-catheter-scam/>.

⁴⁵ *Ibid.*

- In May 2024, a Florida man was sentenced to 96 months in prison for his role in a DMEPOS kickback scheme. He and others owned and operated marketing call centers and telemedicine companies through which they secured physicians' orders for DMEPOS for Medicare beneficiaries without regard to medical necessity. They then furnished the physicians' orders in exchange for bribes from DMEPOS companies that provided the braces to beneficiaries, causing over \$11 million in losses to the Medicare program.⁴⁶

- A California woman was sentenced in December 2023 to 15 years in prison for billing Medicare for over \$24 million by submitting fraudulent claims for medically unnecessary DME—mostly power wheelchairs (PWC)—and PWC repairs. As the *de facto* owner of two DMEPOS supplier companies (both of which were Medicare-enrolled in the names of her out-of-state relatives), the individual orchestrated a scheme in which she paid marketers for patient referrals and then directed them to take patients to physicians, who prescribed medically unnecessary DME (including PWCs) that her companies used to submit fraudulent claims to Medicare. Two other defendants were convicted in this case, including one who worked at both DMEPOS companies as a repair technician.⁴⁷

- A Texas man in March 2023 was sentenced to 66 months in prison for conspiring to defraud Medicare of more than \$2 million. The individual, who owned and operated a Virginia DMEPOS supplier, submitted thousands of fraudulent claims for DME, such as back and knee braces. Working with other companies and individuals, the DMEPOS supplier would unlawfully obtain the personal identification information of Medicare beneficiaries, mail them braces that they never wanted or needed, and then submit fraudulent claims to Medicare.⁴⁸

- In September 2023, a federal district court entered a judgment against a Virginia DMEPOS supplier for damages and penalties under the False Claims Act for over \$12 million. In its complaint filed in district court, the United States alleged that over a nearly 6-year period, Medicare paid the supplier over \$600,000 for medical braces furnished to Medicare beneficiaries related to DMEPOS

prescriptions that the supplier illegally purchased from marketing companies. The DMEPOS supplier paid a fee for each prescription that it purchased and then used these prescriptions (along with personal and medical data provided by the marketing companies) to submit 923 fraudulent Medicare claims.⁴⁹

- A California father and son in March 2024 were sentenced to prison for their roles in fraudulently receiving over \$21 million in Medicare payments. The pair, along with others, conspired to commit Medicare fraud by billing for medically unnecessary DME, such as knee, ankle, shoulder, wrist and back braces. They had established two DMEPOS supplier companies; to find customers, they entered into sham agreements with “marketing” companies that, instead of marketing, provided information about Medicare beneficiaries for \$125 to \$350 each. The packets included, among other things, a signed prescription from a physician (obtained via telemedicine) claiming that the brace was medically necessary for the beneficiary. In almost all cases, however, the physician signing the prescription had no previous doctor-patient relationship with the beneficiary. The two men then billed Medicare through their DMEPOS companies for the unnecessary items.⁵⁰

- A Texas man was sentenced to prison in February 2024 for conspiring to pay health care kickback payments for unnecessary DME, resulting in over \$20 million in claims to—and \$13 million in payments from—the Medicare program. The individual owned and operated two DMEPOS suppliers. Through another entity, the individual secured access to thousands of Medicare beneficiaries' information by paying, on a weekly basis, kickbacks in exchange for signed physician orders for the braces.⁵¹

- In August 2023, a Florida man was sentenced to prison for conspiring to defraud the Medicare program. The individual and another person illegally paid kickbacks of over \$565,000 to buy fraudulent DMEPOS orders, including orders purportedly “signed” by physicians who, in fact, never signed or authorized these orders and did not know their names and identities were being used in this manner. They also

resold some of the fraudulent orders to other DMEPOS suppliers—receiving more than \$425,000 in proceeds—so that those suppliers, in turn, could fraudulently bill Medicare for the DMEPOS. Furthermore, the two individuals acquired five of their own fraudulent DMEPOS supply companies and themselves used fraudulent DMEPOS orders to file more than \$11 million in fraudulent Medicare claims.⁵²

- A Texas woman in December 2024 was sentenced to 60 months in prison for conspiracy to commit health care fraud. According to court documents, she engaged in fraudulent billing practices as the owner of a DMEPOS supplier. Her scheme involved substituting and providing lesser valued items to Medicare beneficiaries and then billing Medicare for the greater valued items. The items were primarily continence supplies and included adult diapers, wipes, and bed liners.⁵³

- Several DMEPOS suppliers in January 2024 agreed to pay \$2.1 million to resolve allegations that they violated the False Claims Act by submitting false claims for payment to Medicare and other federal health care programs. The settlement resolved resolve allegations that over a 9-year period, the companies:

- ++ Sold used beds but billed federal health care programs as if they were new beds.

- ++ Sold various hospital beds and pressure support surfaces to beneficiaries of federal health care programs under a miscellaneous code, which sometimes resulted in the federal program paying a higher price.

- ++ Presented claims to the federal government and its contractors that mischaracterized travel time as DMEPOS repair time in order for it to be reimbursable by federal health care programs.⁵⁴

- A Florida man was sentenced to 87 months in prison in September 2022 for his role in using a DMEPOS company to commit Medicare and Medicaid fraud. Having established the company, he sought to conceal his role as its true owner who exercised control over the company (and the fraud) by listing a nominee or “straw” owner as the owner on its corporate records and bank account. The individual admitted that

⁴⁶ <https://www.justice.gov/usao-nj/pr/florida-man-sentenced-96-months-prison-role-multimillion-dollar-health-care-kickback>.

⁴⁷ <https://www.justice.gov/usao-cdca/pr/redondo-beach-woman-sentenced-15-years-prison-leading-24-million-scam-billed-medicare>.

⁴⁸ <https://www.justice.gov/usao-edva/pr/texas-man-sentenced-2-million-medicare-fraud>.

⁴⁹ <https://www.justice.gov/usao-edva/pr/virginia-medical-equipment-provider-ordered-pay-12-m-medicare-fraud-scheme-civil>.

⁵⁰ <https://www.justice.gov/usao-sdca/pr/father-and-son-duo-sentenced-prison-21-million-dollar-medicare-scheme>.

⁵¹ <https://www.justice.gov/usao-ndga/pr/operator-durable-medical-equipment-companies-sentenced-healthcare-kickback-scheme>.

⁵² <https://www.justice.gov/usao-sdny/pr/florida-business-owner-sentenced-five-years-prison-defrauding-medicare-more-11-million>.

⁵³ <https://www.justice.gov/usao-wdtx/pr/el-paso-medical-equipment-supplier-sentenced-federal-prison-17-million-healthcare>.

⁵⁴ <https://www.justice.gov/usao-sc/pr/durable-medical-equipment-companies-pay-millions-false-claims-settlement>.

he—and not a straw owner—bought lists of Medicare “patients” and then directed a “biller” to submit fraudulent claims to Medicare for DMEPOS that a physician did not prescribe, that were not medically necessary, and that were not being supplied to any Medicare beneficiary or Medicaid recipient. During a three-month period—and under the individual’s direction—the supplier submitted over \$2.3 million in fraudulent claims to Medicare and Medicaid and was paid over \$1.6 million. The proceeds of the fraud were transferred from the supplier’s account to accounts held in the names of shell companies. Those proceeds were then withdrawn from the shell company accounts by others so they could not be traced to the individual.⁵⁵

- A Florida man was sentenced to prison in October 2022 for submitting fraudulent claims to Medicare. The individual owned a DMEPOS supplier. The supplier purported to provide DMEPOS to eligible Medicare beneficiaries. Over a five-month period, the supplier submitted approximately \$2.2 million in fraudulent Medicare claims (and received \$1.4 million in Medicare payments) for DMEPOS that the business never provided and that Medicare beneficiaries never requested.⁵⁶

- A Texas couple pled guilty in April 2025 to defrauding Medicare. The couple operated a DMEPOS supplier that claimed to provide parts and repairs for power wheelchairs, among other services. They admitted that they received millions of dollars for parts and repairs that were never performed or provided. Medicare was billed approximately \$14 million for power wheelchairs, parts and repairs for just 37 Medicare beneficiaries between 2019 and 2023 as a result of their scheme.⁵⁷

- A Georgia woman pled guilty in June 2024 to an information charging her with conspiracy to commit health care fraud. The individual and her conspirators owned, operated, and had a financial interest in DMEPOS companies through which they obtained physicians’ orders for DMEPOS for Medicare beneficiaries without regard to medical necessity. They obtained the DMEPOS orders using marketing call centers and telemedicine companies, caused the submission of false and

fraudulent Medicare claims, and paid illegal kickbacks.⁵⁸

- A South Carolina man was sentenced to 9 years in prison in March 2024 for his role in a nearly \$100 million healthcare fraud scheme. The individual controlled and operated at least 10 DMEPOS companies located throughout the United States. The person and his conspirators used these companies to submit false and fraudulent claims to Medicare for braces that were not medically necessary and/or were obtained through the payment of kickbacks and bribes. Specifically, the companies entered into agreements with an offshore, advertised call center to purchase physicians’ orders so the DMEPOS companies could bill Medicare. When a Medicare beneficiary called the applicable 1–800 number, the beneficiary would be screened for eligibility and then convinced that the beneficiary needed a brace and oftentimes upsold on other braces. The call center would then contact a telemedicine company whose physician or nurse practitioner would issue a prescription without regard to the medical necessity. Beneficiaries were prescribed braces without ever being examined by, seeing, or, in some instances, even speaking to a medical professional.⁵⁹

- A North Carolina woman in April 2023 pled guilty to an information charging her with one count of conspiracy to commit health care fraud. The individual owned and operated various DMEPOS suppliers through which she obtained physicians’ orders for DMEPOS. She paid an individual and others for each DMEPOS order for braces provided to her DMEPOS supply companies. She then billed Medicare for the DMEPOS orders that she obtained in exchange for kickbacks. She observed indicators that these DMEPOS orders were not medically necessary, in part because Medicare beneficiaries would frequently call to complain that they had not ordered the DMEPOS that they received. In addition, to disguise the scheme she put her DMEPOS supplier companies in the names of nominee owners, including her sisters and a friend.⁶⁰

- A Kentucky DMEPOS supplier agreed to pay \$200,000 to resolve allegations that it violated the False

Claims Act by fraudulently billing Medicare and Medicaid for respiratory devices (specifically, non-invasive ventilators) that beneficiaries did not need or use.⁶¹

Elderly diabetics have also been a target for DMEPOS suppliers. For example, a Florida diabetic shoe company and its president agreed in January 2022 to pay over \$5.5 million to settle claims brought under the False Claims Act that it sold custom diabetic shoe inserts that were not actually custom-fabricated in accordance with Medicare standards. The company billed Medicare for the custom version or sold the inserts to other providers who then billed Medicare, which allowed the company to produce and sell more inserts and increase profits by “cutting corners.”⁶²

All of the foregoing indicates several things. First, DMEPOS fraud, waste, and abuse is still a very significant problem, putting hundreds of millions (even billions) of taxpayer dollars at risk and potentially resulting in patient harm, such as in cases where beneficiaries use unnecessary or substandard items. The OIG reiterated the problem in 2024 when it stated: “Although CMS has a number of safeguards in place to prevent bad actors from billing DMEPOS in Medicare, fraudulent billing for DMEPOS continues to be a major concern. Recent cases demonstrate that DMEPOS continues to be a target of fraudulent billing and that new schemes have developed.”⁶³ Second, DMEPOS fraud schemes do not necessarily follow a consistent pattern but can vary widely in their particular facts. Third, DMEPOS fraud, waste, and abuse is not restricted to certain types of items or certain areas of the country but occurs with numerous different product types and in many geographic areas. Considering the wide and ever-changing range of payment safeguard risks associated with DMEPOS supplies, we must continually take measures to address them.

(2) Quality Standards

Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added section 1834(a)(20) of the Act. Section 1834(a)(20) of the Act requires the Secretary to establish and implement DMEPOS quality standards for suppliers

⁵⁵ <https://www.justice.gov/usao-sdfl/pr/miami-man-who-used-durable-medical-equipment-company-front-health-care-fraud-sentenced>.

⁵⁶ <https://www.justice.gov/usao-sdfl/pr/durable-medical-equipment-company-owner-sentenced-health-care-fraud>.

⁵⁷ <https://www.justice.gov/usao-sdtx/pr/harlingen-couple-guilty-multimillion-dollar-medicare-fraud-scheme>.

⁵⁸ <https://www.justice.gov/usao-nj/pr/georgia-chiropractor-admits-149-million-health-care-fraud-and-kickback-scheme-related>.

⁵⁹ <https://www.justice.gov/usao-sc/pr/mt-pleasant-man-sentenced-nine-years-federal-prison-role-one-largest-medicare-fraud>.

⁶⁰ <https://www.justice.gov/usao-nj/pr/north-carolina-woman-admits-participating-health-care-fraud-scheme>.

⁶¹ <https://www.justice.gov/usao-edky/pr/floyd-county-company-agrees-pay-200000-resolve-allegations-fraudulent-billing>.

⁶² <https://www.justice.gov/usao-sdfl/pr/diabetic-shoe-company-agrees-pay-55-million-resolve-false-claims-act-allegations>.

⁶³ <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000867.asp>.

of certain items. As stated in section 1834(a)(20)(D) of the Act, these items are as follows:

- Covered items, as defined in section 1834(a)(13) of the Act, for which payment may be made under section 1834(a) of the Act;
- Prosthetic devices and orthotics and prosthetics described in section 1834(h)(4) of the Act; and
- Items described in section 1842(s)(2) of the Act (for example, medical supplies; home dialysis supplies and equipment; therapeutic shoes; parenteral and enteral nutrients, equipment, and supplies).

Section 1834(a)(20)(E) of the Act authorizes the Secretary to establish the DMEPOS quality standards by program instruction or otherwise after consultation with representatives of relevant parties. CMS first established quality standards via sub-regulatory guidance in 2006 and has updated them as needed since then. Currently accessible at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>, these standards address matters such as the following:

- Administration
- Financial, human resources, and information management
- Equipment and item delivery and set-up
- Patient and caregiver training and instruction
- Patient follow-up.

The standards are both extensive and detailed because we must confirm that the supplier is bona fide and legitimate. Per § 424.57(c)(24), all DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards to enroll in and bill Medicare.

(3) Accreditation

Consistent with section 1834(a)(20)(F)(i) of the Act (and with certain exceptions), DMEPOS suppliers must be accredited by a CMS-approved accrediting organization (AO) to enroll in and bill Medicare. The main purpose of accreditation is to confirm that the supplier meets the DMEPOS quality standards. The accreditation process has been in effect since 2006.

Although § 424.57(c)(24) states that all DMEPOS supplier locations (owned or subcontracted) must be separately accredited, section 1834(a)(20)(F) of the Act exempts certain individuals from the accreditation requirements unless the Secretary determines the quality standards specifically apply to them. The following DMEPOS supplier types are currently exempted:

- Physicians
- Other eligible professionals (as defined in section 1848(k)(8) of the Act), such as a physician assistant or nurse practitioner
- Opticians
- Prosthetists and orthotists
- Qualified audiologists

Certain types of DMEPOS items are also exempt from accreditation, including: (1) DME drugs (inhalation drugs and DME pump-infused drugs); (2) HHAs' medical supplies; and (3) other Part B drugs, such as immunosuppressive and antiemetic drugs.

Per section 1834(a)(20)(B) of the Act, the Secretary designates and approves DMEPOS AOs, of which there presently are eight. To become an AO or be retained or reapproved as one, the AO must meet the requirements of § 424.58. As addressed in greater detail throughout section VI.B. of this proposed rule, these requirements include, but are not limited to the following:

- Completing the application process, which includes the submission of detailed information about the AO's operations and procedures.
- Undergoing various CMS reviews.
- Furnishing ongoing data to CMS about its activities, such as its accreditation decisions, complaints received about suppliers, etc.

In general, DMEPOS suppliers may choose the AO it wishes to accredit them. In performing its DMEPOS accreditation activities—and subject to CMS approval—an AO generally has some discretion in the operational aspects of its review of a supplier's request for accreditation. However, one critical and common component of the review process is the AO's performance of an on-site survey of the supplier. Along with the AO's review of the information the supplier furnishes as part of its accreditation application, the survey enables the AO to examine first-hand the supplier's operations and credentials to help ascertain compliance with the quality standards. Per our subregulatory guidance, DMEPOS suppliers currently must be surveyed once every 3 years following initial accreditation.

(4) Concerns About the Existing DMEPOS Accreditation Process

We are proposing various regulatory changes to our current DMEPOS accreditation process to improve and strengthen it. There are several reasons for this.

First, we have seen an increased number of reports of accredited suppliers not meeting the quality

standards, which has raised questions as to the efficacy of some AO accreditation surveys and reviews. Second, given the aforementioned AO discretion in various aspects of its DMEPOS accreditation processes, we are concerned that differences between the AOs in this regard could lead to inconsistencies in how quality standard compliance determinations are made. Third, although surveys are typically part of the DMEPOS accreditation process, not every supplier receives one. This is especially true for large chain suppliers with 25 or more separately enrolled locations (such as chain pharmacies). We believe this is a potential vulnerability in our enforcement of the DMEPOS accreditation requirement. Fourth, while § 424.58 outlines certain components of the DMEPOS accreditation process (for example, AO data submission to CMS, applying to become an AO), it does not address other important topics that, in our view, should be outlined in regulation. Indeed, CMS regulations regarding the accreditation of certified providers, certified suppliers, and home infusion therapy (HIT) suppliers (found in 42 CFR part 488) contain more extensive provisions than does § 424.58, and we believe some of the protections they afford the Medicare program in facilitating provider and supplier compliance should be duplicated in § 424.58. Fifth, we have since 2006 neither reapproved any AOs nor undertaken a full reassessment of the performance and suitability of our existing AOs. We believe both are now necessary—particularly considering this long passage of time—so we can ensure the DMEPOS accreditation program is functioning effectively. Sixth, and perhaps most importantly, the unique, aforementioned program integrity risks that DMEPOS suppliers continue to pose require, in our view, stricter oversight of the process that helps determines their qualifications.

An additional criminal case underscores our concerns. In March 2025 an individual pled guilty in Federal court (Southern District of Florida) to accepting cash bribes and self-dealing as part of a conspiracy to impede and obstruct the lawful functions of the U.S. Department of Health and Human Services (HHS) and CMS in their administration and oversight of the Medicare program.⁶⁴ According to court documents, the person was a contractor for a DMEPOS

⁶⁴ <https://www.justice.gov/usao-sdfl/pr/miami-inspector-pleads-guilty-scheme-obstruct-us-department-health-and-human-services>.

AO and performed inspections of hundreds of DMEPOS suppliers for compliance with the quality standards. The individual—

- Accepted cash bribes from numerous owners of DMEPOS suppliers to facilitate and expedite the accreditation process so these companies could enroll in and bill Medicare;
- Along with the individual's immediate family, formed DMEPOS companies in the names of family members to conceal the individual's own personal interest in the companies. The person then sold some of these companies to others, having increased their value as Medicare-enrolled DMEPOS suppliers; and
- Directly or indirectly owned some of the suppliers the individual surveyed.⁶⁵

Considering that this case, and perhaps other situations where unqualified suppliers were accredited, may have resulted in many millions of dollars in improper Medicare payments, we believe we must exercise much closer scrutiny over DMEPOS supplier accreditation in general and DMEPOS AOs in particular to prevent such instances from occurring.

In addition, certain CMS concerns about provider and supplier accreditation are not limited to DMEPOS suppliers. In the February 15, 2024, **Federal Register** (89 FR 11996), we published a proposed rule titled “Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions”. This proposed rule would update and supplement provisions in 42 CFR part 488 (hereafter simply part 488) to enhance CMS' oversight of certified provider and supplier AOs; examples of proposed enhancements included addressing conflicts of interest and establishing additional regulatory definitions and procedures for clarity and consistency. We seek to do likewise for DMEPOS accreditation in the subject proposed rule in part by incorporating several provisions in the February 15, 2024, proposed rule into § 424.58, though with modifications to accommodate the unique characteristics of DMEPOS accreditation.

(5) Linkage and Conclusion

We previously noted our desire and obligation to continually strive to reduce DMEPOS fraud, waste, and abuse and, in turn, to limit improper payments and help protect beneficiaries. Although means such as high-risk

screening, site visits, surety bonds, and our existing accreditation program have assisted in this regard, the criminal cases and other concerning situations we have seen make clear that more is needed. Our current DMEPOS payment safeguards are not enough. We view stricter accreditation requirements for both the AOs and DMEPOS suppliers as a mechanism that could effectively supplement our existing measures and halt a certain degree of ongoing fraud, waste, and abuse by facilitating closer and more frequent oversight of the suppliers. While the remainder of this section (section VI.B. of this proposed rule) describes our specific proposals in detail, we present several scenarios—similar to some of the aforementioned criminal cases—where a strengthened accreditation program could help limit or prevent the activities in question:

- Scenario 1—Supplier U is accredited by a DMEPOS AO and is Medicare-enrolled. It undergoes a stock transfer of 60 percent 15 months after initially enrolling, and the new owner assumes control of the business. The new owner is uncommitted to complying with the quality standards and the quality of U's services consequently deteriorate, potentially harming beneficiaries for a considerable period because U's 3-year deadline for another survey will not arrive for another 21 months. However, with more frequent surveys and reaccreditations, such as when the ownership change occurred, the AO could more quickly and closely scrutinize the supplier under its new ownership—before beneficiaries are harmed and further payments to the non-compliant supplier are made.

- Scenario 2—Supplier V is accredited and Medicare-enrolled. Encountering financial problems 1 year into its accreditation, V begins purchasing very substandard (and thus less expensive) DMEPOS in order to cut costs. Without another survey and reaccreditation of V for 2 more years, CMS might have no means of knowing that V's poor-quality products are being furnished to beneficiaries, that these individuals are possibly being harmed, and that Medicare could be paying tens of thousands of dollars for items that do not meet Medicare requirements.

- Scenario 3—Supplier W is accredited and Medicare-enrolled. Nine months after accreditation—or 27 months before its next survey—it begins to engage in fraudulent practices, a few of which are similar to those addressed in the previously noted criminal cases. To help shield its activities, W does not keep records that comply with the DMEPOS quality standards pertaining to

financial management, such as: (1) implementing financial management practices that ensure accurate accounting and billing; and (2) maintaining accounts that link equipment and item(s) to the beneficiary. If surveys and accreditations were required to be annual, however, W's activities could be detected earlier and, given W's failure to comply with the above financial management quality standards, its accreditation and enrollment could be revoked and many Medicare dollars saved.

- Scenario 4—Accredited and enrolled Supplier X becomes so deficient over a multi-month timeframe in (1) furnishing instructions to beneficiaries on how to use equipment and (2) properly setting up the equipment, that several beneficiaries are injured towards the end of this period. X also repeatedly failed to conduct investigations of beneficiary complaints about X's actions. If surveys could be performed with greater regularity, though, the AO could have discovered these violations of various quality standards involving product safety and consumer services before any harm occurred.

- Scenario 5—Y has been a DMEPOS AO for 1 year. It hires two individuals as managing employees who will also participate in surveys and accreditation decisions. One is a physician whose medical license is currently revoked for engaging in fraudulent activity, while the other is a non-physician practitioner whose Medicare enrollment is revoked for furnishing false or misleading information on the Medicare enrollment application. This could raise concerns about the integrity of Y's operations—particularly the physician's participation in surveys—yet existing § 424.58 contains no prohibitions against such hirings.

- Scenario 6—Entity Z seeks to become a DMEPOS AO. As part of its application, it submits the data currently required in § 424.58(b). This data, though, does not include information about the AO's policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who perform surveys for the AO. In fact, there is no explicit prohibition in § 424.58 against, for example, an AO surveyor making an accreditation decision regarding a DMEPOS supplier in which the surveyor has an ownership interest. Given this, AO Z has three individuals who perform surveys of suppliers that the individuals partially own. These suppliers did not meet the quality standards, but the surveyors found them

⁶⁵ Ibid.

compliant regardless, meaning the suppliers would improperly receive Medicare payments despite their quality standard non-adherence. Yet if CMS had had application information on Z's conflict of interest policies and § 424.58 contained a prohibition against such activities, the obvious conflict of interest involving Z could possibly have been avoided and Medicare dollars preserved.

b. Legal Authorities

There are several principal categories of legal authorities for our proposed provisions:

- Section 1834(a)(20)(A) of the Act requires the Secretary to establish and implement quality standards for the suppliers of the items and services described in section 1834(a)(20)(D) of the Act to be applied by recognized independent accrediting organizations.
- Notwithstanding section 1865(a) of the Act, section 1834(a)(20)(B) of the Act requires the Secretary to designate and approve one or more independent AOs for purposes of applying the quality standards referenced in section 1834(a)(20)(A) of the Act.
- Section 1834(a)(20)(F)(i) of the Act (and with certain exceptions) requires the Secretary to mandate that suppliers of the items and services described in section 1834(a)(20)(D) of the Act submit to the Secretary evidence of accreditation by an AO designated under section 1834(a)(20)(B) of the Act.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

2. DMEPOS Accreditation Proposed Provisions

Section 424.58, which governs DMEPOS accreditation, contains the following principal paragraphs:

- Paragraph (a)—Purpose of § 424.58
- Paragraph (b)—AO application and reapproval application procedures
- Paragraph (c)—Ongoing responsibilities of AOs
- Paragraph (d)—Continuing Federal oversight of approved AOs
- Paragraph (e)—AO reconsiderations/appeal rights

Considering the extent of our proposed changes to § 424.58, we propose to entirely reorganize the current paragraph structure and designations. Existing provisions would be moved, revised, deleted, or supplemented as warranted. We believe this restructuring would help stakeholders better understand requirements of § 424.58. Except for

current paragraph (a) or as otherwise noted, all paragraph designations are labeled as proposed new provisions even though the provision may already exist in current § 424.58 under a different paragraph. (For example, current paragraph (b) would be noted as new paragraph (c) even though § 424.58 presently has a paragraph (c)). To the extent needed, we will in this proposed rule cross-reference current § 424.58 paragraph designations to new ones to further assist stakeholders.

In this proposed rule, and unless otherwise indicated—

- “Supplier” refers to a DMEPOS supplier, including its individually enrolled location;
- “AO” refers to an accrediting organization with a DMEPOS accreditation program;
- “Accreditation program” or “program” refers to a DMEPOS accreditation program; and
- “Quality standards” refers to DMEPOS quality standards.

a. Definitions (New § 424.58(b))

We propose several new definitions in § 424.58(b). We believe they would help clarify the regulatory provisions to which they relate.

First, we propose to define “complaint” as an allegation from any party (and via any format) that one of the AO's accredited suppliers may be non-compliant with one or more quality standards or other applicable CMS requirement; the complaint need not involve actual or potential beneficiary harm. As part of the AO approval or reapproval process, current § 424.58(b)(1)(ix) requires the AO to establish procedures for responding to and investigating complaints against its accredited suppliers. Existing § 424.58(c)(1)(iii), meanwhile, requires the AO to monthly provide CMS with notice of such complaints. Given these requirements, we believe a clear definition of “complaint” is warranted. Moreover, we do not believe beneficiary harm should be a prerequisite for meeting the complaint definition, for any type of non-compliance with the quality standards or other applicable CMS requirement is of concern to us.

Second, we propose to define “immediate jeopardy” as a situation where the supplier's non-compliance with one or more quality standards or other applicable CMS requirement has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public. This definition—with minor modifications for purposes of DMEPOS accreditation—has precedent in that it mirrors the term's definition in

§ 488.1 regarding certified providers and certified suppliers. The definition is needed for § 424.58 partly because AOs, under current paragraph (c)(4) thereof, must notify CMS within 2 calendar days of a supplier's deficiency that poses immediate jeopardy.

Third, we propose to define “reasonable assurance” as meaning that an AO has demonstrated to CMS' satisfaction that—

- Its accreditation program requirements meet or exceed the Medicare program requirements;
- The suppliers the AO accredits meet or exceed Medicare requirements; and
- The AO is compliant with all provisions of § 424.58.

As discussed further in this section VI.B. of this proposed rule, we believe AOs should demonstrate that their accreditation programs comply with § 424.58 and all other CMS requirements, hence the need for a reasonable assurance definition. We note that paragraph (1) of our proposed definition duplicates that in § 488.1 in both terminology and purpose.

Fourth, we propose to define “unannounced survey” as meaning:

- A survey conducted without any prior notice of any type (through any means of communication or forum) to the supplier to be surveyed, such that the supplier does not expect the survey until the surveyors arrive; and
- The AO schedules its surveys so that suppliers cannot predict when they will be performed.

It is critical that DMEPOS supplier surveys be unannounced, as they currently are, so that a non-compliant supplier cannot use prior notice of a survey to remedy its deficiencies solely to pass the survey, after which it may resume its non-adherence. Given this, we believe our proposed definition of this term—which, with technical modifications, is similar to the proposed definition of this term in the previously noted February 15, 2024, proposed rule—will emphasize to AOs that no early notification of any kind is permitted.

We solicit comment on the propriety of these definitions and welcome any suggested edits thereto.

b. Initial Application for Approval of AO's Accreditation Program (New § 424.58(c))

Existing § 424.58(b) outlines the process by which an entity may apply or reapply to become an AO. While the processes for both are largely similar, we propose to separate them into two paragraphs for ease of comprehension. Initial application procedures would be

addressed in new paragraph (c) and reapproval application procedures in new paragraph (d).

Current § 424.58(b)(1) outlines information that AOs must submit as part of the application process. This data is intended to help CMS understand the AO's background, operations, planned procedures, skill, number of staff, etc. However, we have not revisited these data elements via rulemaking since promulgation in 2006. Considering, too, the previously noted lack of CMS reapproval or full reassessment of AOs for many years, we believe that more detailed and comprehensive data should be submitted so we can fully ascertain a current or prospective AO's qualifications. We accordingly propose the following changes and additions to existing § 424.58(b)(1), which would be redesignated as new paragraph (c)(1).

(1) Reasonable Assurance Opening Statement (New § 424.58(c)(1))

The opening part of existing paragraph (b)(1) states that an AO applying for approval or reapproval of its DMEPOS accreditation program must furnish certain information to CMS. This requirement would serve as the opening statement for new § 424.58(c)(1) but with two revisions to its current language. First, we would remove the reference to "re-approval" since reapproval application processes would be addressed separately in new § 424.58(d). Second, we would replace the current phrase "the following to CMS:" with "all the following information and materials to demonstrate that the accreditation organization provides reasonable assurance (as defined in paragraph (b) of this section) regarding its program." The new language, which is akin to that in the opening paragraph of § 488.5(a), would emphasize that it would not be enough to merely submit the required information. Rather, the data must be sufficient to give CMS reasonable assurance.

(2) Confirmation of Compliance (New § 424.58(c)(1)(iii))

Existing § 424.58(b)(1)(iii), which would become new § 424.58(c)(1)(iii), starts with language that details the AO's description of its operational processes. We propose to revise this to require a detailed description of the organization's operational, survey, and other accreditation processes to confirm that the suppliers it accredits meet or exceed the DMEPOS quality standards and Medicare program requirements. We believe this expanded data would give us a broader understanding of the

AO's procedures in full, instead of those simply relating to operations.

We propose two other changes involving this paragraph. Current paragraph (b)(1)(iii) contains six elements of the required description, such as: (1) an explanation of the frequency with which surveys will be performed; and (2) guidelines and instructions to surveyors. To improve organizational clarity, we propose to designate these elements as new § 424.58(c)(1)(iii)(A) through (F) in the same respective order they are listed in existing (b)(1)(iii). In addition, new paragraph (c)(1)(iii)(G) would require the description to address how the AO determines whether to perform a survey in situations where it has the discretion to do so; this would have to include a suggested methodology for sampling locations for surveys under a single tax identification number or organization. As explained further in section VI.B.2. of this proposed rule, surveys of DMEPOS suppliers may not be required in all instances. That is, CMS may permit the AO to determine whether a survey is necessary; this could involve, for example, sampling, whereby the AO uses a formula to determine which locations within a particular group (such as a large chain pharmacy) should be surveyed. To help us understand the factors and criteria the organization will consider in its determination and, more importantly, whether it will exercise its discretion prudently, we believe new § 424.58(c)(1)(iii)(G) is necessary.

(3) Redesignation of Existing Data Submission Provisions (New § 424.58(c)(1)(i), (ii), (iv), (v), (vi), and (vii)(A), (B), and (C))

Current §§ 424.58(b)(1)(i), (ii), and (iv) through (vii)(A) through (C) describe additional information the AO must furnish. Although we are not proposing to change the content of these paragraphs, they would constitute, respectively, new §§ 424.58(c)(1)(i), (ii), and (iv) through (vii)(A) through (C).

(4) Conflicts of Interest, Consulting Services, and Number of Surveyors (New § 424.58(c)(1)(vii)(D) and (E))

We propose additional requirements in new § 424.58(c)(1)(vii).

Paragraph (D) would require the AO to explain in detail its policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization's policies and procedures for all of the following:

- The separation of its consulting services from its accreditation services.

- Protecting the integrity of the DMEPOS AO's accreditation program (including the requirements of proposed § 424.58(m) and (n) (discussed later in this section VI.B. of this proposed rule).

- The prevention and handling of potential or actual conflicts of interest that could arise from situations in which a DMEPOS AO owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the AO provides accreditation services. Such interests or relationships include, but are not limited to, the following:

- ++ Being employed as a DMEPOS AO surveyor.

- ++ Being employed by a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Serving as a director of or trustee for a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS AO.

- ++ Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS AO.

- ++ Providing consulting services to a DMEPOS supplier that the DMEPOS AO accredits.

- ++ Having members of their immediate family engaged in any of the above stated activities. The term "immediate family member" would be defined in proposed 424.58(b) as any person with whom the AO owner(s), surveyors or employees have a lineal or immediate familial or marital relationship, including a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. (This definition would be included in proposed revised paragraph (b) of this section.)

- ++ Engaging in any activities during the course of the survey of the DMEPOS supplier that would be or cause a conflict of interest.

- For notifying CMS when a conflict of interest is discovered.

We would also clarify in new paragraph § 424.58(c)(1)(vii)(D)(5) that

for purposes of said paragraph, a conflict of interest exists when a DMEPOS AO, the DMEPOS AO's successors, transferees, or assigns, the DMEPOS AO owner(s), surveyors, or employees, or the immediate family members of the DMEPOS AO owners(s), surveyors and employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS AO accredits.

We discuss in more detail later in this proposed rule our concerns about potential conflicts of interest within a DMEPOS AO's accreditation programs. Along with the aforementioned March 2025 criminal case in the Southern District of Florida, there might be other situations where, for instance, an AO employee or owner has a familial or other relationship with a supplier the AO is about to survey. This could raise questions as to whether the AO will be entirely objective in its survey or review of the supplier at issue. We also note that the previously mentioned February 15, 2024, proposed rule would require the submission of this proposed data as part of the initial application process for AOs seeking to accredit certified providers and certified suppliers. We believe this requirement should be duplicated for DMEPOS AOs in paragraph (D). It is imperative, in our view, that DMEPOS AOs take measures to avoid such conflicts to help ensure the integrity and impartiality of its surveys and accreditation decisions; without this, unqualified suppliers could become accredited and enrolled due to subjective AO determinations, placing the Trust Funds and beneficiaries at risk.

In proposed § 424.58(c)(1)(vii)(E), we would require the AO to outline its policies and procedures for ensuring it always has an adequate number of surveyors. Our concern is that surveys could be delayed—and perhaps more importantly, a particular survey might not be performed as diligently and thoroughly—due to an insufficient number of surveyors. We therefore believe paragraph (E), which would be somewhat similar to current § 488.5(a)(6), is necessary.

(5) AO Program Deficiencies (New § 424.58(c)(1)(viii))

We propose in new § 424.58(c)(1)(viii) that the AO describe its processes for identifying and correcting deficiencies within its accreditation program. It is important for AOs to very frequently review their accreditation programs for vulnerabilities and weaknesses. Without this, AOs may perform their functions in a substandard manner. This risks the

possibility that suppliers receive inadequate scrutiny, which, in turn, could lead to them furnishing items and services while non-compliant with the quality standards. Among other things, improper Medicare payments would result. By describing its procedures for ascertaining and rectifying deficiencies, the AO can help assure CMS that its program will adhere to Medicare requirements and, if there is an indication that compliance may be at risk, it will remedy the matter.

(6) Use of Data To Ensure Program Compliance (New § 424.58(c)(1)(ix))

Existing paragraph (b)(1)(viii) requires the AO to describe its data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. We propose to designate this paragraph as new (c)(1)(ix) and include an additional requirement (taken from § 488.5(a)(11)(i)) that the description explain how the AO uses its data to ensure that its accreditation program adheres to Medicare program requirements. Surveys and accreditation decision-making are obviously critical components of an AO's accreditation program, but there are other AO requirements under § 424.58. Since we need to ensure that the AO will adhere to all of the provisions in § 424.58, we believe an understanding of how the AO will use data to maintain this compliance is necessary.

(7) Complaint Process (New § 424.58(c)(1)(x))

Current § 424.58(b)(1)(ix) requires the AO to explain its procedures for responding to and investigating complaints against its suppliers; this includes processes for coordinating with licensing bodies, ombudsman programs, the National Supplier Clearinghouse (NSC), and CMS. A robust AO process for handling complaints is important because it involves reviewing a supplier's possible violation of a quality standard or other applicable CMS requirement. An AO's failure to properly execute this function could lead to improper Medicare payments to a non-compliant supplier.

We propose several changes to this paragraph, which would be designated as new § 424.58(c)(1)(x).

First, we would add procedures for closing out complaints as part of this information submission requirement. Responding to and investigating complaints is only part of the complaint process. We need to know how the AO would resolve a particular complaint and deem the matter concluded. That is,

we believe our analysis of the AO's qualifications regarding complaints must include an understanding of the complaint's entire life cycle from beginning to end. Without this knowledge, we cannot be assured that the AO will effectively handle the complaint to an appropriate conclusion.

Second, we would change the NSC reference to the applicable National Provider Enrollment (NPE) contractor. This is because the latter entities have replaced the NSC as CMS' DMEPOS enrollment contractors.

Third, new paragraphs § 424.58(c)(1)(x)(A) and (B), respectively, would require submission of the following information:

- The steps and research the AO will undertake in its review of the complaint; and
- How the AO determines whether, in accordance with a complaint, non-adherence to a quality standard or other applicable CMS requirement exists, including the data it considers in its review and when and how it would take action against the supplier.

As with our proposed change regarding complaint closure, we believe the data in existing § 424.58(b)(1)(ix) is insufficient to help us to determine whether the AO will handle complaints thoroughly, consistently, and diligently. Hence, we believe new § 424.58(c)(x)(A) and (B) are warranted.

(8) Redesignation of Additional Data Submission Provisions (New § 424.58(c)(1)(xi) Through (xv))

Existing § 424.58(b)(1)(x) through (xiv) address other types of information the AO must submit, such as: (1) policies and procedures for notifying CMS of non-compliant suppliers; and (2) a list of the organization's currently accredited DMEPOS suppliers. With two exceptions, we are not proposing to revise these paragraphs but only to designate them as new § 424.58(c)(1)(xi) through (xv). The two exceptions are as follows:

- In existing paragraph (xii)(B) (redesignated as new paragraph (xiii)(B)), we propose to include each supplier's accreditation product codes as data the AO must submit with its initial or reapproval application.
- In existing paragraph (xii)(C) (redesignated as new paragraph (xiii)(C)), we propose that the AO must also list each supplier's accreditation effective date with its initial or reapproval application.

Both requirements would help ensure that CMS has sufficient information on each supplier's accreditation type and status.

We note that current § 424.58(b)(1)(xv) requires the AO to agree that it will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We are not designating this paragraph as new § 424.58(c)(1)(xvi) because, as explained later in this proposed rule, we are proposing to include it as part of the larger agreement the AO must sign per proposed new § 424.58(c)(1)(xxiii).

(9) Knowledge and Experience (New § 424.58(c)(1)(xvi))

Section 488.1010(a)(4), which pertains to home infusion therapy supplier accreditation, requires AOs in their applications to furnish information that demonstrates their knowledge, expertise, and experience in home infusion therapy. We propose a similar provision in new § 424.58(c)(1)(xvi) regarding DMEPOS. Despite the volume of information required per existing § 424.58(b), there is no specific requirement that the AO detail its credentials and experience in the DMEPOS arena. Put otherwise, the current data furnished under § 424.58(b) does not, by itself, give us adequate assurance that the AO understands the intricacies of, for example, the quality standards, DMEPOS enrollment and payment, etc. We believe new § 424.58(c)(1)(xvi) would help remedy this.

(10) Review Timeliness (New § 424.58(c)(xvii))

We propose in new § 424.58(c)(xvii) that the AO furnish information about its ability to conduct timely reviews of supplier accreditation applications. This requirement, which mirrors that in § 488.1010(a)(6)(vii), would help us determine whether the AO has adequate resources to handle the accreditation requests it receives.

(11) Decision-Making Process (New § 424.58(c)(1)(xviii))

Akin to § 488.5(a)(13) concerning certified providers and suppliers, new § 424.58(c)(1)(xviii) would require the AO to describe its decision-making process, including its policies and procedures for approving, denying, or terminating a DMEPOS supplier's accreditation status. This must also include an explanation of the reasons for which the AO will deny or terminate a supplier's accreditation. Since, as already mentioned, accreditation decisions are among the most important AO functions, we must have a full understanding of how the AO will make them. This could help us ascertain, for instance: (1) the criteria the AO will use

in its determinations; (2) how broadly or narrowly the AO interprets the quality standards; and (3) the AO's procedures for notifying a supplier of accreditation approval, denial, or termination.

(12) Surveys (§ 424.58(c)(1)(xix))

We propose in new § 424.58(c)(1)(xix)(A) and (B), respectively, that the AO outlines its policies and procedures for the following:

- Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new item type). This must include the circumstances under which the AO will impose a corrective action plan (CAP) in lieu of performing a follow-up survey regarding DMEPOS supplier deficiency.
- Ensuring that all onsite surveys are unannounced, including for preventing unannounced surveys from becoming known to the supplier beforehand.

Given the aforementioned importance of surveys in determining the supplier's compliance with the quality standards, we believe the AO should explain when it will and will not perform a survey. Regarding proposed § 424.58(c)(1)(xix)(B), which parallels § 488.1010(a)(7)(i) for home infusion therapy accreditation, we previously explained the need for surveys to be unannounced. We believe new § 424.58(c)(1)(xix)(B) would help assure us that they will be.

(13) CAPs (§ 424.58(c)(1)(xx))

In lieu of denying or terminating a supplier's accreditation for failing to meet the quality standards, an AO may apply a CAP to the supplier. In general, a CAP permits the supplier to attempt to remedy the problem(s) within a specified timeframe before the AO takes one of these two actions. Existing § 424.58 only references CAPs in paragraph (c)(1)(i) thereof, whereby AOs must provide to CMS various survey-related information, which includes CAPs.

We believe this dearth of CAP provisions in § 424.58 must be addressed. To illustrate, we do not know the following:

- The circumstances under which an AO will impose a CAP and, if a CAP is applied, why the AO chose this approach instead of, as applicable, denial or termination of accreditation.
- The AO's procedures for imposing, monitoring, and terminating a CAP.
- How the AO oversees the supplier's efforts to comply with the CAP and whether a follow-up survey is performed.

- How the AO establishes the CAP's terms (for example, the length of the CAP).

- How the AO ensures that the CAP is adequate to address and correct the deficiencies in question.

- Whether AOs are more inclined to permit CAPs for certain DMEPOS supplier types than for others and whether the supplier's length of enrollment, adverse history (if any), and other factors impact the AO's decision.

We are particularly, though not exclusively, concerned about the first bulleted item. While a CAP (instead of denial or termination) may be justified in some instances if the non-compliance is extremely minor and can be quickly corrected, we have no understanding of the criteria the AO uses in its CAP determinations. In fact, we have received information that, depending on the AO, CAPs are being applied in many instances of non-compliance, even for significant violations of the quality standards. As already noted, compliance with the quality standards is a requirement of § 424.57(c)(24), and non-adherence to any § 424.57(c) supplier standard can result in improper Medicare payments or perhaps grounds for revoking the supplier's Medicare enrollment. If CAPs for such instances of non-compliance are being regularly permitted, we must know the reasons and bases for this. Accordingly, we propose several provisions to enable us to gain a clearer understanding—and, more importantly, to exercise greater oversight—of the AOs' CAP processes. (Additional CAP-related provisions are addressed in section VI.B.2.c.(4). of this proposed rule.)

As part of new § 424.58(c)(1)(xx), and for the foregoing reasons, we propose that the AO outline the policies and procedures via which it will apply a CAP to the supplier. This includes:

- The specific circumstances under which the AO will apply a CAP as opposed to denying or terminating accreditation, and the reason(s) for why the AO believes a CAP in these situations is more appropriate; and
- How a CAP is developed, implemented, and enforced, including—
 - ++ How the AO determines whether a CAP is acceptable;
 - ++ The requirements of (and the timeframe and deadline for) the supplier's resumption of compliance;
 - ++ How the AO ascertains whether the supplier has returned to and maintains compliance; and
 - ++ The circumstances under which the AO will impose a CAP instead of performing a follow-up survey for a supplier deficiency.

(14) Describing and Defining DMEPOS Supplier Deficiencies (New § 424.58(c)(1)(xxi))

We propose in new § 424.58(c)(1)(xxi) that the AO must explain—

- What it considers to be a supplier deficiency and how it defines the term “deficiency”; and
- Whether the AO has different levels of DMEPOS supplier deficiencies.

We are concerned that the meaning of “deficiency” and any AO-identified levels thereof may differ among AOs, resulting in inconsistent determinations. Therefore, we believe we must understand the AO’s policies regarding deficiency classifications.

(15) Potentially Fraudulent Activity (New § 424.58(c)(1)(xxii))

We propose in new § 424.58(c)(1)(xxii) that the AO must describe its processes for: (1) detecting and addressing potential fraud, waste, and abuse by suppliers (including identifying the AO’s definitions of the terms “fraud”, “waste”, and “abuse”); and (2) reporting this conduct to CMS, and, as applicable, law enforcement. While the AO’s principal function under § 424.58 is to perform the accreditation activities described therein, the AO must not disregard possible fraud, waste, or abuse by suppliers. For instance, suppose an AO is performing a survey and discovers that certain records the supplier furnishes to the AO appear to be falsified. We believe the AO should have procedures in place for handling these and other situations and referring them to CMS and, as applicable, law enforcement.

(16) Agreement of Compliance (New § 424.58(c)(1)(xxiii))

(a) Introduction

As part of the AO application process for certified provider and certified supplier accreditation, 42 CFR 488.5 requires the AO to furnish various written acknowledgements stating that the AO will perform certain activities. These include, for example, providing CMS with the following:

- Copies of all survey reports and related information for providers and suppliers seeking Medicare participation.
- Timely notification of when a survey or complaint investigation identifies an immediate jeopardy situation.
- Notification of any proposed changes in the AO’s accreditation program and that it will not implement them without written notice of continued program approval from CMS.

No concomitant requirement to submit acknowledgement statements exists in current § 424.58(b). This is concerning because, in our view, without a written, binding AO commitment to execute functions required under § 424.58, we are less assured the AO will, in fact, do so. Indeed, providers and suppliers enrolling in Medicare must sign a certification statement on their Form CMS–855 application in which they agree to adhere to various requirements, including the Medicare laws, regulations, and program instructions applicable to the provider or supplier. We see no appreciable difference between this certification and one that would require an AO to make similar agreements—a particularly important consideration given that we are entrusting the AOs with the role of confirming DMEPOS suppliers’ compliance with the quality standards. In both cases, millions of Trust Fund dollars could be at stake if we lack confidence in the party’s willingness and readiness to adhere to all Medicare requirements. We accordingly believe that, as in § 488.5, DMEPOS AOs should have to explicitly agree to certain conditions as part of the application process. (We note that some of the requirements in § 424.58(c)(1)(xxiii) would refer to proposed new paragraphs in § 424.58 that will be addressed later in this section of this proposed rule.)

In the opening paragraph of new § 424.58(c)(1)(xxiii), we propose that the AO’s chief executive officer (CEO) (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) provide written acknowledgement that, as a condition of CMS’ approval or continued approval of the AO’s accreditation program, the AO agrees to adhere to the provisions in § 424.58(c)(1)(xxiii). The acknowledgement, which the official must sign and date and which must be on the AO’s letterhead, must list all the data elements in § 424.58(c)(1)(xxiii) and contain the AO’s agreement to comply therewith.

Two matters should be noted regarding this proposal. First, the requirement that the CEO or similar official with binding authority sign the statement is consistent with the provision at § 424.510(d)(3)(1)(C) that an authorized official (as defined in § 424.502) must sign an initial provider enrollment application of behalf of an organization. Second, several of the paragraphs in 42 CFR part 488 require acknowledgement statements as a condition of AO approval. We believe our proposed statements should also apply to reapprovals and continued

approval, particularly the latter. It is not enough for the AO to comply with § 424.58 only upon initial approval and reapproval. We believe the AO should acknowledge that compliance must be constant and that, as discussed further in this proposed rule, a failure to maintain it could result in the termination or suspension of the AO’s approval status.

(b) Data Submission Within 3 Business Days

We propose in new § 424.58(c)(1)(xxiii)(A)(1) and (2), respectively, that the AO must agree to provide CMS within 3 business days of the latter’s request—

- Any of the data described in § 424.58(e)(1)(i); and
- Any other information CMS deems necessary to facilitate its oversight of the AO’s accreditation program.

Concerning (c)(1)(xxiii)(A)(1), AOs are presently required each month under § 424.58(c)(1)(i) (which, as explained later in this proposed rule, will be designated as new paragraph (e)(1)(i)) to furnish CMS with certain information, such as copies of all survey results and CAPs. Considering, again, our role as overseer of Medicare DMEPOS accreditation activities, we must be able to closely and constantly monitor AOs’ activities. Having to wait up to a month to receive copies of survey reports and other survey data is antithetical to this. We believe a 3-business day period would effectively balance our need to secure this data expeditiously and the AO’s need for several days to acquire, organize, and submit the information to us. This does not necessarily mean we will frequently request this information outside of the previously mentioned monthly reports. It only means we reserve the right to ask for it if, in our view, circumstances warrant.

We believe proposed paragraph (c)(1)(xxiii)(A)(2) is especially important. Even with the extensive information submissions we would require in revised § 424.58, this may not capture all the data we need to ensure our effective oversight of the AOs. As the steward of the Medicare Trust Funds, we should be able to collect any additional information required to ascertain whether the AOs are properly executing their respective accreditation programs. We believe the broad scope of paragraph (c)(1)(xxiii)(A)(2) would afford us this flexibility.

(c) Immediate Jeopardy Notifications

We previously noted that existing § 424.58(c)(4) requires the AO to send written notice to CMS within 2 calendar days of identifying an accredited

DMEPOS supplier's deficiency if the latter poses an immediate jeopardy situation; any adverse action the AO accordingly takes must also be identified. Given our obligation to protect Medicare beneficiaries and the consequent need for us to know when their safety may be threatened, we believe that the AO's specific agreement to comply with this requirement (which would be designated as new § 424.58(e)(1)(iii)) is warranted.

(d) Notification of Change in AO Program

Current § 424.58(c)(1)(v) requires an AO to notify CMS on a monthly basis of any proposed changes to its accreditation standards, requirements, or survey process. Any such changes can significantly impact the AO's accreditation program, which, in turn, can affect our responsibility for the DMEPOS accreditation program as a whole. Hence, we propose in new § 424.58(c)(1)(xxiii)(C) that the AO must agree: (1) to furnish this notification to us in writing; and (2) that it will not implement such changes absent prior written notice of continued program approval from CMS consistent with § 424.58(e)(2) (discussed later in this proposed rule).

(e) Termination or Other Change in Supplier's Accreditation Status

Section 488.1010(a)(17)(iv) requires a home infusion therapy supplier AO to acknowledge that it will notify CMS of any decision to revoke or revise the accreditation status of a specific HIT supplier within 3 business days of the date the AO took the action. As accreditation is a requirement for DMEPOS enrollment under § 424.57(c)(24), CMS must know as quickly as possible when a supplier's accreditation is terminated, revoked, withdrawn or amended so we can take similar action concerning the supplier's enrollment; a belated notice from the AO could result in improper payments to an unaccredited supplier. Thus, we propose in new § 424.58(c)(1)(xxiii)(D) that the AO must agree to provide this notification in writing to CMS within 3 business days of the AO's action.

(f) CAP Information

Consistent with our previously mentioned rationale for proposed new § 424.58(c)(1)(xx), we propose in new § 424.58(c)(1)(xxiii)(E) that the AO must agree to inform CMS of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. This must include—

- The reason for the decision;

- A detailed explanation and justification as to why the AO applied a CAP instead of, as applicable, denying or terminating the supplier's accreditation; and
- The details of the supplier's CAP.

(g) Data for CMS Evaluation of Performance

Section 488.5(a)(11)(ii) requires a certified provider or supplier AO to agree to submit timely, accurate, and complete data to support CMS's evaluation of the AO's performance. Data to be submitted includes, but is not limited to, provider/supplier identifying information, survey schedules and findings, and notices of accreditation decisions; the AO must submit this information according to the instructions and timeframes CMS specifies. This regulatory provision encompasses a wide range of data. Though some of it may overlap other data referenced in proposed new § 424.58(c)(1), we believe a general, overarching agreement to furnish the scope and breadth of data addressed in § 488.5(a)(11)(ii) is justified so we can ensure that we have all information necessary to execute our oversight functions. To this end, new § 424.58(c)(1)(xxiii)(F) would duplicate the requirements of § 488.5(a)(11)(ii) (with modest modifications specific to DMEPOS suppliers).

(h) AO Implementation of CMS Changes

There are instances where CMS changes its DMEPOS accreditation program requirements. Current § 424.58(c)(2) requires that within 30 calendar days of said change, the AO must submit to CMS: (i) an acknowledgment of CMS's notification of the change; (ii) a revised crosswalk reflecting the new requirements; and (iii) an explanation of how it will alter its standards to comply with CMS's new requirements within the timeframes that CMS specifies in notification. As it is important for AOs to implement these changes timely and in full, we believe the AO should explicitly commit to do so. New § 424.58(c)(1)(xxiii)(G) would thus require that the AO agree to adhere to the following:

- Submission of the data required in § 424.58(e)(7). (New paragraph (e)(7) would reflect current requirements in paragraph (c)(2).)
- The proposed changes must be submitted to CMS within 30 calendar days of the date of CMS' written notice to the AO.
- The AO must not implement its proposed corresponding changes without prior CMS approval.

(i) Deficiencies

We previously noted that new § 424.58(c)(1)(xxi) would require the AO to explain what it considers to be a DMEPOS supplier deficiency, how it defines the term, and whether it has different levels of deficiencies. However, and to facilitate consistency among the AOs, we believe CMS should retain the discretion to: (1) define the term deficiency; and (2) establish deficiency levels for use across all AO DMEPOS accreditation programs. New § 424.58(c)(1)(xxiii)(H) would thus require the AO to agree to accept and adhere to any CMS-established deficiency definitions and levels and categories thereof.

(j) Surveyors as Witnesses

Consistent with our aforementioned intention to move current § 424.58(b)(1)(xv) to new § 424.58(c)(1)(xxiii), we propose that new § 424.58(c)(1)(xxiii)(I) would require the AO to agree that its surveyors can serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation finding.

(k) Sampling

We earlier addressed in this proposed rule the concept of sampling, in which the AO utilizes a formula to determine which locations within a particular group should be surveyed. We propose to require the AO's agreement in new § 424.58(c)(1)(xxiii)(J) that if CMS permits the AO to perform surveys via a sampling process, the AO: (1) will submit to CMS its planned sampling methodology in detail; and (2) will not undertake sampling until CMS has approved the AO's methodology. Considering that certain suppliers will be not surveyed under a sampling approach, we must ensure that the AO's methodology aligns with CMS' obligation to protect Medicare beneficiaries and the Trust Funds against non-compliant suppliers.

(l) Patient Records

As part of its survey of a supplier, the AO must examine the supplier's patient medical records. This helps confirm that the supplier is actually serving patients and that the items and services furnished to them are legitimate. For this reason, and as stated in sub-regulatory guidance, the reviewed patient medical records must not include: (1) mock files; (2) fictional patients; (3) simulated documentation;

and (4) templates.⁶⁶ Actual records of the patients are required. With the aforementioned importance of verifying the bona fide provision of these items and services, we propose in new § 424.58(c)(1)(xxiii)(K) that the AO agree not to use these four types of records in its surveys. We also propose to include duplicate patient records as a fifth category. This means that the reviewed records must be of the supplier's own patients and not those of another supplier. We have encountered situations where multiple suppliers within a larger organization have similar patient records. We do not believe that records of other suppliers' patients should be considered in the survey, for they do not reflect the items and services that the surveyed supplier itself is furnishing.

Although we have elected to address this topic via rulemaking in new § 424.58(c)(xxiii)(K), we emphasize that we retain the authority under section 1834(a)(20)(E) of the Act to establish, add, and modify DMEPOS quality standards via sub-regulatory guidance.

(m) Costs of Ad-Hoc Surveys

As discussed further in section VI.B.2.d.(7). of this proposed rule, we are proposing in new § 424.58(e)(8)(ii) that CMS may at any time direct the AO to perform a survey of any accredited supplier or a group thereof. Given this, we are concerned there could be delays in the survey's performance due to a potential disagreement between the AO and the supplier regarding which of them pays the cost of a CMS-required survey. To avoid such situations, we believe the cost issue should be resolved well beforehand. Accordingly, we propose in new § 424.58(c)(xxiii)(L) that the AO must agree to have a binding written agreement with each supplier it accredits regarding whether the AO, the supplier, or both will assume the costs of a survey that CMS directs the AO to perform under paragraph (e)(8)(ii) of this section.

(n) Truthfulness and Accuracy

To ensure that the AO understands its obligation to submit accurate and complete data to CMS at all times, we propose in new § 424.58(c)(xxiii)(M) that the AO must agree to submit all required information to CMS both before and after approval of its accreditation program in a truthful, accurate, and complete manner.

(o) Compliance With § 424.58

In general, the components of our proposed § 424.58(c)(1)(xxiii) AO attestation statement address fairly specific elements (for example, an attestation to utilize CMS's deficiency definition). Yet we reiterate that adherence to all provisions in § 424.58 is still required. Merely because § 424.58(c)(1)(xxiii) is silent regarding a certain provision in § 424.58 should not, in our view, exempt the AO from agreeing to comply therewith. Consequently, we propose in § 424.58(c)(1)(xxiii)(N) that the AO in its statement must agree to comply with all of the requirements in § 424.58 at all times. We note this would include agreeing to adhere to the policies, procedures, and practices it outlined under § 424.58(c) as part of its initial or reapproval application and any changes thereto made with prior CMS approval. In making its decision whether to approve or reapprove an AO's accreditation program, CMS relies upon the explanations the AO furnished in the application. Furthermore, in approving any change to an AO's policies, procedures, and practices, CMS does so with understanding that the AO will adhere to the new processes. We therefore believe the AO should abide by: (1) its representations in its application; and (2) any policy, procedural, or practice change that CMS authorized.

(17) Additional Information Needed (New § 424.58(c)(2))

Despite the wide scope of data to be furnished per § 424.58(c)(1), CMS may need additional information to fully assess the AO's credentials. Thus, we propose in new § 424.58(c)(2) that if CMS determines that further data is necessary to make a determination on the AO's request for approval, we would notify the organization and afford it an opportunity to provide this data.

(18) Application Withdrawal (New § 424.58(c)(3))

Similar to § 488.1010(c) with respect to AO applications for HIT supplier accreditation, we propose in new § 424.58(c)(3) that an AO may withdraw its application for approval of its accreditation program at any time before CMS posts the approval described in § 424.58(c)(5) (discussed in section VI.B.2.(b).(20). of this proposed rule). This would give the AO adequate opportunity to withdraw its application if it wishes while setting forth a specific withdrawal deadline.

(19) Reasons for Denial

Section 424.530(a) lists 18 reasons for which CMS can deny provider or supplier enrollment applications, including those from DMEPOS suppliers. Among these grounds are the following as outlined in § 424.530(a)(1) through (4) and (12)(i), respectively:

- The provider or supplier is non-compliant with the enrollment requirements in Title 42.
- The provider or supplier or any owner, managing employee, managing organization, officer, director, authorized or delegated official, medical director, supervising physician, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program, of the provider or supplier is—

++ Excluded by the OIG from Medicare, Medicaid, and any other Federal health care program; or

++ Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

- The provider, supplier, or any owner, managing employee, managing organization, officer, or director of the provider or supplier was, within the preceding 10 years, convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries.

- The provider or supplier has submitted false or misleading information on the enrollment application to become Medicare-enrolled.

- The provider or supplier is terminated, revoked or otherwise barred from participation in a State Medicaid program or any other Federal health care program.

The central purpose of these provisions is to prevent non-compliant and unqualified providers and suppliers—or those that present a program integrity risk—from being eligible to receive Medicare payments. While DMEPOS AOs, unlike DMEPOS suppliers, neither enroll in Medicare nor receive Medicare payments, they are responsible for ascertaining quality standard compliance for potentially hundreds of suppliers that may or do bill Medicare. In other words, in general contrast to a single supplier, an AO's qualifications and performance can impact the payment of hundreds of millions of Medicare dollars. Consequently, considering the likely greater effect an AO has on the Trust

⁶⁶ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>.

Funds, we believe it is especially important to have clear reasons in § 424.58 for which we can deny an AO's application for approval of its accreditation program.

We propose the following denial reasons in new paragraphs (c)(4)(i) through (viii), several of which duplicate those in § 424.530(a), given the latter's effectiveness in keeping unqualified providers and suppliers out of the Medicare program. Specifically, denial of an AO's application can occur if CMS determines that—

- *The AO has failed to comply with all application, data, and agreement submission requirements outlined in § 424.58(c).* In our view, if the applicant does not submit all the required information and agreements in § 424.58(c), the application is deficient, and the AO therefore cannot be approved.

- *The AO has failed to provide reasonable assurance (as defined in paragraph (b)).* CMS must have confidence that the AO's accreditation program will comply with all applicable CMS requirements and, above all, ensure that only qualified DMEPOS suppliers are accredited.

- *The current number of CMS-approved DMEPOS AOs is sufficient to ensure the continued administration of CMS' DMEPOS accreditation program.* We believe that limiting the number of DMEPOS AOs would allow us to exercise closer scrutiny of each AO because there would be fewer to oversee.

- *The AO's DMEPOS program was previously terminated, suspended, or placed on probation by CMS under, respectively, new § 424.58(h), (i), or (j).* As explained further in this section VI.B.2. of this proposed rule, we are proposing that CMS may terminate, suspend, or place on probation an AO's accreditation program in certain circumstances, such as non-compliance with the provisions of § 424.58. In light of the significance of such a CMS action, we do not believe we should be required to approve an AO's accreditation program that was previously found to be deficient in some manner.

The fifth and sixth denial reasons are akin to, respectively, those in previously referenced §§ 424.530(a)(2), (3) and (12) as well as § 424.530(a)(4). (The fifth also includes types of actions in our current definition of "final adverse action" in § 424.502 (for example, revocation of Medicare enrollment).) These are intended to help ensure that neither the AO nor certain entities or individuals closely associated therewith pose program integrity risks.

- The AO, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing board member, W-2 or contracted surveyor, or W-2 or contracted health care or administrative or management services personnel thereof—

- ++ Is OIG excluded;

- ++ Is debarred, suspended, or otherwise excluded from participating in any Federal procurement or non-procurement activity; or

- ++ Within the preceding 10 years:

- ++ Was convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

- ++ Has had a Medicare enrollment revoked under § 424.535;

- ++ Has had a license to provide health care suspended or revoked by any State licensing authority; or

- ++ Has been suspended or terminated from participating in a Federal or State health care program.

- *The AO has submitted false or misleading information on its application in order to gain CMS approval or reapproval as a DMEPOS AO.* The submission of false or misleading information on an AO's application raises serious doubts that the AO can be a reliable partner of the Medicare program, hence the need for this denial reason.

Our proposed seventh and eight denial reasons are as follows:

- The AO is non-compliant with any provision in § 424.58.

- *CMS otherwise determines that approval of the applicant as a DMEPOS AO would not be in the best interests of the Medicare program and its beneficiaries.* (This "best interests" principle is similar to that in previously referenced § 424.530(a)(3).)

The proposed non-compliance denial reason is based on aforementioned § 424.530(a)(1), and we believe it should be an obvious basis for denial. If the entity cannot demonstrate adherence to all provisions of § 424.58, this raises real questions as to whether it can be an effective DMEPOS AO. Regarding the "best interests" ground, there could be isolated instances situations where none of the other proposed denial reasons apply but CMS nonetheless has concerns about how the entity might perform as a DMEPOS AO. Consider this brief, non-exhaustive list of possible examples:

- CMS receives information indicating that the entity—while acting as an AO or as a CMS contractor in another capacity—performed in what CMS believes was a sub-standard manner.

- Past or present feedback from stakeholder groups generates doubts about the prospective AO's capabilities.

- In reviewing the entity's otherwise complete application, CMS concludes, for instance, that:

- ++ Some of the AO's surveyor personnel are insufficiently experienced in the DMEPOS arena.

- ++ The AO's stated policies for avoiding conflicts of interest are inadequate.

- ++ The AO will too frequently apply a CAP to a non-compliant supplier instead of terminating its accreditation.

We recognize that this eighth denial reason (which would constitute proposed paragraph (c)(4)(viii)) could in certain situations overlap with one or more other denial reasons. To illustrate, a prospective AO could fail to provide reasonable assurance (proposed (c)(4)(ii)) based on its non-compliance with several provisions of § 424.58 (proposed (c)(4)(vii)), which accordingly indicates that approving the AO would not be in the best interests of Medicare and its beneficiaries (proposed (c)(4)(viii)). Yet there are a wide range of possible situations where we might have concerns about a particular initially applying or reapplying AO but said scenario is not explicitly addressed in the other denial reasons. We believe proposed (c)(4)(viii) is necessary to account for such cases. As already explained, we have an obligation to protect the Trust Funds from improper payments and Medicare beneficiaries from potential harm, and we therefore do not believe we should be required to approve an AO—even if it is otherwise compliant with § 424.58—if doing so would not be in Medicare's best interests.

(20) Notice of Approval/Denial, Public Notice, and Length of Approval (New § 424.58(c)(5) Through (7))

Existing § 424.58 does not address when and how an AO is notified of CMS' decision to approve or deny its application for approval of its accreditation program. To clarify these issues, we propose to incorporate several procedures in §§ 488.1010(d) and 488.1020 within new § 424.58(c)(5) and (6), respectively. Under § 424.58(c)(5), CMS would send notice of its decision to the AO within 210 calendar days from the date CMS determines that the AO's application is complete. The notice would include: (i) the basis for the decision; (ii) if applicable, the effective date of approval; and (iii) if applicable, the length of the approval (not to exceed 6 years). Under proposed new § 424.58(c)(6), CMS would announce on

its website its decision to approve or deny the application. This announcement would be posted within 210 calendar days from the date that CMS determines that the AO's application was complete. If the application is approved, the posting would also state the approval's effective date (no later than the notice's publication date) and length (6 years or less).

Three things must be emphasized with respect to these proposals.

First, the procedures in § 488.1020 regarding HIT accreditation are largely similar to those in § 488.5(e)(2) concerning certified provider/supplier accreditation. Hence, there is a well-established, effective CMS process for announcing AO application decisions. In general, we see no reason to alter this process for DMEPOS accreditation. However, unlike with § 488.1020 and § 488.5(e)(2), we are proposing to publish our decision on our website rather than in the **Federal Register**. We believe this would allow us to more quickly notify stakeholders of this determination.

Second, the 210-day timeframe is necessary because we must have adequate time to carefully and thoroughly review all AO applications (and the detailed information furnished therewith). AOs, as noted, have an indispensable role in confirming that DMEPOS suppliers are compliant with the quality standards, and we must ensure that the applying AO has the ability to perform this task.

Third, the maximum period of an AO DMEPOS program's approval would be 6 years. We stress that this would not mean each program would be approved for 6 years, or even 4 or 5. Approval could be for any length of time within that range that CMS deems appropriate. There could be circumstances where, for instance, CMS approves a particular AO's program but only for a fairly short period to assess the AO's performance before—, if the AO seeks reapproval—potentially committing to a longer timeframe. To make clear CMS' discretion in this regard, we propose in new § 424.58(c)(7) that CMS may approve an accreditation program for any period up to a maximum of 6 years.

3. AO Reapproval Process (New § 424.58(d))

New § 424.58(d) would outline the procedures involving an AO's application for reapproval of its DMEPOS accreditation program. As previously mentioned, and except as otherwise noted, these procedures would generally duplicate those for

initial applications in terms of content and rationale.

We propose in new § 424.58(d)(1)(i) that except as stated in paragraph (d)(1)(ii), an approved DMEPOS AO that seeks to continue as such must apply for reapproval of accreditation at least 9 months before its current approval term expires. We believe the earliest possible reapproval application submission is needed to afford CMS—prior to the current approval's expiration—sufficient time to: (1) review the application; (2) consider the AO's past performance; and (3) render a decision. We also propose in paragraph § 424.58(d)(1)(i), however, to have the discretion to grant the AO an additional 30 days to reapply. This would enable us to address situations where, for instance, the AO wishes to reapply but needs more time to finalize its submission.

We previously noted our concern that we have not reapproved any AO since the DMEPOS accreditation program's inception in 2006. Considering this nearly two-decade period, we believe it is imperative to commence a reapproval process for all current AOs as soon as possible after the effective date of any finalization of our proposals. Therefore, we propose in § 424.58(d)(1)(ii) that CMS may require AOs to submit reapproval applications under paragraph (d) any time after January 1, 2026, which would be the effective date of our revisions to §§ 424.57 and 424.58. The application would have to be submitted within 60 calendar days of CMS' submission request; if it is not, CMS terminates the AO's DMEPOS accreditation approval. This would afford the AO adequate time to prepare its application without unduly delaying our AO reapproval initiative described in § 424.58(d)(1)(ii). At the same time, we believe this deadline must be met so that the AO does not indefinitely retain its status pending the completion of the general reapproval process. If the AO wishes to continue its DMEPOS accrediting status, it must comply with all requirements in § 424.58, including proposed paragraph (d)(1)'s 60-day timeframe.

We propose in new § 424.58(d)(2) that as part of its reapproval application submission: (1) the AO would have to furnish all information and statements identified in § 424.58(c)(1); and (2) CMS could request additional information under § 424.58(c)(2). This is to ensure that CMS would have enough data on hand to make its determination and secure the important AO agreements specified in § 424.58(c)(1)(xxiii).

Furthermore, we propose in new § 424.58(d)(3) through (7) to duplicate

our proposals in § 424.58(c)(3) through (7), respectively. The same rationales would apply—namely, to: (i) establish clear reapproval application withdrawal procedures; (ii) to protect the Trust Funds against non-compliant AOs and potential program integrity risks; (iii) give CMS adequate time (a maximum of 210 days) to render its decision; and (iv) reiterate CMS' discretion regarding the length of the approval period.

4. Ongoing Responsibilities of a CMS-Approved AO (New § 424.58(e))

Existing § 424.58(c)(1) through (6) outline activities an approved AO must undertake on an ongoing basis. These functions, some of which have already been mentioned, are respectively:

- Monthly submission of data concerning the AO's activities (for example, copies of surveys; notice of accreditation decisions and complaints received; information about actions taken against suppliers, etc.).
- Submission of the acknowledgment, cross walk, and explanation in response to a change in CMS requirements.
- Allowing the AOs' surveyors to serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation determination.
- Notification to CMS within 2 calendar days of a supplier's immediate jeopardy deficiency.
- Within 10 calendar days of receiving CMS notice that CMS intends to withdraw the AO's approval, provide written notice of the withdrawal to all the AO's accredited DMEPOS suppliers.
- Annually furnish CMS-specified summary information regarding the prior year's accreditation activities and trends.

These requirements would be included within new § 424.58(e). However, and as further explained, we also propose certain changes to them.

a. Submission of Monthly Information, Requested Information, and Immediate Jeopardy Deficiencies (New § 424.58(e)(1))

There are five categories of data in current § 424.58(c)(1)(i) through (v) that the AO must furnish on a monthly basis. We propose several revisions thereto.

First, in the opening paragraph of (c)(1) (which we are redesignating as new paragraph (e)(1)(i)), we propose to change the reference “on a monthly basis” to “no later than the last day of each month.” We believe the latter is clearer in terms of when the deadline for monthly submission is.

Second, existing paragraph (c)(1)(i) requires monthly submission of copies of all accreditation surveys, together with any survey-related information that

CMS may require (including CAPs and summaries of findings with respect to unmet CMS requirements). Paragraph (c)(1)(i) would become new paragraph (e)(1)(i)(A), with the parenthetical in the previous sentence regarding CAPs and summaries constituting new paragraph (e)(1)(i)(A)(1). In new § 424.58(e)(1)(i)(A)(2), and for the same reason behind proposed new § 424.58(c)(1)(iii)(G), we propose that the required data must include the instances in which the AO had the discretion to perform a survey but elected not to, including the reason(s) behind the AO's decision.

Third, we propose to delete the requirement in current § 424.58(c)(1)(iii) of monthly notice to CMS regarding complaints. This is because we are proposing in new § 424.58(e)(3)—as discussed in section VI.B.2.d.(3). of this proposed rule—a separate process and timeframe for the AO's submission of complaint data to CMS.

Fourth, we propose to add new paragraph (e)(1)(i)(C) that would require monthly notice of resolved deficiencies. As already mentioned, any DMEPOS supplier deficiency—even if it has been resolved and regardless of whether it invoked immediate jeopardy considerations—is of concern to us since it involves non-compliance with the quality standards or other applicable CMS requirement. Hence, we believe CMS should be made aware of them.

We are not proposing to change the basic content of existing paragraphs (c)(1)(ii) and (iv) regarding, respectively, the monthly reporting of accreditation decisions and adverse actions. These two provisions, with slight technical modifications, would serve as new paragraphs (e)(1)(i)(B) and (D), respectively.

Current § 424.58(c)(1)(v) requires the AO to report proposed changes in its accreditation standards or requirements or survey process on a monthly basis. It also states that CMS may withdraw its approval of the AO's accreditation program if the AO implements these changes without prior CMS approval. We are proposing to delete this requirement because, as discussed in section VI.B.2.d.(2). of this proposed rule, the question of AO process and standard changes will be addressed more thoroughly in new § 424.58(e)(2).

In new § 424.58(e)(1)(ii), we propose that—

- CMS may at any time request the AO to submit any of the information described in new paragraph (e)(1)(i) or any other data CMS deems necessary to facilitate its oversight of the AO's accreditation program; and

- The AO must furnish this data to CMS within 3 business days of the request.

We noted in our discussion of proposed § 424.58(c)(1)(xxiii)(A) our concern about not receiving data that could be critical to our oversight responsibilities for several weeks after our request. We must be able to obtain this information much sooner if circumstances warrant, thus the need for § 424.58(e)(1)(ii).

We also previously discussed current § 424.58(c)(4) and its 2-day notification requirement regarding immediate jeopardy deficiencies. We propose to retain this requirement as part of new § 424.58(e)(1)(iii).

b. AO Standard or Requirement Changes (New § 424.58(e)(2))

As mentioned earlier, existing § 424.58(c)(1)(v) requires the AO each month to notify CMS of any proposed changes to its accreditation standards, requirements, or survey process; the AO cannot implement the change without prior CMS approval. Given our responsibility for ensuring that suppliers meet all accreditation requirements and comply with the quality standards, it is imperative that we: (1) be made aware of changes in how an AO accredits suppliers; and (2) have the authority to either authorize or prohibit the AO's proposed revision. To illustrate, it would be very problematic if an AO changes its requirements without our knowledge such that it became easier for a potentially non-compliant supplier to become accredited. For this reason, we are not proposing to revise the basic requirements of § 424.58(c)(1)(v). Yet we believe that additional safeguards are needed so that we: (1) become aware of planned changes earlier than we presently do; and (2) have enough information to fully understand the breath of the revision. We therefore propose several changes to § 424.58(c)(1)(v), which would become new § 424.58(e)(2).

First, we propose in the opening paragraph of § 424.58(e)(2) to incorporate the existing notice requirement in current § 424.58(c)(1)(v) with two additions. One addition would require the notice to be written. This is current practice, but we wish to include this in regulation. The other would state that the scope of § 424.58(e)(2) includes the addition, modification, or removal of a DMEPOS product service category to the list of categories for which the AO accredits DMEPOS suppliers. We have received questions from AOs as to whether such changes, per current § 424.58(c)(1)(v), require prior CMS

approval. To confirm that they do, we believe this addition is necessary.

Second, new § 424.58(e)(2)(i) would require the AO to submit the notice at least 60 calendar days before the proposed change's intended effective date. Paragraphs (e)(2)(i)(A) and (B) would also require, respectively, the notice to include—

- A detailed explanation of the revisions and the rationale for them; and
- A detailed crosswalk (in table format) containing the exact language of the AO's revised accreditation requirements and the applicable Medicare requirements for each.

We believe these changes would help ensure that we receive adequate advance notice of, and sufficient information regarding, the proposed changes.

In new § 424.58(e)(2)(ii), we propose that CMS would furnish the AO written approval or disapproval of the proposed change within 30 calendar days of the revision's effective date. This provision would clarify for the AO what it can expect regarding the timing of CMS' decision.

In new § 424.58(e)(2)(iii), we propose to largely restate the existing policy in § 424.58(c)(1)(v) that CMS may terminate or suspend its approval of the AO if the latter implements the change before or without CMS approval. This would emphasize to the AO the need for prior CMS acquiescence to the revision.

c. Complaints (New § 424.58(e)(3))

We previously noted that existing § 424.58(c)(1)(iii) requires the AO to provide monthly notice to CMS of all complaints involving suppliers. As with certain other information falling under current § 424.58(c)(1), we are concerned that only requiring the reporting of complaints on a monthly basis could leave us unaware for weeks of allegations of suppliers' non-compliance with the quality standards or other applicable CMS requirement. Again, considering our obligation to safeguard the Trust Funds against improper payments and to protect beneficiaries, we believe complaint data should be furnished to us more frequently. We accordingly propose the following requirements in new § 424.58(e)(3).

In paragraphs (e)(3)(i)(A) through (C), we propose that upon receipt of a complaint, the AO must, respectively—

- Provide written notice of the complaint to CMS no later than 5 calendar days after receipt;
- In accordance with its existing policies and procedures, perform an initial review of the complaint to determine whether, based on the complaint and any other data, the

supplier may be non-adherent to one or more quality standards or other applicable CMS requirement; and

- Within 21 days after receiving the complaint, conduct a survey of the supplier if the initial review determines that such non-compliance may exist.

Paragraph (e)(3)(i)(A) would ensure that we receive the complaint expeditiously. The requirements in paragraph (e)(3)(i)(B) would help the AO assess the validity of the complaint, while the survey under paragraph (e)(3)(i)(C) would confirm said validity if evidence of non-compliance exists. We believe that having a standardized notification and investigative process would: (1) clarify CMS' expectations for handling complaints; and (2) allow for each complaint to be thoroughly considered and vetted before any action is taken against the supplier.

To also ensure that CMS is notified not only of the complaint itself but also the AO's determination on the matter, we propose new § 424.58(e)(3)(ii). This would require the AO—at least 10 calendar days after completing the action in, as applicable, paragraph (e)(3)(i)(B) or (C)—to give CMS written notice of the result of the initial review or, as applicable, the survey. Too, the notice must inform CMS of any action the AO took or intends to take regarding the supplier, such as a termination of accreditation or imposition of a CAP.

d. CAPs (New § 424.58(e)(4))

Although proposed § 424.58(c)(1)(xx) requires the AO during the application process to describe the policies and procedures it would use to decide whether to impose a CAP, it does not require the AO to notify CMS of specific instances where a CAP was indeed imposed, including when done in lieu of denying or terminating the supplier's accreditation. We believe such notification is important so we can ascertain the AO's: (1) compliance with the CAP policies contained in its application for CMS approval or reapproval; and (2) judgment in imposing CAPs instead of denying or terminating accreditation. To this end, we propose in the opening paragraph of new § 424.58(e)(4) that the AO must give CMS written notice of any decision to apply a CAP to a particular supplier no later than 10 calendar days after its decision. The notice must include—

- The reason for the decision;
- A detailed explanation and justification as to why the AO imposed a CAP instead of, as applicable, denying or terminating the supplier's accreditation; and
- The terms of the supplier's CAP (for example, deadline for compliance, the

AO's plans for enforcement and ensuring compliance).

These three requirements would be designated as new § 424.58(e)(4)(i), (ii), and (iii), respectively.

e. Accreditation Denials and Terminations (New § 424.58(e)(5))

We propose in new § 424.58(e)(5)(i) that the AO must give CMS written notice of any decision to deny, terminate, revoke, withdraw, or amend a supplier's accreditation within 5 calendar days of the decision; the notice must identify the reason for the AO's determination. Knowledge of supplier denials, terminations, etc. is no less important for us than our awareness of other AO matters, such as CAPs and complaints. Indeed, this information could help CMS detect potentially systemic issues and trends among suppliers. For instance, suppose the data indicates that a substantial number of prospective suppliers failed to comply with Quality Standards X, Y, and Z. In response, CMS could focus part of its DMEPOS supplier program integrity efforts on ensuring that currently accredited suppliers are adhering to X, Y, and Z, perhaps by requesting an AO to perform ad-hoc surveys of certain suppliers that are limited to these three quality standards.

While we believe this proposed rule would improve the DMEPOS accreditation program by, in part, strengthening and enhancing the requirements with which AOs must comply, we recognize the relative independence that AOs must retain in their operations and particularly their accreditation decision-making. We can establish regulatory parameters for the AO process, but the AO, rather than CMS, is regularly on-site verifying suppliers' quality standard compliance. We therefore must often defer to the AO's judgment on these matters to the extent that: (1) the AO's decision was consistent with CMS regulations and policies; and (2) we are satisfied with the AO's rationale for the decision. Nonetheless, there are several situations where we believe we must require that the AO take action because of the serious program integrity risk the situation entails. Although any supplier that is non-compliant with certain quality standards is of concern to us, more concerning is if the supplier is not even at the location it claims to be, is not operational, is unlicensed, or cannot be accessed. All these situations raise the possibility that the supplier could be an illegitimate operation, a situation we have repeatedly seen over the years with DMEPOS suppliers. At a minimum, they represent clear cases where compliance

with the quality standards would be impossible and could not be remedied by a CAP, given the fundamental defects in the supplier's qualifications.

For these reasons, we propose in new paragraphs (e)(5)(ii)(A)(1) through (5), respectively, that notwithstanding any other provision in § 424.58, an AO must deny or terminate a supplier's accreditation if—

- The supplier fails to meet the licensure requirements in § 424.57(c)(1)(ii);
- The supplier is not operational (as that term is defined in § 424.502);
- The supplier's location fails to meet the accessibility requirements in § 424.57(c)(7)(i)(B);
- The supplier's Medicare enrollment is revoked due to non-compliance with one or more DMEPOS quality standards and the reenrollment bar under § 424.535(c) has not expired; or
- Directed by CMS.

We emphasize that proposed paragraph (e)(5)(ii)(A)(5) would only be utilized in isolated instances considering, again, the AO's general discretion in its decisions. This would mostly, though not exclusively, occur if CMS obtains information—to which the AO may not have been privy—that the DMEPOS supplier is non-compliant with the quality standards and accordingly revokes the supplier's Medicare enrollment. Another, less frequent situation could be if CMS learns that the supplier is engaging in fraudulent conduct; such a supplier obviously should not be accredited. In short, CMS under paragraph (e)(5)(ii)(A)(5) would not direct AO decisions as a matter of course but strictly in exceptional circumstances. To ensure that the AO nonetheless carries out a CMS-directed accreditation denial or termination, we propose in new paragraph (e)(5)(ii)(B) that the AO must: (1) deny or terminate the supplier's accreditation within 3 business days after receiving written notice from CMS to do so; and (2) provide CMS written notice that it has taken this action within 5 business days of receiving the written direction from CMS.

f. Annual Summary of Data and CMS Changes (New § 424.58(e)(6) and (7))

Current § 424.58(c)(6) requires the AO to provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. Although we are not proposing to change this requirement, we propose to designate it as new § 424.58(e)(6).

We previously noted that as part of the AO statement that proposed § 424.58(c)(1)(xxiii) would require, the AO per § 424.58(c)(1)(xxiii)(G) must—in

response to CMS notification of a change in the quality standards, survey process, or other requirement—furnish CMS with corresponding changes in the AO's requirements. We propose in new § 424.58(e)(7) to outline the required timeframe and content of this data submission.

The opening paragraph of § 424.58(e)(7)(i) would: (1) include the requirement in proposed § 424.58(c)(1)(xxiii)(G); (2) state that the AO's submission of concomitant revisions is to ensure continued comparability with the quality standards, survey process, and other requirements; and (3) require the AO to report its proposed changes to CMS no later than 30 days after receiving CMS' written notice. In addition, new paragraphs (e)(7)(i)(A) through (C) would include the data submission elements and formats required in existing § 424.58(c)(2), specifically—

- An acknowledgment of CMS's notification of the change;
- A revised crosswalk reflecting the new requirements; and
- An explanation of how the AO will modify its standards to conform to CMS's new requirements within the timeframes outlined in the notice it received from CMS.

In new § 424.58(e)(7)(ii), we would state that the AO cannot implement its proposed corresponding revisions without CMS approval. This requirement would help CMS ensure that the AO understands and accurately implements CMS' revisions.

g. Performance of Surveys (New § 424.58(e)(8))

As already noted, not every supplier receives an accreditation survey. For instance, CMS currently permits AOs to undertake sampling for large supplier chain surveys. Factors an AO considers in determining which chain locations are surveyed include: (1) the supplier's physical location (for instance, whether it is in a high-fraud area); and (2) the types of products the supplier furnishes.

We have received information that various DMEPOS suppliers that were not surveyed were later found to be non-compliant with the quality standards and other CMS requirements. We have emphasized throughout section VI.B. of this proposed rule CMS' obligation to prevent improper Medicare payments and to protect beneficiaries. By permitting AOs to forgo surveys in certain instances, we risk the potential for patient harm and for millions of Medicare dollars to be paid to non-compliant suppliers. It is possible that considerable monies over the years have been paid to such parties and that, to

the extent it indeed occurred, this could have been avoided had a survey been conducted. Therefore, we believe we must revisit the current process and establish in regulation stricter and broader requirements regarding the performance of surveys. Consequently, we propose the following requirements in new § 424.58(e)(8).

Proposed opening paragraph (e)(8) and paragraph (e)(8)(i)(A) would state, respectively, that except as otherwise directed or permitted in writing by CMS (for instance, allowing sampling), the AO must perform a survey of all supplier locations for which the supplier seeks accreditation or reaccreditation with the AO. (This includes, but is not limited to, accreditations: (1) for a new item type the supplier has not previously furnished; or (2) as required under 42 CFR 424.551, discussed later in this section of VI.B. of this proposed rule.) Per our concerns about non-surveyed suppliers, we believe the blanket survey requirement in paragraph (e)(8)(i)(A) is necessary. Nevertheless, we also recognize that isolated and limited instances of sampling or other survey exemptions could be warranted. While we are unable to specify or predict in this proposed rule what those instances may be and do not commit to allowing survey exceptions, we believe our administration of the DMEPOS accreditation program requires that we have the flexibility to address particular circumstances as they arise.

New paragraph (e)(8)(i)(B) would require the AO to perform all surveys as unannounced surveys. While the caveat in proposed opening paragraph of (e)(8)(i) would permit us to waive this requirement in certain situations, we do not anticipate doing so given the previously noted importance of preventing prior notice to the supplier.

In new paragraph (e)(8)(i)(C), we propose that the AO cannot accredit the supplier location before: (1) the survey is conducted; and (2) the AO deems the supplier compliant with the quality standards. As stated, the survey's purpose is to confirm this adherence. If we permitted accreditation prior to both the survey and the AO's finding that compliance exists and the supplier accordingly billed Medicare, many thousands of dollars in improper payments could result. To avoid this, we believe paragraph (e)(8)(i)(C) is necessary.

We also propose in new paragraph (e)(8)(ii) that CMS may, at any time, direct the AO to perform a survey of an accredited supplier or a group thereof. We do not believe surveys should be restricted to initial accreditation and re-

accreditation situations, especially considering the aforementioned 3-year time gap between them. Suppliers must at all times be compliant with the quality standards and not merely upon initial accreditation and reaccreditation. To help verify that such adherence is consistently maintained, we believe we need discretion to direct an AO to conduct a survey at any given time. Having to wait until reaccreditation to resurvey the supplier could lead in the interim to improper payments to a supplier that has fallen out of adherence to the quality standards. Moreover, this discretion should not be limited to cases of an actual or suspected supplier deficiency, a matter we also propose to include in paragraph (e)(8)(ii). For example, assume a particular supplier is located in a high-fraud geographic area or had prior (but since resolved) compliance issues. We must have the authority to exercise closer scrutiny of the supplier through a survey if, in our view, the circumstances warrant it.

We further propose in new paragraph (e)(8)(iii) that when performing a survey, the AO must also confirm that the supplier is licensed in accordance with § 424.57(c). Although we believe most AOs perform this task during the survey, we seek to require this in regulation considering the importance of the supplier's compliance with State (and not only Federal) laws.

h. Surveyor Witnesses (New § 424.58(e)(9))

We have cited current requirements in § 424.58(c)(3) that the AO allow its surveyors to serve as witnesses if CMS undertakes an adverse action against a supplier in response to an accreditation finding. Consistent with our reorganization of § 424.58, we propose to designate this requirement without change as new paragraph § 424.58(e)(9).

i. Entrance of Data Into System (New § 424.58(e)(10))

Notwithstanding our proposed additional reporting requirements, we remain concerned about our ability to access accreditation and survey data immediately. There could be instances where we need prompt information about a particular supplier and cannot wait for the AO to send it to us. To illustrate, we may receive data indicating that a supplier may be out of adherence to a particular standard in § 424.57(c), meaning that improper payments are potentially being made to a non-compliant supplier. To assist in our review of this matter and, if non-compliance is found, to take action against the supplier and halt the payments as quickly as possible, real-

time information about the supplier's accreditation history, survey results, deficiencies, CAPs, etc., would be of assistance; indeed, such data could indicate past problems with this supplier. Real-time information would also allow us to detect trends and patterns in supplier accreditations, which, in turn, could help us rapidly implement changes to accreditation practices and procedures, direct the performance of surveys, and take other steps necessary to protect the Trust Funds. Perhaps most importantly, up-to-date information would help ensure that payments to DMEPOS suppliers are accurately made; for example, the sooner we learn through system access of a supplier's termination of accreditation, the sooner we can revoke the supplier and stop payments. In sum, our aforementioned role in preventing improper payments requires us to have immediate access to data that can assist us in this regard.

For these reasons, we propose in new § 424.58(e)(10) that if directed by CMS, the AO must enter accreditation, survey, product code, and other data into a CMS-designated system. This system, to which CMS and the NPEs would have access, would enable us to review accreditation data at any time. To preserve our operational flexibility, we are not outlining in this proposed rule either the specific system involved or the timing, content, and exact extent of the data entry. We may even later determine that the data entry is unnecessary if an alternative means of accessing this information in real-time is established. The implementation of § 424.58(c)(10) is thus contingent upon CMS determining that the entry is needed, hence the "if directed" caveat at the beginning of paragraph (c)(10).

j. Adverse Actions (New § 424.58(e)(11))

We proposed under new § 424.58(c)(4)(v) that CMS could deny an AO's application for approval or reapproval of its accreditation program if the AO, or any AO owner, managing employee, governing body member, surveyor, or health care or administrative or management services personnel has any of the adverse actions specified in § 424.58(c)(4)(v). We propose in new § 424.58(e)(11) to duplicate this denial reason as a general prohibition against such relationships on an ongoing basis, not simply as part of the AO's application determination. We believe this would further underscore the importance of ensuring that parties associated with the AO do not pose program integrity risks.

5. Continuing Federal Oversight of AOs (New § 424.58(f))

Existing § 424.58(d) outlines procedures for our ongoing review of AOs. While we intend to retain some of the provisions of this section, which would become new § 424.58(f), we believe changes to parts of its contents and structure are necessary to improve clarity and strengthen our oversight.

The opening paragraph of current § 424.58(d) states that the paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved DMEPOS AO. We propose to revise this to state that CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis; means of monitoring include, but are not limited to, the reviews identified in such paragraph (f). We believe this new language would clarify that CMS' oversight procedures are not restricted to those in paragraph (f). Also, as explained in section VI.B.2.f. of this proposed rule, the current § 424.58(d) regarding terminations of AOs will be in proposed new paragraph (h). Hence, the designation of § 424.58(d) as new § 424.58(f) will not include these paragraphs or any other reference to AO terminations.

a. Equivalency Reviews (New § 424.58(f)(1))

As described in current § 424.58(d), an equivalency review involves our comparison of the AO's standards (and the AO's application and enforcement thereof) to CMS requirements and processes. Paragraphs (d)(1)(i) through (iii) outline the following instances in which CMS may perform this review: (i) CMS imposes new requirements or changes in its survey process; (ii) the AO proposes new standards or changes in its survey process; or (iii) the AO's term of accreditation expires. We believe that retaining these three paragraphs in new paragraph (f)(1) would imply that we can only perform equivalency reviews in these three situations, which is not our intention. For reasons already noted, we must be able to constantly monitor the AO's operations—even if none of the three previous scenarios apply—and equivalency reviews are an important means of doing so. Consequently, we propose in new paragraph (f)(1) that we may perform an equivalency review at any time; the contingencies in existing (d)(1)(i) through (iii) would not be included in paragraph (f)(1).

b. Validation Survey of Suppliers (New § 424.58(f)(2))

Another means of validating the AO's accreditation processes is to review the AO's survey procedures. Addressed in the opening paragraph existing § 424.58(d)(2), this can involve CMS or its designated survey team—

- Performing a survey of an accredited DMEPOS supplier;
- Examining the results of the AO's survey of a supplier; and
- Observing an AO's survey of a supplier onsite.

After the review, CMS identifies whether (as stated in current § 424.58(d)(2)(i) through (iii)), the review indicates the following:

- At least a 10 percent disparity between the AO's and CMS' respective survey findings for non-immediate jeopardy standards.
- Any disparity between the AO's and CMS' respective survey findings for standards constituting immediate jeopardy.
- Regardless of the disparity rate, there are widespread and systemic problems in the AO's processes such that accreditation by the AO no longer provides CMS with adequate assurance that suppliers meet or exceed Medicare requirements.

Additional provisions regarding CMS' performance of a supplier survey (as a means of ascertaining the AO's performance) are addressed in existing § 424.58(b)(2). Specifically, the latter states that CMS performs supplier surveys on a representative sample basis or in response to substantial allegations of non-compliance.

We propose several modifications to the foregoing provisions to both consolidate and streamline our requirements and to enhance our ability to perform the aforementioned reviews. First, we propose to incorporate all provisions regarding validation surveys within new § 424.58(f)(2) rather than continue to have them split (as they currently are) between § 424.58(b)(2) and (d). We believe this would facilitate clarity and consistency.

Second, we propose in new paragraph (f)(2)(i) that CMS may survey suppliers to validate the AO's survey process. Such surveys can be comprehensive or focus on certain standards or requirements. We note that paragraph (f)(2)(i) would not include the three survey situations in the opening paragraph of existing § 424.58(d)(2), the provisions in § 424.58(d)(2)(i) through (iii), or references to sample bases and substantial allegations of non-compliance in § 424.58(b)(2). We believe that paragraphs (b)(2) and (d)(2), as

currently written, could be erroneously read as restricting our flexibility to: (1) conduct supplier surveys; and (2) reach conclusions that indicate problems with the AO's accreditation program. To illustrate, consider the following interpretations:

- Under paragraph (b)(2), CMS can only perform supplier surveys on a representative sample basis or in response to substantial allegations of non-compliance.
- Under the opening paragraph of § 424.58(d), the only types of permissible CMS supplier surveys are those mentioned in that paragraph.
- Under paragraphs (d)(2)(i) through (iii), any disparity rate of less than 10 percent or any detected problems that are not widespread or systemic prohibits CMS from taking any action against the AO based on the surveys.

Although we have never interpreted these paragraphs so narrowly, we wish to avoid any confusion on the matter and therefore will not include them in proposed paragraph (f)(2)(i). Instead, the latter would be broader and, in the process: (1) give CMS greater discretion regarding the types of supplier surveys that can be performed; and (2) allow CMS to conclude that the AO's accreditation program has deficiencies even if a minimum 10 percent disparity is not reached or the problems the surveys found are neither widespread nor systemic. In our view, any disparity percentage or detected problem is concerning because it could have led to a non-compliant supplier obtaining or retaining accreditation, potentially resulting in improper payments or beneficiary harm.

Third, existing § 424.58(b)(3) through (6) state, respectively, that—

- If CMS discovers that the supplier is non-adherent to the quality standards, CMS may revoke the supplier's billing number or require the AO to perform a subsequent full survey at the AO's expense;
- A supplier selected for a validation survey must authorize: (1) the survey to occur; and (2) the CMS survey team to monitor the correction of any deficiencies found during the survey;
- If the selected supplier does not comply with the existing authorization requirements of paragraph (b)(4), it does not meet the quality standards and may have its supplier billing number revoked; and
- If the survey finds that the supplier is non-compliant with one or more quality standards, the supplier no longer meets the quality standards and may have its supplier billing number revoked.

Except for changing “supplier billing number” to “enrollment” (the latter being the more accurate term), we do not propose revisions to these requirements, which we would respectively designate as new § 424.58(f)(2)(ii), (iii), (iv), and (v).

c. Deficiencies (§ 424.58(f)(3))

As part of the proposed statement under new § 424.58(c)(1)(xxiii), new paragraph (H) thereof would require the AO to agree to accept and adhere to any CMS-established deficiency definition as well as levels and categories of deficiencies. The aim of this is to enhance consistency among the AOs in how they determine whether a deficiency exists. To reiterate CMS' discretion in both this regard as well with respect to CMS' authority to establish quality standards under section 1834(a)(20) of the Act, we propose in new § 424.58(f)(3)(i) that CMS may define the term “deficiency”, establish levels and categories of deficiencies, and revise the quality standards. New § 424.58(f)(3)(ii) would require the AO in its accreditation activities to apply and adhere to: (1) any CMS-established definition of deficiency and categories and levels thereof; and (2) all CMS-established quality standards.

d. Additional Reviews (§ 424.58(f)(4))

We propose in new § 424.58(f)(4)(i)(A) to expand upon the reviews addressed in new § 424.58(f)(1) and (2) and permit CMS—at any time and for any reason—to conduct a review of the AO's processes or performance to—

- Validate the AO's representations to CMS (for example, its statements in new paragraph (c)(1)(xxiii)); or
- Assess the AO's adherence to its own policies and procedures, the provisions of § 424.58, and all other CMS requirements.

We also propose in new § 424.58(f)(4)(i)(B) that the scope, length, and timing of the review would lie within CMS' discretion. Furthermore, evidence of the AO's potential non-compliance with any of the policies and requirements addressed in new § 424.58(f)(4)(i)(A) is not required for CMS to perform a review.

In new § 424.58(f)(4)(ii)(A) through (H), we propose to list some of the types of reviews that CMS may perform either collectively or individually. Paragraphs (f)(4)(ii)(A) and (B) would respectively reference the reviews in new § 424.58(f)(1) and (2). Paragraphs (f)(4)(ii)(C) and (D) would reflect two of the previously mentioned reviews in existing § 424.58(d)(2): examining the results of an AO's surveys of suppliers

and observing onsite an AO's survey of a supplier. Proposed new paragraphs (f)(4)(ii)(E) through (H) would address the following reviews of the AO's onsite operations, similar to those for certified providers and suppliers in 42 CFR 488.8(h):

- Conducting onsite inspections of the AO's operations and offices.
- Requesting and reviewing documents.
- Interviewing AO personnel.
- Observing AO internal meetings concerning the accreditation process.

These proposals in new § 424.58(f)(4) are needed to give us greater flexibility and more means with which to assess the AO's performance. Indeed, current § 424.58 only references equivalency reviews, supplier surveys, and the AO's periodic submission of data as vehicles via which we can perform this task. We must be able to tailor the format, timing, and scope of our reviews to address particular circumstances. For instance, if we have reason to believe that an AO's surveys are being performed by unqualified personnel, we may seek to interview the surveyors to assess their knowledge and credentials. Even if we have not received any indication of non-compliance, we believe it is prudent to perform periodic AO reviews (that is, outside of the AO initial application and reapproval application processes) to confirm continued compliance—for such analyses may, in fact, reveal AO non-adherence to § 424.58. In short, only through a wide range of regular reviews can we be assured that the AO is conducting its accreditation activities consistent with all requirements.

6. Terminations of CMS-Approved AO Accreditation Programs (New § 424.58(g) and (h))

a. Voluntary Terminations

Sections 488.5(c)(2), 488.8(g)(2), and 488.1045(a) outline procedures via which an AO can voluntarily terminate its existing CMS-approved certified provider/supplier or HIT supplier accreditation program (respectively). To ensure that DMEPOS AOs seeking to voluntarily termination follow a specific, uniform process for doing so and, more importantly, that CMS is given adequate notice thereof, we propose to establish similar procedures in new § 424.58(g).

In paragraph (g)(1), we propose that an AO may voluntarily terminate its CMS-approved DMEPOS accreditation program at any time. In doing so, the AO per paragraphs (g)(1)(i) and (ii), respectively, must—

- Inform CMS of its decision no less than 120 calendar days before the termination effective date; and

- Provide written notice at least 90 days before the termination effective date to each of its accredited suppliers but not before notifying CMS of its decision under the previous bullet. The notice to each supplier must—

- ++ Describe the provisions in proposed new paragraph (g)(2) (discussed shortly) concerning the expiration dates of the supplier's accreditation with the terminating AO; and

- ++ Inform the supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminating AO expires and the effective date of its accreditation with a different AO) will result in the revocation of its enrollment under § 424.535.

We believe these requirements would give CMS and impacted suppliers sufficient notice of the AO's intentions and the implications of the AO's withdrawal. We consider the notification regarding lapses in accreditation particularly important, for the supplier must ensure it always remains accredited.

In new paragraph (g)(2), we propose that unless the supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirements, the supplier's accreditation with the terminating AO remains effective until the earliest of: (1) the expiration of its current term of accreditation with the terminating AO; and (2) the effective date of its accreditation with a different CMS-approved AO. We do not believe a supplier's accreditation should be correspondingly and automatically terminated when an AO voluntarily terminates its DMEPOS accreditation program. The AO's decision, in our view, is separate and distinct from the question of whether the supplier still complies with the quality standards and all other accreditation requirements. So long as the supplier remains compliant therewith, its accreditation should typically remain intact until one of the two aforementioned contingencies occurs.

b. Involuntary Terminations

(1) Reasons

Current § 424.58(d)(4)(i) and (ii) list two reasons for which CMS can terminate its approval of an AO's DMEPOS accreditation program:

- Accreditation by the AO no longer adequately ensures that its suppliers comply with the quality standards, and that failure to meet these requirements could (i) jeopardize the health or safety of Medicare beneficiaries and (ii)

constitute a significant hazard to public health; or

- The AO has not met its obligations regarding initial application or reapproval application procedures.

We believe these termination reasons may be too limited. For example, existing § 424.58(d)(4)(i) can only apply if the failure could jeopardize beneficiaries or public health. We do not believe the latter should be a prerequisite for termination. If the program does not ensure that suppliers meet the quality standards—which is the principal reason for the DMEPOS accreditation program in the first place—that alone is of great concern because it could result in improper payments. Put otherwise, the issue is not only beneficiary safety (critical though that matter is) but also protection of the Trust Funds. With respect to § 424.58(d)(4)(ii), the AO's obligations are not restricted to those involving the initial and reapproval application processes. They instead are constant throughout the entirety of the AO's period of CMS approval and require the AO's ongoing compliance with § 424.58. We believe our involuntary termination reasons should be much broader so as to address the previous situations and to ensure we have the ability to safeguard the Medicare program.

We thus propose the following provisions in new § 424.58(h).

In new paragraphs (h)(1)(i)(A) through (D), respectively, we propose that we may terminate our approval of an AO's accreditation program if CMS determines that—

- The AO no longer demonstrates reasonable assurance (as defined in paragraph (b));
- The continued approval of the AO's accreditation program poses an immediate jeopardy to the patients of the entities accredited under that program or otherwise constitutes a hazard to the public health;
- The AO is non-adherent to any provision of § 424.58. This includes, but is not limited to, situations where the AO has failed to comply with—

- ++ A term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or
- ++ A policy, procedure, or practice it outlined under paragraph § 424.58(c) as part of its initial or reapproval application or CMS-approved change thereto under § 424.58(e)(2) or (e)(7); or

- A pattern or practice exists of the AO's accredited suppliers being revoked under § 424.535(a) for failing to adhere to the quality standards.

We previously stated that as part of its initial or reapproval application, the AO must submit the information described

in paragraph (c)(1) to provide reasonable assurance. With reasonable assurance a crucial element of CMS' assessment of the AO's credentials and operations, we believe the failure to maintain it justifies termination under paragraph (h)(1)(i)(A). Paragraph (h)(1)(i)(B), meanwhile, mirrors the language in § 488.8(d) and existing § 424.58(d)(4)(i) regarding immediate jeopardy.

We recognize the broad nature of proposed paragraph (h)(1)(i)(C). Yet as already noted, AOs must at all times adhere to § 424.58, the terms of its statement in § 424.58(c)(1)(xxiii), and its current policies, procedures, and practices. Any failure to do so could lead to not only improper payments but also unsafe or low-quality services being provided by non-compliant suppliers. In light of our obligation to prevent this, we believe we must have the discretion to terminate the AO's approval in such instances. This does not mean CMS will automatically do so, especially in instances of very minor non-compliance. As discussed in the following sections of this proposed rule, there are other actions we might take in such cases. Nevertheless, given the wide variety of non-compliance situations that could arise, we believe termination should at least be an option.

As for proposed paragraph (h)(1)(i)(D), § 424.535(a) outlines several reasons for which we can revoke a provider's or supplier's (including a DMEPOS supplier's) enrollment based on a pattern or practice of conduct. These include, for example, a pattern or practice of: (1) submitting claims that fail to meet Medicare requirements; and (2) prescribing Part B or D drugs that is abusive or represents a threat to the health and safety of the Medicare program. The "pattern or practice" concept is intended to address situations where a sequence of provider or supplier actions indicates a potentially systemic problem. We believe this principle should apply to the AO's oversight of DMEPOS suppliers. If we find that a number of an AO's currently accredited suppliers fail to meet the quality standards, this could signify that the AO is not effectively ensuring its suppliers' compliance with the quality standards, perhaps due to insufficiently thorough surveys. Our proposed termination basis could help spur AOs to very closely examine its suppliers for compliance during the latter's initial accreditations and reaccreditations. We note, though, that we neither define "pattern or practice" in § 424.535(a) nor propose to do so in § 424.58. This is because we must be able to address each case based on its unique facts and circumstances.

We also propose under new § 424.58(h)(1)(ii) that CMS could terminate its approval of the AO's accreditation program effective on the date of the termination notification letter to the AO (described in proposed new paragraph (h)(2)) or any date thereafter. Considering, as already stated, the risks to the Trust Funds and Medicare beneficiaries that AO non-compliance could lead to (such as continued substandard services offered by non-compliant suppliers), we believe that having to wait 30 days, 60 days, or longer before the termination is effective could result in considerable improper payments and possible patient harm. While we are including an "or any date thereafter" caveat to § 424.58(h)(1)(ii) to account for situations where a slightly later date might be warranted, we believe these will be rare.

(2) Processes

We propose in new § 424.58(h)(2) through (5) to outline operational procedures for terminating an AO's approval and to address the consequent impact on suppliers. Doing so would help the AOs, suppliers, and other stakeholders understand what to expect when a termination occurs. To promote uniformity with existing processes, and with some exceptions, §§ 424.58(h)(2) through (4) would be akin to various provisions in §§ 488.1030(f), 488.8(e), and 488.1045(b).

Under proposed § 424.58(h)(2), CMS would give written notice to the AO of its termination decision. The notice must include the reason for and effective date of the termination. Under § 424.58(h)(3), and as with AO initial application submissions, CMS would announce its decision (and the effective date thereof) on its website. This would help ensure the public is made aware of the termination as soon as possible.

In § 424.58(h)(4), and so affected suppliers receive individualized notice beyond the CMS website announcement, the terminated AO would have to give written notice of the termination and its implications to each of its accredited suppliers within 30 calendar days after the CMS website announcement. The notice to each supplier would have to—

- Explain the provisions in § 424.58(h)(6) concerning the expiration dates of the supplier's accreditation with the terminated AO; and
- Inform the supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminated AO expires and the effective date of its accreditation with a different AO) results in its enrollment being revoked under § 424.535.

We also propose the following in new § 424.58(h)(5) and (6)(i)(A) through (C), respectively:

- The terminated AO would have to work collaboratively with CMS to direct its accredited suppliers to the remaining CMS-approved AOs within a reasonable period of time.
- Unless the supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirement, the supplier's accreditation with the terminated AO remains effective until the earliest of—
 - ++ The expiration of its current term of accreditation with the terminated AO;
 - ++ The effective date of its accreditation with a different CMS-approved AO; or
 - ++ A date specified by CMS based on the circumstances of the termination of the AO's approval.

We believe new paragraphs (h)(4), (5), and (6)(i) would ease suppliers' transition to a new AO by: (1) explaining the implications of the termination; (2) facilitating CMS-AO collaboration; and (3) emphasizing that—as with proposed §§ 424.58(g)(2) regarding voluntary terminations—the supplier's accreditation does not automatically end with the AO's departure. By the same token, paragraph (h)(4) and the required letter would stress to the supplier that there can be no gaps in its accreditation. This may require the supplier to promptly seek accreditation with another AO before its current accreditation expires.

We note two additional matters regarding proposed § 424.58(h)(6)(i). First, the opening language thereof that states "unless the supplier is otherwise determined" merely reiterates that the supplier's accreditation status remains intact only if it is still in compliance with the quality standards and all other accreditation requirements. Second, and with respect to paragraph (h)(6)(i)(C), there could be isolated instances where CMS may assign to a supplier an accreditation termination date that is earlier than the dates in proposed paragraphs (h)(6)(i)(A) and (B). This would most commonly occur when we have concerns that the terminated AO may not have surveyed or assessed certain suppliers with the requisite thoroughness and efficiency, which raises significant questions as to whether the supplier was compliant with the quality standards. Should CMS specify such a date, CMS would under new paragraph (h)(6)(ii) notify the affected supplier in writing thereof and identify the deadline by which the supplier must be reaccredited by a different AO. CMS would ensure that the deadline is far enough in advance to

give the supplier time to be reaccredited.

In addition, we propose in new § 424.58(h)(7) that the terminated AO must refund to a supplier all payments the latter made to the AO in accordance with the supplier's request for accreditation or reaccreditation but before the AO notified the supplier of its final determination regarding the supplier's request. We do not believe an AO whose approval has been terminated should be able to keep the monies the supplier paid it when the requested service—accreditation or reaccreditation—was not fully rendered (that is, the final decision was not made). Fundamental fairness to the supplier requires, in our review, the refund of such payments.

7. AO Suspensions and Probations (New § 424.58(i) and (j))

Termination is presently the only remedy available to CMS under § 424.58 to address AO performance issues. Although we proposed in § 424.58(h)(1) to expand the grounds for which termination can apply, we recognize the seriousness of a termination and would generally only take this step in exceptional circumstances. Yet under current § 424.58, this could leave the non-compliance unresolved because of our lack of other, perhaps more suitable remedies. In other words, we do not believe AO non-compliance should only be addressable by an all-or-nothing, termination-or-no termination approach. Having multiple available remedies would allow us to correspond our action to the relative severity of each case.

a. Suspension

We propose in new § 424.58(i) to have the ability to suspend an AO's accreditation program. Under paragraph (1)(i), suspension could occur if we determine that the AO no longer demonstrates reasonable assurance (as defined in paragraph (b)) or is non-compliant with any provision of § 424.58. The non-compliance can include, but is not limited to, situations where the AO has failed to—

- Comply with a term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or
- Adhere to a policy, procedure, or practice it outlined under § 424.58(c) as part of its initial or reapproval application or a CMS-approved change thereto under § 424.58(e)(2) or (e)(7).

We also propose that CMS may suspend the AO's accreditation program if there is a pattern or practice of the AO's accredited suppliers being revoked under § 424.535 for failing to comply with the quality standards.

These grounds are also applicable to terminations but are sufficiently broad to enable us to apply a lesser sanction if the circumstances warrant. (For example, the § 424.58 non-compliance may not be significant enough to, in our view, justify a termination).

New § 424.58(i)(2) would outline a suspension's components. Paragraph (i)(2)(i) would state that except as otherwise specified or permitted by CMS, the AO could not conduct any DMEPOS accreditation activities while suspended. We believe the opening caveat is necessary should we need the AO, despite its suspension, to perform certain functions, such as completing an ongoing survey. Paragraph (i)(2)(ii), meanwhile, would state that—

- CMS determines the length of the suspension, which would be a maximum of 1 year; and
- Upon the expiration of the suspension period, CMS either lifts the suspension or terminates the AO's approval.

Aside from the maximum 1-year period, we do not believe a fixed suspension length should be established in regulation. Since every situation will differ, we must have the discretion to tailor the suspension length to the specific facts of the case; to illustrate, the non-compliance at issue may be substantial enough to warrant a suspension but only for a fairly brief period because the non-compliance can be resolved expeditiously. We believe a 1-year maximum is appropriate because if the AO cannot rectify the non-compliance within such an extensive timeframe, this indicates systemic issues that can warrant termination.

For the same reasons behind proposed paragraph (h)(2) regarding terminations, we propose in new paragraph (i)(2)(iii) that CMS may suspend the AO's program effective the date of the suspension notification letter described in paragraph (i)(3) or any date thereafter.

We propose in new paragraph (i)(3) that CMS sends written notice of the suspension decision to the AO. The notice would include the reason(s) for, the effective date of, the length of, and the terms of the suspension (for instance, application of a CAP; whether the AO may perform certain functions during the suspension; etc.), as well as the steps the AO must take to have the suspension lifted. To confirm that the AO received the notice, we propose in new paragraph (i)(3)(ii) that the AO must notify CMS of this in writing within 3 calendar days of receipt.

In new paragraph (i)(3)(iii), we propose that no later than 3 calendar days after our receipt of the acknowledgement in paragraph (i)(3)(ii),

CMS would post on its website a notice of the suspension. We do not believe publication in the **Federal Register** would be practical since, in some cases, the suspension may conclude before **Federal Register** publication. Moreover, publication on our website would allow us to rapidly notify stakeholders of the suspension well before it expires.

Paragraph (i)(4) would address the status of the suspended AO's accredited suppliers. Akin to supplier statuses with AO voluntary and involuntary terminations, we propose in new paragraphs (i)(4)(i)(A) through (C), respectively, that if the AO's accreditation program is suspended, the accreditation status of its suppliers remains effective through the length of the suspension unless—

- The supplier's current term of accreditation with the suspended AO expires during the suspension;
- The supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirement; or
- CMS specifies a different accreditation termination date based on the circumstances of the suspension of the AO's accreditation program.

New paragraph (i)(4)(ii)(A) would state that if paragraph (i)(4)(i)(A) applies, the supplier must be recredited by: (1) its AO if the latter's suspension has been lifted; or (2) a different CMS-approved AO. New paragraph (i)(4)(ii)(B) would state that if paragraph (i)(4)(i)(C) applies, CMS notifies the affected supplier in writing of the deadline by which the supplier must be recredited. Meanwhile, new paragraph (i)(4)(iii) would reiterate that any lapse in the supplier's accreditation results in the supplier's revocation of enrollment. Both (i)(4)(ii) and (iii) are intended to help ensure there are no gaps in the supplier's accreditation status under § 424.58.

New paragraph (i)(5) would address the circumstances under which a suspension is lifted and the processes associated therewith. In paragraphs (i)(5)(i)(A) through (C), respectively, we propose that CMS would lift a suspension if all of the following are met:

- The reasons for it no longer exist.
- The AO demonstrates reasonable assurance (as defined in paragraph (b)).
- The AO is in compliance with all provisions of § 424.58.

We believe that even if the specific issue that led to the suspension has been corrected, it is possible that other instances of non-compliance exist, hence the need for paragraphs (i)(5)(i)(B) and (C).

In paragraph (i)(5)(ii), and for the same reasons behind proposed paragraphs (i)(3)(i) through (iii), we propose that if the suspension is lifted, CMS would—

- Send the AO written notice that the suspension has been lifted;
- Require the AO to notify CMS in writing of its receipt of the notice within 3 calendar days of such receipt; and
- No later than 3 calendar days after receipt of the AO's acknowledgement, publish on its website a notice of the lifting of the AO's suspension and the reasons for it.

We propose in new paragraph (i)(6) to duplicate proposed paragraph (h)(7) regarding refunds. Irrespective of whether a termination or a suspension is involved, our concern remains the same: the potential for the AO to retain payments for a service it did not fully furnish. We do not believe the supplier should, in effect, be financially penalized for the AO's non-compliance that led to the termination or suspension. We note that the suspension would not be lifted before all required refunds to suppliers under paragraph (i)(6) have been paid.

In new paragraph (i)(7), we propose that nothing in paragraph (i) would prohibit CMS from suspending an AO's accreditation program more than once. This would help preserve our flexibility to take the most appropriate action to address AO non-compliance; for example, a second suspension may be more appropriate than a suspension followed by a termination several years later.

b. Probation

To further enhance our ability to address AO non-compliance in a manner proportional to the degree thereof, we propose to establish a process in new § 424.58(j) for placing an AO's accreditation program on probation in lieu of a termination or suspension. We note that Part 488 contains a probation process for AOs that accredit certified providers, certified suppliers, and HIT suppliers. However, our provisions in new § 424.58(j) would differ somewhat from those (for example, concerning the maximum length of the probationary period) given the different characteristics of the DMEPOS accreditation program and our need to have the latitude to address AO non-compliance in the most appropriate manner.

In paragraph (j)(1), we propose to have the discretion to place an AO's accreditation program on probation and require its successful completion of a CAP in the following instances—

- CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

- CMS determines that the AO is non-compliant with any provision of § 424.58. This could include the aforementioned terms, conditions, procedures, etc., described in proposed new paragraphs (h)(1)(i)(C) and (i)(1)(ii).

- CMS determines that there is a pattern or practice of the AO's accredited suppliers being revoked under § 424.535 for not complying with the quality standards.

- The suspension period for the AO under paragraph (i) has expired and CMS determines that a subsequent probationary period and associated CAP are warranted.

In paragraph (j)(2)(i), we propose that CMS would give the AO written notice of its decision to place it on probation. To ensure that the AO understands the basis for and the particulars of the probation, the notice would include—

- The reason(s) for CMS' decision;
- The length of the probationary period, which would not exceed 1 year;
- The CAP's terms;
- The requirements and deadline for achieving compliance; and
- An explanation of how CMS would monitor the AO's efforts to resume adherence under the CAP (for example, performing reviews under paragraph (f)).

We propose in new paragraph (j)(2)(ii) that except as otherwise prescribed in the CAP, the AO could continue its accreditation activities as normal.

In new paragraph (j)(3)(i), we propose that when the probationary period concludes, CMS would notify the AO in writing of—

- Whether the AO is in compliance with all requirements of § 424.58;
- The reason for the determination in the previous bullet; and
- The consequences of the determination (for example, termination or suspension of accreditation, successful completion of and cessation of the probationary period and CAP).

In paragraph (j)(3)(ii), we propose that we may send this notice, terminate the probationary period, and end the CAP prior to the end of designated probationary period if we determine that the AO is again compliant, for this would eliminate the continued need for the probation and CAP.

Several aspects of new paragraph (j) must be addressed. First, the probationary period and the CAP would be intertwined, meaning the latter would be the core element of the former. Second, CMS, rather than the AO, would establish the terms of the CAP.

We believe this would better ensure that the issues resulting in the probation will be addressed. Third, there could be instances where although a suspension has been lifted, we need to closely monitor the AO's resumption of activities via probation and a CAP. We believe this would be a prudent step in ensuring that the prior problems do not resurface and that new ones do not arise. Fourth, CMS would retain the discretion to limit or not limit the AO's accreditation activities during the probationary period. This would help us balance the type and degree of AO non-compliance with the need to avoid unduly disrupting the AO's ongoing DMEPOS program activities. Finally, we are not proposing to post notice of the probation and CAP on the CMS website, for the AO under these actions would typically be able to continue their activities without interruption.

8. CMS Discretion, Change in Non-Compliance Actions (New § 424.58(k))

We have stressed the importance of CMS having several types of administrative actions to address AO non-compliance. To confirm CMS' discretion to determine which action should be imposed and, if circumstances warrant, to escalate a currently imposed action to a more significant one, we propose the following in new § 424.58(k). First, under paragraph (k)(1), CMS could impose an action in § 424.58(h), (i), or (j) in lieu of another such action in paragraph (h), (i), or (j) if the same ground(s) for either exists. For example, if the AO is non-compliant with the requirements at § 424.58, CMS could terminate the AO's approval rather than suspend the accreditation program or place it on probation. Second, § 424.58(k)(2) would state that CMS could terminate—

- An AO's probation (either before or in accordance with the probationary period's original expiration date) and impose a suspension or termination if a ground for either of the latter actions exists; or
- An AO's suspension (either before or in accordance with the suspension's original expiration date) and impose a termination if a basis for termination exists.

The main reason for § 424.58(k)(2) is that we do not wish to be tied to a particular action for an extended period if, for instance, additional problems with the AO arise that warrant a more substantial action. To illustrate, assume we placed an AO on probation with an initially assigned period of 3 months. If an immediate jeopardy situation arises a month into the probation, we must have

the ability to immediately terminate the AO without having to wait until the 3-month probationary period expires.

9. Reconsiderations and Rebuttals (New § 424.58(l))

a. Denials and Involuntary Terminations

Current § 424.58(e)(1) outlines the reasons for which an AO may file a written request for reconsideration of a CMS determination that the AO does not provide reasonable assurance that the suppliers it has accredited meet the quality standards. The procedures of the reconsideration process are outlined in § 424.58(e)(2) through (9). We propose to remove all these reconsideration provisions from § 424.58 and, in new § 424.58(l) instead utilize the reconsideration processes in 42 CFR part 498 for denied and involuntarily terminated AOs. There are two reasons for this. First, the part 498 procedures are currently available for providers and suppliers whose enrollments are denied or revoked under § 424.530 or § 424.535, respectively. We view the denial of an AO's application for approval and the involuntary termination of said approval as akin to these two situations. Second, Part 498, unlike existing § 424.58(e), contains procedures for appeals beyond the initial reconsideration level, such as to the Administrative Law Judge (ALJ) and the Department Appeals Board (DAB). We believe these appeal rights should be available to denied or involuntarily terminated AOs to the same extent as with denied or revoked providers and suppliers.

Section 498.3(b) lists situations in which CMS makes an initial determination. We propose to add new paragraphs (b)(21) and (22) to § 498.3. The former would include denials under paragraph (c)(4) or (d)(4). The latter would include involuntary terminations under paragraph (h)(1). We would also state in new § 424.58(l)(1) that the AO could request a reconsideration under part 498 of any of these three initial determinations.

b. Suspensions and Probationary Periods

With respect to suspensions and probationary periods, neither of these would involve the elimination of the AO's DMEPOS accreditation program approval altogether (as would a termination) but, in many cases, merely the temporary cessation of or potential restrictions on the AO's activities. Both involve interim measures rather than permanent action on our part. Considering also that the suspension or probationary period may be brief

(especially with probationary periods), the period in question may have expired before the end of the AO's timeframe for requesting a reconsideration under 42 CFR part 498.

For these reasons, we believe a rebuttal process—similar to that in § 424.546—would be more appropriate than a reconsideration process for AOs whose accreditation programs have been suspended or placed on probation. It is shorter and more expedited—consistent with the potentially shorter suspension and probationary periods—than the reconsideration process. Yet it still affords the affected AO an opportunity to be heard. It has long been used for certain interim CMS actions that do not involve the party's permanent removal from engaging in certain Medicare activities. These interim actions include, but are not limited to—

- A deactivation under § 424.540, which involves a stoppage (but not a termination) of a provider's or supplier's Medicare billing privileges.
- A Medicare payment suspension (or offset or recoupment of Medicare payments) under § 405.372 or § 405.373, respectively.

We propose in new paragraph (l)(2) to outline the procedures via which an AO may rebut a CMS determination to suspend or place on probation its DMEPOS accreditation program. As previously noted, these procedures duplicate the existing rebuttal process in § 424.546 for a deactivation of Medicare billing privileges.

In new paragraph (l)(2)(i)(A), we propose that if an AO receives notice from CMS that its DMEPOS accreditation program has been suspended or placed on probation, the AO has 15 calendar days from the date of such notice to submit a rebuttal to CMS. We believe that a 15-day period, which is currently used for deactivation rebuttals, effectively balances the needs to: (1) promptly take measures to safeguard DMEPOS program integrity; and (2) ensure that the AO has time to submit a rebuttal.

In new paragraph (l)(2)(i)(B), we propose that CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (l)(2)(i)(A). This would enable CMS to account for special circumstances that may justify a longer period (for example, circumstances beyond the AO's control would prevent it from submitting a timely rebuttal).

In new paragraph (l)(2)(ii)(A) through (D), we propose that any rebuttal must—

- Be in writing;
- Identify the facts or issues about which the AO disagrees with CMS'

determination, including the reasons for disagreement;

- Include all documentation the AO wants CMS to consider in its review of its determination; and
- Be submitted in the form of a letter that is signed and dated by the AO's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative (as defined in 42 CFR 498.10). We would also include the provisions from § 424.546(b)(4) regarding legal representatives (for example, a required statement that the representative has the authority to represent the AO).

We believe the provisions in paragraph (l)(2)(ii) are necessary to ensure: (1) a uniform and standard process for submitting AO rebuttals; (2) that there is written documentation of the AO's contentions; (3) that CMS has sufficient information to perform its review; and (4) that the AO authorized the rebuttal submission.

In paragraph (l)(2)(iii), we propose that the AO's failure to submit a timely and compliant rebuttal would constitute a waiver of all rebuttal rights under paragraph (l)(2). This provision would not only specify the consequences of an untimely or non-compliant rebuttal but also help encourage the AO to abide by paragraphs (l)(2)(i) and (ii) should it choose to rebut a suspension or probation.

In paragraph (l)(2)(iv), we propose that upon receipt of a timely and compliant AO rebuttal, CMS reviews it to determine whether the imposition of the suspension or probation was correct. We believe this provision would adequately notify AOs of the scope of CMS' review.

In paragraph (l)(2)(v), we propose that CMS would not be required to delay the imposition of the suspension or probation pending the completion of CMS' review of the rebuttal. This provision is needed so CMS can expeditiously enforce the program integrity protections associated with the suspension or probation while recognizing the AO's ability to challenge the suspension or probation via the rebuttal process. If CMS determines that the suspension or probation was erroneous, it would be reversed.

In new paragraph (l)(2)(vi), we propose that a CMS determination made under paragraph (l)(2) would not be an initial determination under § 498.3(b) and therefore, would not be appealable. This would clarify for AOs that a rebuttal is the only administrative remedy available for suspension or probation.

10. Consulting (New § 424.58(m))

As previously mentioned, CMS issued a February 15, 2024, proposed rule addressing several topics regarding certified provider/supplier accreditation. One such subject was consulting services provided by AOs, their consulting divisions, or separate business entities to Medicare-participating health care facilities. One example of consulting services the proposed rule cited involves an AO's review of facility standards and promised early intervention and action through simulation of a real survey, such as a mock survey with comprehensive written reports of findings. This situation is of particular concern to us. The purpose of the DMEPOS accreditation survey is to objectively assess the supplier's compliance with the DMEPOS quality standards without the AO's prior aid in helping the supplier achieve such compliance. That is, the supplier should be able to adhere to the quality standards on its own merits. We believe it would be a conflict of interest if the AO had effectively "coached" the supplier on how to pass the survey that the AO later performed. In addition, the AO might be reluctant to find non-compliance on the survey—even though such non-compliance exists—because this could reflect poorly on the AO's pre-survey assistance. Either situation could lead to an unqualified DMEPOS supplier becoming accredited and enrolled. For this reason, we believe that certain protections against this activity are warranted and thus propose the following provisions.

In new § 424.58(m)(1), we propose to define the terms "consulting" and "consulting services" for purposes of proposed paragraph (m). The terms would mean those services furnished by a DMEPOS AO (or by its consulting division or separate business entity (such as a company or corporation) that furnishes such services) for the review of a DMEPOS supplier's standards, processes, policies, and functions for compliance with the AO's standards, the DMEPOS quality standards, or other Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey.

We note two things about this proposed definition. First, it encompasses the previously referenced situation regarding prior assistance and mock surveys. It also includes language from the February 15, 2024, proposed

rule, concerning the various organizational components of the AO to which the consulting prohibition would apply, such as the AO's consulting divisions. This would help foster consistency with that proposed rule. Second, the definition would not be restricted to consulting that is fee-based. We recognize that the February 15, 2024, proposed rule focused on paid consulting services. Yet we believe the critical factor is the provision of the DMEPOS AO consulting service itself rather than whether payment was made. In other words, the assistance furnished in helping the supplier prepare for and pass the survey—instead of the monetary compensation—is what triggers the risks of a conflict of interest and subsequent potential for an otherwise unqualified supplier to become accredited.

In new paragraphs (m)(2)(i) through (iii), we propose that, except as provided in proposed § 424.58(m)(3), an AO or its consulting division or separate business entity (such as a company or corporation that provides consulting) may not provide consulting services in the following instances:

- To any new supplier before the completion of the initial accreditation survey, meaning the first survey of a supplier that has not previously received accreditation services from that AO. If a supplier is later voluntarily or involuntarily terminated from that AO's services and thereafter retains the services of that same AO or a new one, the first survey of that supplier by the same or new AO would be considered an initial accreditation survey.
- To a supplier the AO accredits within 6 months prior to the supplier's next scheduled re-accreditation survey. A re-accreditation survey would be any subsequent accreditation survey the AO performs after the initial survey.
- To a supplier to which the AO furnishes accreditation services, in response to a complaint the AO receives concerning that supplier.

These three prohibitions are similar to those included in the February 15, 2024, proposed rule and, in our view, would help address our previously referenced concerns regarding consulting services.

In paragraphs (m)(3)(i) through (iv), respectively, we propose the following four situations—which the February 15, 2024, proposed rule also addressed—where an AO, its consulting division, or separate business entity may provide consulting services to the suppliers it accredits.

The first is during the 6-month period after an initial or re-accreditation survey is performed. In the immediate months following the survey, we believe the risk

of consultative influence on the survey's objectivity is reduced.

The second is when CMS or its contractor receives and investigates complaints about an AO's accredited supplier where an immediate jeopardy deficiency or basis for revocation of enrollment under § 424.535 is identified. However, the consulting may occur only after the investigation is completed and can only address those issues identified in the investigation. The difference between this scenario and that in proposed paragraph (m)(2)(iii) is that CMS, rather than the AO, performs the review of possible non-compliance. Hence, the potential that the AO will conduct the review in a subjective manner is moot.

The third and fourth are as follows:

- Consulting services provided to suppliers that the AO does not accredit at the time the services are furnished.
- General education the AO furnishes about its accreditation program.

Neither of these situations invokes the concerns we previously addressed regarding coaching and subjectivity.

In paragraph (m)(4), we propose that the AO must furnish to CMS upon CMS' request and with each initial and reapproval application under paragraphs (c) and (d) of this section, a report containing the following information:

- Whether the AO or an associated consulting division or company the AO has established furnishes consulting services.
- The names, National Provider Identifiers, and addresses of all suppliers to which the AO or its associated consulting division or company has furnished consulting services during the prior 6-month timeframe.
- The dates such services were provided to each supplier.
- Whether the AO has ever furnished, or is currently furnishing, accreditation services to any supplier identified in the report.
- For each supplier listed in the report, the dates of: (1) its most recent accreditation survey; and (2) the next re-accreditation survey due to be performed.
- A description of the consulting services provided to each supplier in the aforementioned report.

This information, which mirrors that in the February 15, 2024, proposed rule, would help CMS ascertain whether the AO is compliant with the provisions of paragraph (m).

In paragraph (m)(5)(i), we propose that the DMEPOS AO, its consulting division, or separate business entity must have and comply with the

following written consulting policies and procedures. At a minimum, these policies and procedures, which are referenced in the February 15, 2024, proposed rule regarding certified providers and suppliers, must include the following:

- The AO's consulting services must be furnished by a separate division of the AO or separate business entity (such as a company or corporation) that is separate from the AO's accreditation division.
- The AO's consulting division or separate business entity must maintain separate staff from that of the AO's accreditation divisions to ensure that—
 - ++ The consulting division personnel do not conduct the AO's accreditation division functions; and
 - ++ The AO's accreditation division staff do not conduct consulting division functions.
- An AO's accreditation staff and surveyors are prohibited from marketing the AO's consulting services to the AO's accreditation clients.

We believe proposed paragraph (m)(5)(i) would help further prevent conflicts of interests regarding these services by requiring a separation of units and staffs that perform accreditation activities from those providing the consulting services.

To help verify the AO's compliance with paragraph (m), we also propose in new paragraph (m)(5)(ii) that an AO that provides consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application for initial approval or reapproval.

11. Other Relationships Involving Potential Conflicts of Interest (New § 424.58(n))

a. AO/Supplier Relationships

The February 15, 2024, proposed rule not only addressed consulting services but also noted relationships between AO officials and the suppliers the AO accredits. The proposed rule expressed concerns, which we share with respect to DMEPOS AOs and suppliers, that such a relationship could unduly influence the AO's survey performance and results and, consequently, the AO's accreditation decision. To illustrate, we explained in that proposed rule that an AO owner, surveyor, or employee involved in a survey of a provider or supplier with whom said individual has a relationship or interest relationship could have compromised judgment (consciously or unconsciously) regarding that facility; such a surveyor

could be inclined to minimize or ignore deficiencies or possibly persuade the other survey team members to do so.⁶⁷ This is, in fact, what occurred in the previously mentioned March 2025 Southern District of Florida criminal case. Even in situations where the owner, surveyor, or employee with the interest or relationship is not part of the survey team, the individual could attempt to influence the team's decision by, for example, advocating on the supplier's behalf.⁶⁸

As already stated in this section VI.B. of this proposed rule, objectivity in the AO's survey and decision-making process is of the utmost importance. The relationships and interests described in the previous paragraph—and in our earlier discussion of proposed § 424.58(c)(1)(vii)(D)—can place this concept at risk, mostly by potentially enabling suppliers that are, in actuality, non-compliant with the quality standards to nonetheless pass the survey and obtain or retain accreditation. The result would be unqualified suppliers improperly receiving payments from Medicare and possibly harming beneficiaries. Like with our consulting

proposals, we believe that safeguards against this type of influence are needed. We therefore propose to include them in new paragraph (n)(1); with modifications, these provisions are similar to those included in the February 15, 2024, proposed rule.

In paragraph (n)(1)(i), we propose that if an AO owner, surveyor or employee (currently or within the previous 2 years) has or had an interest in or relationship (as described in proposed § 424.58(c)(1)(vii)(D)) with a DMEPOS supplier accredited by the AO, the AO owner, surveyor, or employee is not permitted to—

- Participate in the survey of that DMEPOS supplier;
- Have input into the results of the survey and accreditation for that DMEPOS supplier;
- Have involvement with the pre-or post-survey activities for that DMEPOS supplier; or
- Have contact with or access to the records for the survey and accreditation of that DMEPOS supplier.

We believe these prohibitions would help reduce the risk that an AO owner, surveyor, or employee will improperly influence the DMEPOS supplier's survey and accreditation.

We proposed in new § 424.58(c)(1)(vii)(D) to define

“immediate family member” to help explain some of the conflict-of-interest affiliations that fall within that paragraph. So as to tie this definition to proposed (n)(1), we propose in new paragraph (n)(1)(ii) that, for purposes of new paragraph (n)(1), the term “immediate family member” would have the same meaning as that in paragraph (b).

Per proposed § 424.58(c) and (d), the conflict-of-interest information described in § 424.58(c)(1)(vii)(D) must be furnished with the DMEPOS AO's initial and reapproval applications. Given this data's importance and the need to avoid conflicts-of-interest, however, we propose in new paragraph (n)(1)(iii) that CMS may request any and all of this information at any time outside of the initial approval and reapproval processes.

To help the public better understand the relationship between the current proposed rule and the February 15, 2024, proposed rule, we have prepared the following table. It identifies three sets of our proposed provisions that, to varying degrees, duplicate certain provisions in the February 15, 2024, proposed rule but contains several notable differences.

⁶⁷ 89 FR 12011.

⁶⁸ Ibid.

TABLE 36: COMPARISON BETWEEN PROPOSED AO RULES

Provision	Proposed AO DMEPOS Rule	February 15, 2024, Proposed Rule	Differences
Definition of unannounced survey	See proposed 424.58(b)	Same as proposed 424.58(b)	Only difference is change from “facility” to “DMEPOS supplier” in proposed 424.58(b) (which only applies to DMEPOS suppliers)
Consulting	Prohibit all consulting services by an AO and its associated consulting divisions or companies to any DMEPOS to which the AO provides accreditation services: (1) prior to an initial accreditation survey; and (2) within 6 months of the next scheduled re-accreditation survey.	Prohibit all fee-based consulting services by an AO and its associated consulting divisions or companies to any health care provider or supplier to which the AO provides accreditation services: (1) prior to an initial accreditation survey; and (2) within 12 months of the next scheduled re-accreditation survey.	DMEPOS timeframe is 6 months instead of 12 months due to the proposed annual reaccreditations. So as to not hinder otherwise legitimate consulting arrangements, DMEPOS restrictions limited to situations involving mock surveys performed by an AO. DMEPOS prohibitions would not be limited to “fee-based” consulting. It is the consulting service itself and the impact it could have on the survey’s integrity – rather than whether compensation is involved – that is our central concern.
Conflict-of-Interest (COI)	AO submission of COI policies with each initial and reapproval application and upon CMS request.	AO submission of COI policies with each initial and reapproval application.	More infrequent submissions would reduce burden.

b. NPE/AO Relationships

NPEs (of which there are two nationwide) process DMEPOS Form CMS–855S enrollment applications. This involves, for example, (1) verifying the data the supplier furnished on or with the application; (2) performing a site visit; and (3) ensuring the supplier meets all Medicare requirements. The latter includes confirming that the supplier is accredited per § 424.58.

None of our current DMEPOS AOs are NPEs or parents or subsidiaries thereof; that is, there are no organizational relationships or ties between existing DMEPOS AOs and NPEs. This is important for the same overriding reason behind proposed paragraph

(n)(1): the need for objectivity. Consider the following hypotheticals:

- *Scenario 1:* An NPE’s owner is a DMEPOS AO. The AO accredits 100 new DMEPOS suppliers within a given period, and the NPE enrolls them. Over the succeeding months, the NPE receives information from parties other than the AO that a significant number of these suppliers are, in fact, non-compliant with the quality standards and other enrollment requirements. Since its owner accredited these suppliers, the NPE may be reluctant to revoke their enrollments because it could reflect poorly on the owner and possibly jeopardize its status as a DMEPOS AO.

- *Scenario 2—*The NPE itself is an AO. After accrediting a particular

supplier, the entity—in its capacity as an NPE—detects problems with the supplier’s initial enrollment application or later finds that grounds exist for deactivating the supplier’s billing privileges under § 424.540. In either case—and wanting to maintain a good relationship with the supplier—the NPE may decline to deny the application or deactivate the supplier out of concern the supplier may utilize a different AO in the future. This could result in non-compliant suppliers receiving or continuing to receive many thousands of Medicare dollars.

However, our concerns are not limited to NPEs. We believe that any CMS contractor with any oversight responsibility of DMEPOS suppliers could also present conflict-of-interest

issues. These could include, but would not be limited to, Durable Medical Equipment Medicare Administrative Contractors (DME MACs), which process DMEPOS claims, and contractors that perform site visits of DMEPOS suppliers. To illustrate, suppose a DMEPOS site visit contractor (SVC) is also a DMEPOS AO. The entity performed a survey of, and accredited, DMEPOS Supplier X. In its role as an SVC, it conducted a site visit of X 3 months later. Although X did not appear meet the definition of “operational” in § 424.502, the entity might be reluctant to make this finding because it could cast doubts on the thoroughness of its AO survey 3 months earlier. This could result in the supplier becoming enrolled and receiving payments while non-operational.

To avoid such conflict-of-interest situations and to help facilitate the impartiality of DMEPOS AO accreditation decisions, we propose in new § 424.58(n)(2) that an entity may not serve as a CMS-approved DMEPOS AO if it is currently a CMS contractor—or an owner or subsidiary thereof (regardless of the ownership percentage involved).—with any oversight responsibility of DMEPOS suppliers. We also solicit comment on whether this prohibition should extend to situations where, similar to paragraph (n)(1), there are familial relationships between owners and employees of DMEPOS AOs and the CMS contractor—for instance, whether an organization should be prohibited from being a DMEPOS AO if it has owners or employees who are immediate family members of NPE owners or employees.

12. AO Changes of Ownership (New § 424.58(o))

Section 488.5(f) contains robust procedures for when an AO undergoes a change of ownership (as that term is defined in § 489.18(a)(1) through (3)). They address matters such as: (1) the notice and accompanying information and acknowledgments the AO must furnish to CMS; and (2) the impact on the AO’s accredited providers and suppliers. However, § 424.58 contains no process for AO ownership changes. We note that § 488.1030, which addresses HIT supplier accreditation, states in paragraph (g) that an AO seeking to undergo a change of ownership is subject to the requirements at § 488.5(f). We propose the same cross-referencing approach in new § 424.58(o), under which DMEPOS AO changes of ownership would be governed by § 488.5(f).

13. Requirement for Suppliers To Be Accredited (Revisions to § 424.57)

As already noted, § 424.57 primarily addresses conditions of payment and supplier standards that suppliers must meet to enroll in and bill Medicare. Yet it also addresses accreditation requirements for DMEPOS suppliers; specifically, § 424.57(c)(22) states that these suppliers and all of their locations must be accredited by a CMS-approved AO to receive and retain a supplier billing number. Given our proposed strengthening of the DMEPOS accreditation program requirements in § 424.58, we believe corresponding enhancements to § 424.57 are necessary. Whereas our § 424.58 proposals focus to a considerable degree on the AO’s execution of its DMEPOS program, our revisions to § 424.57 would pertain mostly to the supplier’s need to be accredited to enroll in Medicare.

a. Requirement of Survey (§ 424.57(c)(23))

Section 424.57(c)(23) requires all suppliers to notify their AO when a new DMEPOS location is opened. Significantly, it also states that the AO may accredit the new supplier location for three months after it is operational without requiring a new site visit. We propose to remove the latter statement from § 424.57(c)(23) because it contradicts proposed § 424.58(e)(8)(i)(A) and (C). These two paragraphs state, respectively, that unless CMS otherwise directs or permits in writing, the AO: (1) must survey all suppliers seeking accreditation or reaccreditation; and (2) cannot accredit the supplier before the survey is conducted and the AO concludes that the supplier is adherent to the quality standards. In our view, allowing a supplier to become accredited for 3 months without the important vetting of a survey and the AO’s review of the survey results presents a serious risk of beneficiary harm and improper Medicare payments, which we must prevent. Accordingly, revised § 424.57(c)(23) would be limited to stating that all suppliers must notify their AO when a new DMEPOS location is opened.

b. Accreditation Frequency (§ 424.57(c)(22) and (24))

(1) Structural Change

Section 424.57(c)(24) states that all DMEPOS supplier locations, whether owned or subcontracted, must meet the quality standards and be separately accredited in order to bill Medicare. As this requirement mirrors that in § 424.57(c)(22) to some extent, we propose to move the current language in

§ 424.57(c)(24) to § 424.57(c)(22). Revised § 424.57(c)(22) would state the following:

- All DMEPOS suppliers and all of their locations (whether owned or subcontracted) must meet the quality standards and be separately accredited to enroll in and bill Medicare.
- The accreditation must indicate the products and services for which the supplier is accredited in order for the supplier to receive payment for those products and services. (This language is in current § 424.57(c)(22).)
- An accredited supplier’s enrollment may be denied or revoked if CMS determines that it is non-compliant with the quality standards. (This language is currently in § 424.57(c)(24).)

(2) Accreditation Periods (Revised § 424.57(c)(24))

Part 488 contains several provisions regarding the frequency with which surveys must be performed. For instance:

- Section 488.5 outlines the requirements of the AO’s accreditation or reaccreditation application. Paragraph (a)(4)(i) thereof states that the AO must describe the frequency of surveys it will perform and must agree to resurvey every accredited provider or supplier within 36 months after the prior accreditation effective date.
- Sections 488.710(a), 488.730(a), and 488.1110(a) have a similar 36-month survey requirement for HHAs and hospices, respectively.

We have issued sub-regulatory guidance stating that DMEPOS suppliers, as previously noted, must undergo an unannounced survey once every 3 years following initial accreditation. However, neither § 424.57 nor § 424.58 address the frequency with which surveys must be performed or how often a supplier must be reaccredited. While, as mentioned, HHAs and hospices fall with the high-risk categorical screening level under § 424.518, we reiterate that perhaps no other provider or supplier type over the decades has been the subject of CMS’ provider enrollment program integrity efforts more than DMEPOS suppliers; as an example, DMEPOS suppliers are the only provider or supplier type that is required to acquire and maintain a surety bond as a condition of enrollment. The program integrity issues for DMEPOS suppliers very much remain, and we are concerned that performing surveys only once every 3 years provides inadequate protection for the Medicare program. As previously underscored in this section VI.B. of this proposed rule, non-compliant suppliers can endanger the Trust Funds as well as

beneficiaries. We believe the best means of ensuring supplier compliance is through closer and more frequent monitoring of suppliers. In our view, the longer a DMEPOS supplier goes without the scrutiny of a survey and reaccreditation, the greater the chances the supplier will fall out of compliance with the quality standards during this period. We also believe that more frequent surveys and reaccreditations will spur suppliers to maintain consistent adherence to the quality standards, for they will know their next survey would be much sooner than every 3 years.

Moreover, we do not believe that the 3-year survey cycle for HHAs and hospices mandates the same for DMEPOS suppliers. Each provider and supplier type and the program integrity risks they pose are different, and we must address them based on their own particulars; there is no “one-size-fits-all” approach that can be taken for all provider and suppliers. If there is a particular group of providers or suppliers that poses and has historically posed an exceptional program integrity threat to the Medicare program—and DMEPOS suppliers have presented such a threat, especially in light of the continuing fraud schemes we have seen that have not necessarily been duplicated in scope and volume with other higher risk provider and supplier types—we must take measures commensurate with the threat. Put otherwise, the frequency of surveys and other reviews must be tailored to the risk the provider or supplier type in question presents.

For these and other reasons described in this section VI.B. of this proposed rule, we propose in revised § 424.57(c)(24) that DMEPOS suppliers must be surveyed and reaccredited at least once every 12 months. We recognize that this could prove burdensome for DMEPOS suppliers, but we again emphasize the importance of protecting the Trust Funds and the health and safety of Medicare beneficiaries.

c. Changes in Majority Ownership and the “36-Month Rule”

For Medicare certified providers and suppliers, the general purpose of a state survey or accreditation review is to determine whether the provider or supplier is in compliance with its regulatorily prescribed conditions of participation or conditions of coverage (hereafter collectively referenced as CoPs). CoPs are federal requirements that a certified provider or supplier must meet to participate in the Medicare program. As they generally focus on

health and safety protections, CoPs are crucial in ensuring that providers and suppliers are legitimate, bona fide entities capable of furnishing quality care and following safety requirements. Though it is a provider enrollment provision, § 424.550(b)(1) recognizes the importance of survey and accreditation processes (hereafter sometimes collectively referenced as the “survey process”) for HHAs and hospices. They help confirm the HHA’s or hospice’s compliance with the CoPs and the quality and safety requirements they entail. To this end, § 424.550(b)(1) states if an HHA or hospice undergoes a change in majority ownership (occasionally referenced as a “CIMO”) by sale within 36 months after the effective date of the HHA’s or hospice’s initial enrollment in Medicare or within 36 months after the HHA’s or hospice’s most recent CIMO, the provider agreement and Medicare billing privileges do not convey to the HHA’s or hospice’s new owner. Instead, the prospective provider/owner of the HHA or hospice must: (1) enroll in Medicare as a new (initial) HHA or hospice; and (2) obtain a state survey or an accreditation from an approved accreditation organization. (This is sometimes referenced as the “36-month rule”). As defined in 42 CFR 424.502, a CIMO occurs when a party acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA’s or hospice’s initial enrollment or most recent CIMO. CIMOs can include an acquisition of majority ownership through the cumulative effect of asset sales, stock transfers, consolidations, or mergers.

Section 424.550(b)(1) was promulgated in 2009 and modified in 2010 and 2023. There were two principal objectives behind its establishment.

First, there was a trend in the HHA community whereby an HHA applied for Medicare certification, underwent a survey, and became enrolled in Medicare, but then was immediately sold without having seen a Medicare beneficiary or hired an employee. These brokers, in other words, enrolled in Medicare exclusively to sell the HHA rather than to provide services to beneficiaries. This practice enabled a purchaser of an HHA from the broker to enter Medicare with no survey, which, in turn, sometimes led that owner to soon sell the business to another party. This “flipping” or “turn-key” mechanism, in short, was used to circumvent the survey process.

Second, we were more broadly concerned about the lack of scrutiny of

new owners as a whole, not merely in cases of flipping. We made clear in the CY 2010 HH PPS final rule (74 FR 58078) that the intent of § 424.550(b)(1) goes beyond the flipping issue.⁶⁹ We explained that if an HHA undergoes a change of ownership, CMS generally does not perform a survey pursuant thereto. CMS consequently has no sure way of knowing whether the HHA, under its new ownership and management, is compliant with the HHA CoPs. Unless CMS can make this determination, there is a risk that the newly purchased HHA, without having been appropriately vetted, will bill for services when it is out of compliance with the CoPs.⁷⁰ We had the same concerns regarding hospices, and in 2023 accordingly added hospices to § 424.550(b)(1)’s purview.

We have already discussed at length in this section VI.B. of this proposed rule the long-standing fraud, waste, and abuse risks in the DMEPOS supplier community and the threat this poses not only to the Trust Funds but also to patient safety. Enhancing this dilemma is the fact that when a DMEPOS supplier ownership change crosses the 50 percent threshold, the AO typically does not perform a survey to assess compliance with the quality standards. We therefore cannot determine whether the DMEPOS supplier under its new majority ownership will be committed to adhering to all Medicare requirements and to protecting beneficiaries. There have been a significant number of such DMEPOS supplier ownership changes over the years, many of which have occurred within 36 months of initial enrollment or the supplier’s most recent CIMO—sometimes, in fact, within only a few months of initial enrollment or the previous sale. In addition, several such cases have involved the previously mentioned flipping practice, meaning the DMEPOS supplier enrolls solely to sell the business to another party. All of these concerns mirror those behind the establishment and 2023 expansion of this “36-month rule”. Considering the very elevated program integrity risk that the DMEPOS supplier type has historically posed, it is imperative that every vulnerability we detect is properly addressed. Such a vulnerability indeed exists regarding DMEPOS suppliers no less than it did for HHAs and hospices. We must ensure that DMEPOS suppliers under their new ownership receive the same level of scrutiny that initially enrolling DMEPOS suppliers do.

⁶⁹ 74 FR 58118.

⁷⁰ Ibid.

We accordingly propose in new § 424.551 to mirror the provisions of existing § 424.550(b)(1) such that a DMEPOS supplier undergoing a CIMO must enroll as a new DMEPOS supplier and be newly accredited and surveyed under § 424.58. We also propose to do the following:

- Duplicate § 424.502's definition of change in majority ownership within § 424.551 (though slightly tailored to apply to DMEPOS suppliers).
- Revise § 424.540(a)(8) to state that CMS can deactivate the enrollment of a seller of a DMEPOS supplier if the supplier undergoes a CIMO in accordance with § 424.551. (As noted in section VI.A. of this proposed rule, § 424.540(a)(8) currently includes HHAs, and we are proposing to include hospices therein, too.)

- Add new paragraph (h) to § 424.57 to emphasize that a DMEPOS supplier must comply with the provisions of § 424.551 if it undergoes a CIMO. (This would help link § 424.57 to § 424.551.)

We note that § 424.550(b)(2) contains several exceptions to the 36-month rule. Specifically, even if an HHA or hospice undergoes a CIMO, the requirement in § 424.550(b)(1) that the HHA or hospice enroll as a new HHA or hospice and undergo a survey or accreditation does not apply if any of the following four exceptions (outlined in § 424.550(b)(1)) are implicated:

- The HHA or hospice submitted 2 consecutive years of full cost reports since initial enrollment or the last CIMO, whichever is later.

- An HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

- The owners of an existing HHA or hospice are changing the HHA's or hospice's existing business structure (for example, from a corporation to a partnership (general or limited)), and the owners remain the same.

- An individual owner of an HHA or hospice dies.

These exceptions were added to § 424.550(b) in a final rule published in the **Federal Register** on November 17, 2010, titled, "Medicare Program; Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices" (75 FR 70372). We promulgated them because the HHA community had expressed concerns that the 36-month rule could inhibit bona fide HHA ownership transactions; for example, prospective new owners may not wish to have to enroll as a new HHA and will therefore decline to purchase the entity. We believed that our

exceptions struck a solid balance between the need for more scrutiny of new owners via the survey process while not inadvertently obstructing legitimate transactions involving legitimate parties. As an illustration, a CIMO resulting from an internal restructuring can frequently pose less of a risk of "flipping" than an HHA that—2 months after initial enrollment—is sold to another party strictly to maneuver around the survey process. These exceptions, in our view, still soundly balance the two aforementioned considerations. We accordingly propose to duplicate existing § 424.550(b)(2)(ii) through (iv) as exceptions within proposed new § 424.551, though current § 424.550(b)(2)(i) would not be mirrored because DMEPOS suppliers do not submit cost reports.

14. Solicitation of Comments

In light of the volume of changes we are proposing to the DMEPOS accreditation program, we would appreciate feedback thereon from AOs, DMEPOS suppliers, and other stakeholders. We are particularly interested in receiving comments on the following topics addressed in this proposed rule:

- The amount and types of additional information that AOs would have to submit with their initial and reapproval applications per new § 424.58(c) and (d). For instance—

- ++ Whether there is data we are proposing to collect that is unnecessary, superfluous, or duplicative of other requested information; and

- ++ Whether there is information that should be submitted beyond what we are proposing to require.

- Whether there are any grounds beyond those proposed at § 424.58(e)(5) for which the AO should be required to deny or terminate a supplier's accreditation and, if so, what those grounds are.

- The requirement in proposed § 424.58(e)(8)(i) that, except as otherwise directed or permitted by CMS, the AO perform a survey of all suppliers seeking accreditation or reaccreditation with the AO.

- Whether there are any grounds beyond those listed in § 424.58(h), (i), and (j) for which CMS should be able to, respectively, terminate, suspend, or place on probation the AO's accreditation program and, if so, what those grounds are.

- Whether DMEPOS suppliers should be surveyed and reaccredited under § 424.57(c)(24) less frequently than every 12 months and, if so, what the

survey and reaccreditation timeframe should be.

15. Conclusion

The collection of information and regulatory impact analysis sections of this proposed rule address the net cost burden associated with our DMEPOS accreditation provisions. We project that it would exceed \$128 million annually. We understand the financial impact this could have on the DMEPOS community. However, this would be more than offset by the over \$660 million in annual savings to the Medicare Trust Funds and the taxpayers due primarily to the removal of fraudulent and non-compliant DMEPOS suppliers from the Medicare program. Of no less importance, we believe that more frequent surveys, ad-hoc surveys, and stricter requirements for AOs will encourage DMEPOS suppliers and AOs to be much more vigilant in maintaining and verifying compliance with the quality standards. To illustrate, with ad-hoc surveys, a DMEPOS supplier will not know whether or when it will be selected for such a survey, meaning that the supplier could feel compelled to never allow itself to fall out of compliance with the quality standards, even for an extremely brief period. With the quality standards being designed in large part to protect beneficiaries, we believe that greater compliance therewith could reduce risks to patients' health safety from, for example, substandard DMEPOS items, inadequate equipment instructions, and poor customer service.

We hence conclude that notwithstanding the burden associated with these requirements, the saving of potentially billions of taxpayer dollars and the preservation of beneficiary safety justify it.

C. Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(ii))

1. Background

The Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Payment Integrity Information Act of 2019 (Pub. L. 116–117). As stated in the CERT 2024 Medicare FFS Supplemental Improper Payment Data report, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims had an improper payment rate of 21.4 percent, accounting for approximately 6.1 percent of the overall Medicare FFS

improper payment rate.⁷¹ Over the years we have implemented conditions of payment and other requirements to decrease the improper payment rate for DMEPOS.

Currently, the scope of payment for medical supplies, appliances, and devices, including prosthetics and orthotics, are defined at 42 CFR 410.36(a) and the scope and certain conditions for payment of durable medical equipment (DME) are described at § 410.38. Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. Conditions of payment vary by item but are specified in statute and in our regulations. These conditions are further detailed in our manuals and in local and national coverage determinations. Additionally, for certain DMEPOS items we require suppliers to follow a prior authorization process through which a request for provisional affirmation of coverage is submitted for review before a DMEPOS item is furnished to a beneficiary and before a claim is submitted for payment.⁷² Prior authorization plays an important role in ensuring Medicare's coverage, coding, and payment requirements are met, allowing suppliers a provisional assurance of claim coverage.

On December 30, 2015, we published a final rule in the **Federal Register** titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (80 FR 81674), hereinafter referred to as the "December 2015 final rule," that established a permanent prior authorization program nationally. The December 2015 final rule was based on the authority outlined in section 1834(a)(15) of the Act, which permits the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, based on prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Specifically, the December 2015 final rule established a new provision at § 414.234 that specified a process for prior authorization of DMEPOS items

frequently subject to unnecessary utilization.

In addition, § 414.234(b) details criteria needed for inclusion on the Master List of Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements ("Master List"). Placement on the Master List makes an item eligible for CMS to require prior authorization as a condition of payment. CMS selects items from the Master List that will require prior authorization as a condition of payment, and we publish notice of such items in the **Federal Register**.

Prior authorization supports ongoing efforts to safeguard beneficiaries' access to medically necessary items and services, while reducing improper Medicare billing and payments. This is important because documentation of practitioner involvement, including their orders for DMEPOS items and documented medical necessity (as assessed under prior authorization), is all used to support proper Medicare payment for DMEPOS items.

In the November 8, 2019, **Federal Register**, we published a final rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" (84 FR 60648), hereinafter referred to as the "2019 ESRD PPS & DMEPOS final rule."

In the 2019 ESRD PPS & DMEPOS final rule, we finalized technical corrections; updates to definitions and documentation requirements; standard elements of a DMEPOS order; established one harmonized Master List; revised factors for placing an item on the Required Prior Authorization List; and established the authority to exempt compliant suppliers from the prior authorization process. We noted that we believe this exemption process meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and supplier burden. Specifically, § 414.234(c)(1)(ii) clarifies that CMS may elect to exempt suppliers from prior authorization upon

demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process. We did not provide specifics on this exemption process in the regulatory text. However, we received comments suggesting that prior authorization be reserved for aberrant billers and suggesting that CMS consider compliance incentives to waive prior authorization for suppliers that are compliant with billing requirements. We stated that we would consider these suggestions in future rulemaking.

2. Provisions of the Proposed Rule

Prior authorization for certain DMEPOS items ensures that Medicare beneficiaries continue to receive medically necessary items while protecting the Medicare Trust Funds from improper payments, and at the same time keeping the medical necessity documentation requirements unchanged for suppliers. We propose to add language to § 414.234(c)(1) that provides additional specificity for the exemption process in § 414.234(c)(1)(ii).

To reduce supplier burden and effectively utilize contractor resources, we propose to clarify circumstances under which CMS would exempt a supplier from the prior authorization process in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS withdraws the exemption. We would exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during an initial or periodic assessment. We believe that, by achieving this percentage, the supplier would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a supplier to achieve 100 percent compliance to qualify for an exemption because unintentional and sporadic errors could occur that are not deliberate or systematic attempts to submit claims that are not payable. In addition, we propose that we would withdraw an exemption if evidence becomes available, based on a review of claims, that the supplier has begun to submit claims that are not payable based on Medicare's billing, coding or payment requirements. If the rate of non-payable claims submitted becomes higher than 10 percent during a periodic assessment, we would withdraw the exemption.

In proposed § 414.234(c)(1)(ii)(B), we would provide 60-day notice of an

⁷¹ <https://www.cms.gov/files/document/2024-medicare-fee-service-supplemental-improper-payment-data.pdf>.

⁷² https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/dmepos/downloads/dmepos_pa_required-prior-authorization-list.pdf.

exemption from mandatory prior authorization requirements. Similarly, we propose to provide 60-day notice if an exemption is withdrawn, to give the supplier time to begin submission of prior authorization requests, in compliance with mandatory requirements.

We solicit comments on these proposals.

VII. DMEPOS Competitive Bidding Program

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs (CBPs) in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of competitively priced DMEPOS items and services, including:

- Certain DME and medical supplies (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.
- Enteral nutrients, equipment, and supplies (enteral nutrition) described in section 1842(s)(2)(D) of the Act.
- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act.
- Lymphedema compression treatment items (as defined in section 1861(mmm) of the Act) for which payment would otherwise be made under section 1834(z) of the Act.

1. Benefits of the DMEPOS CBP

The DMEPOS CBP utilizes bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.

The primary goal of the DMEPOS CBP is to reduce excessive Medicare payments for DMEPOS items and services by awarding contracts to a group of suppliers with the lowest bid amounts that have the capacity to furnish the items and services needed in each CBA. In accordance with section 1847(b)(2)(A)(iii) of the Act, contracts cannot be awarded if the total amounts to be paid to contract suppliers in the area are not expected to be less than the total amounts that would otherwise be paid under the DMEPOS fee schedules. Another goal is to provide the best value DMEPOS to achieve positive health outcomes for Medicare beneficiaries. In

accordance with section 1847(b)(2)(A)(i) of the Act, contracts cannot be awarded to any supplier that does not meet the quality standards established in accordance with section 1834(a)(20) of the Act. From 2011 through 2018, both of these goals were successfully accomplished for many categories of DMEPOS items and services mandated for inclusion under the program that had the highest volume in terms of total allowed charges. The DMEPOS CBP provides additional benefits that are arguably just as important as lowering excessive payment rates. In general, when the DMEPOS CBP lowers the allowed amounts paid for items and services, it decreases the incentive for committing fraud. Limiting the number of contracts awarded in a competition also reduces the number of suppliers with which a contract supplier must compete for Medicare business. The lower the number of contracts awarded, the greater the chance a supplier receiving a contract has to maintain a steady stream of business and potentially increase their volume of business. The lower the number of contract awards, the more valuable the contracts become, creating a greater incentive for bidding entities to bid more competitively.

Another important benefit of the DMEPOS CBP is that it ensures access to covered DMEPOS items and services. Pursuant section 1847(b)(3)(A) of the Act, the terms of an awarded contract requires under 42 CFR 414.422 that a contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. For example, a supplier with a contract to furnish oxygen and oxygen equipment, a product category that includes highly profitable items like oxygen concentrators, and less profitable items like liquid oxygen, must provide access to liquid oxygen as a term of their contract. Contract suppliers may not elect to only furnish the more profitable items and services included in a product category under their contract or to only furnish the items and services to beneficiaries who are less costly to serve (due to, for example, lower shipping or delivery costs for those that live in close proximity to the contract supplier's location). In contrast, suppliers of items not included under the DMEPOS CBP are not mandated to furnish any item or service to any beneficiary. They may elect not to serve beneficiaries in hard-to-reach places or not to furnish items such as liquid oxygen and oxygen

equipment that are not as profitable as other items such as stationary oxygen concentrators.

2. Standard Payment Rules for DMEPOS Items and Services and Competitive Bidding Demonstrations

Medicare began paying for DME and orthotics (leg, arm, back, and neck braces) on a fee schedule basis beginning January 1, 1989, in accordance with section 1834(a) of the Act. The fee schedule payment rules for orthotics were subsequently relocated under new section 1834(h) of the Act. In 2001, payment on a fee schedule basis was implemented for enteral nutrition covered under the prosthetic device benefit defined under section 1861(s)(8) of the Act based on the authority provided by section 1842(s)(2) of the Act. The Medicare allowed payment amounts for these DMEPOS items and services are based on the lower of the supplier's actual charge on the claim or the fee schedule amount for the item. Prior to implementation of the fee schedules, payment for these items and services was made in accordance with the reasonable charge payment methodology mandated by section 1842(b)(3) of the Act, which based the Medicare allowed payments for these items in a given calendar year based on what suppliers charged for furnishing the items and services in the preceding calendar year. The reasonable charge payments began in 1966 and increased each year without any limit on inflation until October 1986.

The statute mandates a very specific methodology for calculating the fee schedule amounts. The fee schedule amounts for DME, which were first implemented in 1989, are based on the average of the reasonable charges paid for the item during 1986 and 1987 in each State, increased on an annual basis by covered item update factors in accordance with section 1834(a)(14) of the Act. The statewide fee schedule amounts for the contiguous United States are limited by a national ceiling and floor based on the median of the statewide fee schedule amounts (ceiling) and 85 percent of the median of the statewide fee schedule amounts (floor). The fee schedule amounts for orthotics are based on the average of the reasonable charges paid for the item during 1986 and 1987 and are increased on an annual basis by covered item update factors in accordance with section 1834(h)(4) of the Act. For areas within the contiguous United States, the fee schedule amounts are based on the average reasonable charges in ten regions of the United States. The regional fee schedule amounts are

limited by a national ceiling and floor based on 120 percent of the average of the regional fee schedule amounts across all States (ceiling) and 90 percent of the average of the regional fee schedule amounts across all States (floor). The fee schedule amounts for enteral nutrition were the nationwide fee schedule amounts from 2001 through 2015. The nationwide fee schedule amounts were based on the lower of the average of the reasonable charges paid for the item in 1995 or 2000, increased on an annual basis by update factors in accordance with section 1842(s)(1)(B) of the Act. In 2016, the fee schedule amounts for enteral nutrition were adjusted based on information from the DMEPOS CBP and converted to statewide fee schedule amounts. For items of DME and orthotics that were not paid for under Medicare during 1986 and 1987, the fee schedule amounts for the items are established using the fee schedule amounts for comparable items or supplier price lists in accordance with regulations at 42 CFR 414.238. For items of enteral nutrition that were not paid for under Medicare in either 1995 or 2000, the fee schedule amounts for the items are established using the fee schedule amounts for comparable items or supplier price lists in accordance with regulations at 42 CFR 414.112.

Complaints and reports about excessive rental payments for DME began in the 1960s and early 1970s. As early as May 1972, the idea of using competitive bidding to reduce reasonable payments was presented in a report by the Government Accountability Office (GAO), then referred to as the General Accounting Office.⁷³ In response to rapidly growing expenditures for DME in the early 1980s, CMS, then referred to as the Health Care Financing Administration, contracted with Abt Associates, Inc. to design Medicare competitive bidding demonstrations for DME, which were planned to go into effect in 1987 in nine metropolitan statistical areas (MSAs). However, Congress imposed a funding moratorium on the demonstrations before they could be implemented. Throughout the 1980s and 1990s,

excessive Medicare payments for DME continued to be the focus of reports by the Department of Health and Human Services, Office of Inspector General (OIG) and the GAO, as well as media outlets and Congressional Hearings. Section 4319 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33) mandated demonstration projects for competitive bidding for oxygen and oxygen equipment and other Part B items and services, other than physician services. CMS contracted with Abt Associates, Inc. to design the competitive bidding demonstrations mandated by the BBA of 1997, and many aspects of the demonstrations designed in the 1980s were incorporated into the demonstrations held in Polk County, Florida, for oxygen equipment and supplies, hospital beds and accessories, enteral nutrition, urological supplies, and surgical dressings from October 1, 1999 through September 30, 2002, and in San Antonio, Texas, for oxygen equipment and supplies, hospital beds and accessories, wheelchairs and accessories, general orthotics, and nebulizer drugs from February 1, 2001, through December 31, 2002. The Medicare payment amounts under the demonstrations were lowered by approximately 19 percent. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged.

The DMEPOS CBP was modeled after the successful demonstration programs from the late 1990s and early 2000s. For more information about the demonstrations, refer to the proposed rule titled, “Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,” published in the **Federal Register** on May 1, 2006 (hereafter referred to as the “2006 proposed rule”) (71 FR 25654). During the initial development of the DMEPOS CBP, we received substantial feedback from the Program Advisory and Oversight Committee (PAOC), mandated by section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, to provide advice to the Secretary with respect to the following functions:

- The implementation of the Medicare DMEPOS CBP.
- The establishment of financial standards for entities seeking contracts

under the Medicare DMEPOS CBP, taking into account the needs of small providers.

- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS CBP.

- The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.

- The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

The DMEPOS CBP was initially implemented using the final rule titled, “Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues,” published in the **Federal Register** on April 10, 2007 (72 FR 17992), hereafter referred to as the “2007 final rule.” Additional changes were made to the DMEPOS CBP in subsequent rulemaking.

3. Phased In Implementation of the DMEPOS CBP

As discussed previously, section 1847(a) of the Act directs us to phase in items into the DMEPOS CBP. Section 1847(b)(3)(B) of the Act mandates that the contracts awarded to suppliers under the CBP must be recomputed not less often than once every 3 years. Section 1847(a)(1)(B) and (D) of the Act mandate the phase-in of the DMEPOS CBP in nine of the largest MSAs (known as “Round 1”) implemented on January 1, 2011, followed by 91 additional large MSAs (known as Round 2) implemented on July 1, 2013, and finally in additional areas, which do not necessarily need to be tied to MSAs. Although the DMEPOS CBP is mandated to be expanded into areas throughout the United States, no timeframe is provided for when all areas must be phased in under the DMEPOS CBP. In accordance with section 1847(a) of the Act, rural areas and areas with low population density within urban areas that are not competitive may be excluded from the DMEPOS CBP, unless there is a significant national market through mail order for a particular item or service. In accordance with this directive, we initiated several rounds of the DMEPOS CBP, as summarized in table 37:

⁷³ “Need for Legislation to Authorize More Economical Ways of Providing Durable Medical Equipment Under Medicare,” B–164031 (4), May 12, 1972.

TABLE 37: COMPETITIVE BIDDING ROUNDS AND CONTRACT PERIODS

Calendar Year	Round 1 Areas (9 Metropolitan Statistical Areas (MSAs))	Round 2 Areas (90 MSAs) and National Mail Order
2011	Round 1 1/11/2011 - 12/31/2013	--
2012		
2013		
2014	Round 1 Recompete 1/1/2014 - 12/31/2016	Round 2 & National Mail Order 7/1/2013 - 6/30/2016
2015		
2016		
2017	Round 1 2017 (recompete) 1/1/2017 - 12/31/2018	
2018		
2019	Temporary Gap Period	
2020		
2021	Round 2021 (recompets for Round 1 and Round 2) 1/1/2021 - 12/31/2023	
2022		
2023		
2024	Temporary Gap Period	
2025		

For competitions under the DMEPOS CBP prior to July 1, 2016, there were some CBAs that included MSAs that spanned multiple states. However, starting on July 1, 2016 (Round 2 Recompete), those CBAs were subdivided so that there are no multi-state CBAs. This has resulted in the DMEPOS CBP operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the DMEPOS CBP has not yet been phased-in, including approximately 275 MSAs, which we refer to as non-competitive bidding areas (non-CBAs).

In competitions under the DMEPOS CBP prior to Round 2021, bidding entities bid for contracts for furnishing multiple items and services, identified by Healthcare Common Procedure Coding System (HCPCS) Level II codes, under several different product categories. The product categories included in the CBPs prior to and including Round 2021 are as follows.

- National Mail Order CBA: Diabetes testing supplies.
- Round 1 2017 and Round 2 Recompete: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies;

Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive airway pressure (CPAP) devices, and respiratory assist devices (RADs)); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies.

- Round 2021: OTS Back Braces and OTS Knee Braces.

In past rounds of competition, CMS allowed a 60-day bidding window for bidding entities to prepare and submit bids. Our regulation at § 414.412 specifies the rules for submission of bids under the DMEPOS CBP. Each bid submission is evaluated, and contracts are awarded to qualified bidding entities in accordance with the requirements of section 1847(b)(2) of the Act and regulations at § 414.414, which specify conditions for awarding contracts, including a financial standard evaluation of each bidding entity that submits a bid. This process included a review of tax records, credit reports, and other financial data, which led to the calculation of a financial score, similar to processes used by lenders when evaluating the viability of a company. All bidding entities must meet the

financial standards established for the program to be offered a contract. Applying financial standards to bidding entities is needed to assess the expected financial health and quality of bidding entities, and to ensure that the selected bidding entities are able to continue to serve market demand throughout the duration of the contract period.

4. Bid Surety Bonds

Section 522(a) of the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) requires bid surety bonds and State licensure for entities submitting bids under the DMEPOS CBP and was implemented as part of the final rule titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model," published in the **Federal Register** on November 4, 2016 (81 FR

77834). Section 522(a) of MACRA added section 1847(a)(1)(G) of the Act to require bidders to submit a bid surety bond by the deadline for bid submission. We implemented section 522(a) of MACRA during the next round of competitive bidding following enactment of MACRA, which was Round 2021, even though Round 2021 began after the time period specified in the statute. Section 1847(a)(1)(H)(i) of the Act provides that in the event that a bidder is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidders included in the calculation of the single payment amount (SPA) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and the Secretary will collect on the bid surety bond(s). In instances where a bidder does not meet the bid surety bond forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidder within 90 days of the public announcement of the contract suppliers for such product category and area. Detailed conditions of the bid surety bonds were clarified in the 2016 final rule (81 FR 77931). Implementing regulations at § 414.412(h) were later amended in the final rule titled, “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS,” published in the **Federal Register** on November 14, 2018, (83 FR 56922) to require bidders to obtain bid surety bonds, and if an entity is offered a contract for any product category for a CBA, its composite bid for such product category and area is at or below the median composite bid rate for all bidders included in the calculation of the SPA(s) for the product category/ CBA combination, and the entity does not accept the contract offered, the bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective bonding company. We believe the bid surety

bond requirement encourages all bidding entities to submit substantiated bid amounts—that is, to further prevent bidding entities from submitting a low bid amount to have a better opportunity in being offered a DMEPOS Contract.

B. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

In order to incentivize bidding entities to submit competitive bids and in order to ensure that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D, we are proposing to make modifications to the process for selecting the number of contract suppliers sufficient to furnish items and services in a competition and the methodology for establishing SPAs for lead and non-lead items. We also propose, in lieu of self-reported supplier capacity, to estimate supplier capacity in accordance with 42 CFR 414.414(e)(2) using data on actual contract supplier capacity from previous rounds of the DMEPOS CBP. We are soliciting comments on these proposals.

1. Background

The DMEPOS CBP is a program in which Medicare-enrolled DMEPOS suppliers submit bids and compete to receive a limited number of contract(s) to furnish DMEPOS items and services, identified by HCPCS codes, within different product categories in different CBAs throughout the nation. The bids from contract suppliers under the program are used to calculate SPAs to pay the contract suppliers in lieu of the payment amounts they would otherwise receive under the standard payment rules under sections 1834(a)(2) through (7), 1834(h), 1834(z), and 1842(s) of the Act. Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. The contract supplier collects a coinsurance payment from the beneficiary equal to 20 percent of the applicable SPA as well as any unmet Part B deductible. The total payment made to the contract supplier by Medicare and the beneficiary cannot exceed the SPA. For DMEPOS items and services that are not paid for under the DMEPOS CBP, a non-participating supplier has the option to collect more than the Medicare allowed amount from the beneficiary, a practice referred to as balance billing. Balance billing is not allowed under the DMEPOS CBP.

a. Rules in Effect Prior to Round 2021 of the DMEPOS CBP

In accordance with the 2007 final rule (72 FR 17992), prior to Round 2021, bidding entities submitted a bid amount for each item in a product category. These bid amounts were combined into one composite bid for each bidding entity, aggregating their bids for all items in a product category. To compute a composite bid, historical DMEPOS utilization data was used to assign weights to each item in each product category based on the national volume of the item in proportion to the national volume of all items in the product category. The composite bid for a bidding entity equaled the item’s weight multiplied by the item’s bid amount and summed across all items in the product category, which was used to determine the expected costs for all items in the product category based upon expected volume. Once a composite bid was calculated for each entity that submitted a bid in the competition, the composite bids were arrayed in order from lowest to highest. CMS began the contract award process by awarding a contract to the supplier with the lowest composite bid and then awarding contracts to the next supplier in the array. This process was repeated until there were enough suppliers to meet the projected demand⁷⁴ in the CBA for the items in the product category. The composite bid for the bidding entity where the cumulative capacity of the bidding entities for furnishing the items and services meets or exceeds projected demand is referred to as the pivotal bid. The array of bidding entities with bids at or below the pivotal bid are referred to as the winning contract suppliers or the winning array of suppliers. The bids for these contract suppliers are used to establish the SPAs for the items and services in the product category for each CBA.

Prior to Round 2021, the SPA for each item in the product category was calculated based on the median of the winning contract suppliers’ bids for each item. As explained in the 2007 final rule, we believed that setting the SPA based on the median of the contract suppliers’ bids satisfies the statutory requirement that SPAs are to be based on bids submitted and accepted. This resulted in a single payment for an item under a DMEPOS CBP that was representative of all acceptable bids, not just the highest or the lowest of the

⁷⁴ As explained in the 2007 DMEPOS final rule (72 FR 18039), demand for items and services was projected using Medicare claims data for allowed services during the previous 2 years, trended forward to the contract period.

winning bids for that item (72 FR 18045). Using the median of the winning bids as opposed to the lowest or highest bids is consistent with how Medicare has established allowed payment amounts for DMEPOS items since the beginning of the Medicare program. Under the reasonable charge payment methodology in place from 1966 through 1988, payment was based on the lower of the supplier's customary charge (the 50th percentile of charges from the supplier), or the prevailing charge for the item (the 75th percentile of customary charges for the item from suppliers in a given locality). The fee schedule amounts used to pay claims for DMEPOS beginning in 1989 are based on average reasonable charges for the items. The lowest or highest charges for an item were never used to establish the Medicare allowed payment amount for the DMEPOS item.

At the start of the DMEPOS CBP in 2011, CMS inflated demand for items and services in the CBAs so that more contracts would be awarded than needed to better ensure access to items and services under the new program. Prior to the finalization of the median of winning bids methodology, CMS explained to its Program Advisory and Oversight Committee that although a number of suppliers will be paid below what they bid, an approximately equal number of suppliers will be paid more than they bid.⁷⁵

From the inception of the DMEPOS CBP in 2011 and implementation of subsequent rounds through 2018, CMS implemented a very successful program using item weights, composite bids, and SPAs that were based on the median of the winning contract suppliers' bids for each item. Using the median of the winning bids resulted in 40 to 80 percent reductions in payment amounts under the program, even though more contracts were awarded than needed to meet an inflated demand target for items and services, because use of the median of winning bids reduces the impact of "outlier" bids at the top and bottom of the array of winning bids on the payment amount established for all contract suppliers. Suppliers accepted their contract offers at the median of the

winning supplier bids approximately 92 percent of the time consistently from round to round, Medicare and taxpayers saved money, and access to quality items and service was preserved. Section 1834(a)(1)(F) of the Act requires CMS to adjust fee schedule amounts for DME items and services furnished in non-CBAs based on the SPA pricing. Sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act provide discretion to adjust fee schedule amounts for OTS orthotics and enteral nutrition, respectively, furnished in non-CBAs based on SPA pricing. Adjustments to the fee schedule amounts have been in place for these items and services for several years and contract suppliers have accepted payment at the adjusted rates as payment in full for approximately 99 percent of all claims with no significant downward trends in utilization, and no negative changes in beneficiary health outcomes, as determined by CMS's health outcome claims monitoring.

b. Changes Implemented with Round 2021 of the DMEPOS CBP

Significant changes to the DMEPOS CBP were made as part of the final rule entitled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS" published in the **Federal Register** on November 14, 2018 (83 FR 56922) to improve the competitiveness and sustainability of the program. Effective January 1, 2019, and beginning with Round 2021, a "lead item" pricing methodology was established for submitting bids, calculating composite bids for bidding entities, determining pivotal bids, and calculating SPAs. The methodology for calculating SPAs was changed from the median of the winning contract suppliers' bid amounts for each item in the product category to the maximum winning contract supplier bid amount for a "lead item" in the product category, which is used to calculate the SPAs for all items in the product category. Under these rules, instead of submitting bid amounts for each item in the product category, the bidding entity submits a single bid amount for a "lead item" in the product category and this bid amount represents the bidding entity's "composite bid" for

furnishing all items in the product category. The "lead item" in each product category is defined in our regulations at § 414.402 to mean the item, in a product category with multiple items, with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition. The bids for the lead item are used to establish the SPAs for both the lead item and all other items (non-lead items) in the product category. In accordance with § 414.416(b)(1), the SPA for a lead item furnished under a CBP is equal to the maximum bid amount submitted for that item by bidding entities whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. Additionally, under § 414.416(b)(2), the SPA for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under the DMEPOS fee schedule. The SPAs for the non-lead items within the product category are determined by multiplying the lead item SPA by a relative ratio. The ratios are based on the historic differences in the fee schedule amounts for the lead item and non-lead items. In accordance with § 414.416(b)(3), the SPA for a non-lead item in a product category furnished under a CBP is equal to the SPA for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item.⁷⁶

The lead item pricing methodology was adopted to prevent a phenomenon that had been occurring under the DMEPOS CBP known as "unbalanced bidding," where bidding entities submitted low bid amounts for higher volume items under the product category because these bid amounts had a greater impact on their composite bid, and higher bid amounts for lower volume items under the product category because these bid amounts had a lesser impact on their composite bid. This resulted in skewed pricing results where SPAs for lower cost items with fewer features such as a manual hospital bed without side rails were higher than SPAs for higher cost items with more features such as a semi-electric hospital bed with side rails. Lead item pricing maintains the historic differences in

⁷⁵ As required by section 1847(c) of the Act, the Secretary of Health and Human Services established the Program Advisory and Oversight Committee (PAOC), which advised the Secretary on a range of implementation topics for the DMEPOS CBP. The PAOC comprised of a broad mix of relevant industry, consumer, and government parties. Specifically, the membership included beneficiary/consumer representatives, manufacturer representatives, supplier representatives, certification/standard representatives, Federal and State program representatives, a physician and a pharmacist.

⁷⁶ Calendar year 2015 is the last year the fee schedule amounts were not adjusted based on information from the CBP.

prices for these items, while streamlining the bidding process and significantly decreasing the burden for bidding entities since they only have to submit one bid amount for each competition (product category and CBA). Previously, the bidding entity had to submit bid amounts for every item in the product category, which for some product categories such as standard power wheelchairs and standard manual wheelchairs was over a hundred separate bid amounts.

c. Projecting Demand for Items and Services and Estimating Supplier Capacity for Furnishing Items and Services

In determining the number of contract suppliers for a competition, we aim to limit the number of contract suppliers to ensure they are incentivized to submit a competitive bid. As discussed in section B.1.d. of this proposed rule, awarding too many contracts decreases the incentive for a bidding entity to submit a competitive bid—given that bidding entities would be more likely to be awarded a contract regardless of the submitted bid amount. At the same time, in determining the number of contracts to award in a competition, we balance a number of other considerations set forth at sections 1847(b)(2)(A)(iv) and (b)(4)(B) of the Act. Section 1847(b)(4)(A) of the Act, allows the Secretary to limit the number of contract suppliers in a CBA to the number needed to meet projected demand for items and services covered under the contracts and also directs the Secretary to consider whether the bidders can furnish enough items or services to meet the anticipated needs of individuals within the contract's geographic area on a timely basis. Section 1847(b)(4)(B) of the Act also specifies that the Secretary shall award contracts to multiple entities submitting bids in each area for an item or service and section 1847(b)(2)(A)(iv) of the Act specifies that individuals must have access to multiple contract suppliers in the CBA or else contracts may not be awarded in that area. In balancing these considerations, we codified in current regulations at 42 CFR 414.414(e) our process for selecting the number of contract suppliers to be awarded a contract for a competition.

From 2011 through 2023, the methodologies and procedures used for projecting demand for items and services and estimating a supplier's capacity for furnishing items and services as a contract supplier remained virtually unchanged. These methodologies were designed to overestimate demand and underestimate

capacity to ensure access under the program when it began. These methodologies inflated the projected demand target for items and services, awarded no capacity for contract suppliers new to an area or product category, and limited a contract supplier's estimated capacity to their historic levels if they did not meet certain financial standards. Soon after the program was implemented in 2011, it was apparent that more contracts were being awarded under the program than needed to meet demand for items and services; however, CMS decided to continue using these methodologies during each round of competition up to and including Round 2021. While more contracts were awarded than needed to meet demand, this was balanced by establishing SPAs using the median of winning bids rather than a higher amount such as the maximum winning bid, thus still achieving the goal of lowering payment amounts and achieving savings under the DMEPOS CBP.

Under current regulations at 42 CFR 414.414(e)(1), which were revised as part of the November 14, 2018, final rule (83 FR 57018), we first calculate the expected beneficiary demand in the CBA for the lead item in the product category. This methodology accounts for actual historic beneficiary utilization of the lead item in the product category prior to each round of the DMEPOS CBP, while also considering the expected growth in the number of Medicare beneficiaries in the CBA as well as the expected growth in utilization of the lead item in the product category in the CBA. Specifically, under this methodology, CMS calculates the projected beneficiary demand for the lead item by multiplying the actual historic beneficiary utilization by a percent increase that is derived from increasing historic utilization by both the expected increase in number of beneficiaries and the expected increase in utilization, in general. If either the change in number of beneficiaries or the change in utilization in the CBA is expected to be negative, the negative trend is not included in the projection of demand and is instead set equal to one. In addition, the projected beneficiary demand is not reduced based on the number of items that would likely be furnished by grandfathered suppliers, which typically furnish approximately 15 percent of rented durable medical equipment items and related accessories (83 FR 57024). In accordance with section 1847(a)(4) of the Act and regulations at 42 CFR 414.408(j),

suppliers of rented DME and oxygen and oxygen equipment can become “grandfathered suppliers” and continue furnishing these items under the DMEPOS CBP if the rental agreement or supply arrangement with the beneficiary began prior to the start of the contract period. CMS has thus inflated the demand target in order to provide more contract suppliers for beneficiaries to choose from by using historic utilization, trending this forward by both the expected increase in number of beneficiaries and the expected increase in utilization and by not decreasing the number to account for fraudulent claims, decreases in the number of beneficiaries, or the percentage of demand that is accounted for by grandfathered suppliers or other non-contract suppliers under the exceptions at 42 CFR 414.404(b) for physicians, hospital outpatient departments, physical therapists, and occupational therapists. In the past, this did not compromise savings under the program when the median of winning bids was used to establish SPAs rather than a higher payment such as the maximum winning bids.

After determining the projected beneficiary demand, pursuant to 42 CFR 414.414(e)(2), we then calculate the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category. The capacity is currently based on the bidding entity's self-reported projection of how many items they could furnish at the amounts they bid. If a bidding entity reported a capacity that was less than their historic capacity, the capacity for the bidding entity was adjusted up to the level of their historic capacity; however, the capacity was never increased above their historic capacity.

Pursuant to 42 CFR 414.414(e)(5), CMS then analyzes each eligible bidder's financial health to assess its ability to furnish its estimated capacity against the projected beneficiary demand in each competition.

- If a bidder's financial score⁷⁷ meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount, CMS accepts the bidder's capacity at the greater of its estimated or historical capacity (based on claims

⁷⁷ CMS uses the required tax return extract and the required financial documents to calculate standard accounting ratios for each bidder. These ratios, along with the credit report and numerical credit score or rating, are used to compute the bidder's financial score. The methodology for computing bidders' financial scores has remained consistent throughout all rounds of the DMEPOS CBP.

data). However, if a bidder's financial score does not meet this threshold, the bidder is a new supplier (does not have 12 months of actual financial statements and submits at least one month of pro forma statements), or the bidder is a specialty supplier, CMS only accepts its capacity at its historical amount.

- If a bidder's accepted capacity is greater than 20 percent of projected beneficiary demand in the CBA, CMS adjusts the bidder's capacity to 20 percent of projected beneficiary demand to ensure at least five contracts are awarded for each competition, in accordance with 42 CFR 414.414(h).

Pursuant 42 CFR 414.414(e)(3) and (4), we then array the composite bids from the lowest composite bid price to the highest composite bid price and calculate the pivotal bid for the product category using the projected beneficiary demand and supplier demand calculated in accordance with 42 CFR 414.414(e)(1) and (2), as discussed previously. The pivotal bid, as defined under 42 CFR 414.402, is the lowest composite bid based on bids submitted by bidding entities for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category. In accordance 42 CFR 414.414(e)(5), contracts are awarded to all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category (and that meet the supplier eligibility requirements specified in the regulations and the *Request for Bids Instructions*) are selected as winning contract suppliers for the competition.

In order to ensure that the number of contract suppliers selected will meet beneficiary demand, CMS conducts a secondary analysis to determine if additional contract suppliers should be awarded contracts. Part of this analysis examines if bidding entities awarded contracts need (and are planning) to expand operations and need time to ramp up to meet projected beneficiary demand. To do so, CMS analyzes the most recent 12 months of claims data that was not available when we first conducted this analysis for all contract suppliers that should be awarded contracts under the initial analysis. Using this data allows CMS to account for any unforeseen increases in utilization as almost a year has passed since the original calculation of the projected beneficiary demand. This secondary analysis further scrutinizes bidders' capacity to confirm that they are capable of furnishing items at levels exceeding their historical capacity in the competition prior to calculating the final SPAs. Beginning with Round 2021,

bidders were no longer required to submit expansion plans as part of this process in accordance with the calendar year 2019 final rule titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS" and published in the **Federal Register** on November 14, 2018 (83 FR 56922). This is performed by separating bidders into three groups that factor in each bidder's financial health, experience furnishing the lead item, and ramp-up revenue percentage.⁷⁸ Expansion plans were required in rounds prior to Round 2021 for suppliers that were new to an area, new to a product category, or submitted an estimated capacity that represented substantial growth over current levels.

Group 1:

- Meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; and

- Has experience furnishing the lead item in the CBA; and

- Has sufficient ramp-up revenue.

CMS accepts the higher of the estimated or historical capacity for Group 1 bidders.

Group 2:

- Meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; and

- Does not have experience furnishing the lead item in the CBA, but has experience furnishing the lead item in other CBAs for which the bidder has submitted a bid; and

- Has sufficient ramp-up revenue.

CMS uses an experience factor to determine the capacity for Group 2 bidders by dividing the CBAs in which a bid was submitted where the bidder has experience furnishing the lead item by the total CBAs in which a bid was submitted for the lead item.

⁷⁸ Ramp-up revenue is determined by multiplying a bidder's projected growth (that is, taking the bidder's estimated capacity minus its historical capacity) by the preliminary SPA for the lead item. To determine if a bidder has sufficient ramp-up revenue to support its estimated capacity, its ramp-up revenue is divided by the bidder's actual revenue to produce a percentage. The purpose of this process is to act as a safeguard to ensure bidders are not over-estimating their ability to expand.

Group 2 bidders will have their capacity adjusted by multiplying the bidder's estimated capacity, in each of the competitions where they do not have experience, by the experience factor. For example, if a bidder submitted 10 bids for enteral nutrition and only had experience in half of those competitions, the bidder would have its estimated capacity lowered by 50 percent for the competitions where it does not have experience.

Group 3:

- Does not meet the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; or

- Is a new supplier or a specialty supplier; or

- Does not have experience furnishing the lead item in any CBA for which the bidder has submitted a bid; or

- Does not have sufficient ramp-up revenue

CMS accepts the historical capacity for Group 3 bidders, which is zero for bidders with no experience furnishing the lead item.

As initially stated, it is important to note that this secondary analysis is only used as a method for offering additional contracts and will not remove any bidding entities from the initial winning array (that is, bidding entities whose bids were at or below the pivotal bid). That is, the pivotal bid amount set during the initial capacity analysis is never lowered, even if this secondary analysis determines that beneficiary demand can be met with fewer suppliers. As a result, this secondary analysis removes the 20 percent of projected beneficiary demand limit (explained in the second bullet in step 1 noted previously) because Step 1 already ensures that at least five contracts are awarded for each competition in accordance with § 414.414(h).

If the secondary analysis determines that no additional bidders are needed to meet beneficiary demand, the preliminary SPAs established under the initial analysis are set as the final SPAs for the competition as explained in the next section. However, if the secondary analysis determines that additional bidders are needed to meet beneficiary demand, CMS continues through the array (bidders that are eligible for a contract offer are arranged by lowest to highest lead item bid amount) until bidder capacity meets or exceeds beneficiary demand for the competition. Once CMS adds enough bidders to where the cumulative accepted capacity of the bidders selected in the array meets beneficiary demand, the pivotal

bid is increased accordingly, and the resulting SPAs are set as the final SPAs for the competition.

As established in at 42 CFR 414.416(b)(1) the SPA for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. Once the pivotal bid is determined and the selection of winning contract suppliers is finalized, the SPAs are calculated based on the maximum submitted bid amount of contract suppliers in the winning array.

In order to ensure that small suppliers, meaning a supplier generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue, have an opportunity to be considered for participation under the CBP in accordance with section 1847(b)(6)(D) of the Act, the special rules at § 414.414(g) establish a goal of awarding at least 30 percent of the total number of contracts to small suppliers. CMS then determines which percentage of bidders in the winning array of bids are small suppliers. If less than 30 percent, CMS will offer a contract to the next eligible small supplier(s) until the 30 percent small supplier target is reached or there are no more eligible small suppliers for the competition. Additional contracts may be awarded when a bid disqualification is overturned. Additional contracts may also be awarded if needed to meet demand when a contract offer is declined. Finally, in accordance with § 414.414(i), additional contracts may be awarded after CMS initially awards contracts, if necessary, to meet demand.

d. Problems Associated With Awarding More Contracts Than Needed To Meet Demand for Items and Services

The current process for calculating total supplier capacity in accordance with 42 CFR 414.414(e)(2), which is calculated based upon the supplier's estimated capacity levels once awarded a contract, and for projecting beneficiary demand in accordance with 42 CFR 414.414(e)(1), which, as described previously is inflated above historic levels even in situations where the Medicare fee-for-service beneficiary population is declining in the CBA, results in the awarding of significantly more contracts than needed to meet actual demand for items and services in the CBA. Although access to multiple suppliers is mandated by section 1847(b)(2)(A)(iv) of the Act, awarding an excess number of contracts can reduce

the competitiveness of the program, which results in higher payment amounts—hurting potential savings. Large suppliers especially have limited to no incentive to submit competitive bids in such an environment (where excessive numbers of contracts are awarded). To highlight this issue, take for example if there were only two or three very large national chain suppliers that were all awarded contracts in most of the CBAs from 2011 through 2018, it is possible that any one of these suppliers alone would have been able to meet most of the actual demand for the particular item or service in many of the CBAs. For example, if two chain suppliers become contract suppliers for a competition round after round regardless of what bid amount they submit, they would learn that they could submit a bid amount that is higher than they would be willing to accept and still be added as a contract supplier for the competition, which in turn would have a negative impact on savings under the competition. We observed this issue in the Round 2 Recompete (2016). We found that on average, 13 contracts were awarded per competition, but typically 4 contract suppliers were sufficient to meet the beneficiary demand in the CBA for the lead item in the product category. In general, 4 of the selected contract suppliers had no utilization and 5 of the contract suppliers had low utilization (that is, furnishing items and services to less than 5 percent of the applicable beneficiary population). Most DMEPOS product categories have historically been dominated by a few large national chain suppliers, and we have seen a downward trend in the total number of suppliers and more concentration among the large suppliers in terms of volume and market share. From 2022 to 2024, the number of medical supply companies enrolled as DMEPOS suppliers decreased by 7 percent from 6,438 to 5,973. Over this same 2-year period, Medicare Part B enrollment also decreased by 5 percent from 35.3 million to 33.4 million, while the number of allowed services attributed to enrolled DMEPOS suppliers grew from 1.97 billion to 2.11 billion. While savings were generally favorable under this approach, this evidence indicates that future competitions would have been increasingly strained to recompile items and services.

2. Current Issues

The lead item pricing and maximum winning bid amount SPA methodologies were implemented under Round 2021 of the DMEPOS CBP (refer to table 37 for an explanation of the CBP rounds). CMS

competed 16 product categories in 130 CBAs in Round 2021, although the product category for non-invasive ventilators was removed in April 2020 following the exercise of the Defense Production Act due to the coronavirus disease 2019 (COVID-19) PHE. Of the remaining 15 product categories, 13 were included in previous rounds of the CBP, while OTS back and knee braces were competed for the first time. Within the 130 CBAs, there were over 2,000 competitions and CMS received and reviewed over 49,000 bids. The Round 2021 contracts went into effect in 127 CBAs for the OTS back braces and OTS knee braces product categories, resulting in estimated Medicare savings of \$934 million. Pursuant to 42 CFR 414.414(f), CMS announced that it would not award competitive bidding contracts for 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings.⁷⁹

The competitions for contracts in Round 2021 were largely unsuccessful in achieving savings because the methodology for calculating SPAs was changed from the median of winning bid amounts used in previous rounds to the maximum winning bid amount, but CMS made no changes to how the number of contracts awarded in a competition is calculated. As discussed, the current process for selecting the number of contracts to award results in significantly more contracts than needed to meet actual demand for items and services in the CBA and this process has resulted in higher payment amounts than the payment amounts that would have been established if the number of contracts was limited to the number needed to meet actual demand for items and services in the CBA. By calculating SPAs based on the maximum bid amount submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category, CMS began setting payments based on the highest of the bid amounts from suppliers not needed to meet the demand for items and services in the CBA. In addition, these maximum winning bid amounts were often an outlier price (a bid amount from a single bidding entity that is significantly higher than the bid amounts from other bidding entities). Consequently, adjusting the methodology for setting the SPA without adjusting the number of contracts awarded eliminated the

⁷⁹ <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Round-2021>.

ability of the program to achieve savings because the SPAs that would have been used to pay contract suppliers would have resulted in total payments to contract suppliers that greatly exceeded the total amounts that would otherwise be paid. When the maximum winning bid amount is used to establish the SPA	rather than a bid amount from lower in the winning array of bidders, it is more likely that an outlier bid amount will be selected as the SPA, which is problematic. Table 38 shows the actual bid amounts submitted for a Round 2021 competition (the competition is not	identified to protect the confidentiality of the bidding entities). The bid amounts are for the bidding entities that would have been awarded contracts based on the current methodologies for projecting demand and determining supplier capacity for meeting demand. BILLING CODE 4120-01-P
---	--	---

TABLE 38: BID AMOUNTS FOR BIDDING ENTITIES IN “WINNING RANGE” FOR SAMPLE ROUND 2021 COMPETITION

No. in Array	Bid Amount	Note
36	\$189.00	Maximum winning bid amount
35	\$150.00	
34	\$135.00	
33	\$131.66	
32	\$124.00	
31	\$120.00	
30	\$120.00	
29	\$114.95	
28	\$110.00	
27	\$105.00	
26	\$99.88	
25	\$99.00	
24	\$98.00	
23	\$97.97	
22	\$94.64	
21	\$89.95	
20	\$89.00	
19	\$83.78	
18	\$81.75	Median – \$82.76
17	\$78.90	
16	\$77.64	
15	\$77.62	
14	\$72.07	\$74.25 = 2021 Amount Otherwise Paid
13	\$69.50	
12	\$68.00	
11	\$65.52	
10	\$65.00	
9	\$62.99	
8	\$62.37	
7	\$62.00	
6	\$61.88	
5	\$60.00	
4	\$60.00	
3	\$59.90	
2	\$53.29	
1	\$41.00	

BILLING CODE 4120-01-C

Pursuant to 42 CFR 414.414(f), contracts were not awarded for this product category and CBA because the total payments that would have been

made to contract suppliers based on the maximum winning bid amount of \$189.00 would have greatly exceeded the payment amounts that would have otherwise been made at \$74.25, the

adjusted fee schedule amounts calculated in accordance with 42 CFR 414.210(g)(10) using bid amounts from previous rounds of competition. This table shows the impact of outlier pricing

on the SPA that results when using the maximum winning bid method. The maximum winning bid of \$189 is \$39 and 26 percent higher than the next highest bid of \$150. This real-life scenario demonstrates that just adding one additional bidding entity has a significant impact on the amount that all the contract suppliers would be paid, particularly when their bids do not include capacity numbers above their historical norms. In contrast, the median of winning bids is right in the middle of the array of bids and is not affected greatly by the outlier bid of \$189. Removing the bidding entity with the \$189 bid from the array only decreases the median by one dollar from \$82.76 to \$81.75. In this specific example, had the number of contracts awarded been limited to 14 rather than 36, then the payment amount would have been lower than the amount that would otherwise have been paid and contracts could have been awarded (assuming no other proposals in this rule were otherwise adopted and only the median bid methodology was in effect). Of the 36 bidding entities in this example, 9 were new bidding entities and the policy for new bidding entities is to count their capacity as zero, meaning they were not needed to meet demand. An additional 13 bidding entities did not indicate that they could expand their capacity beyond historic levels if awarded a contract. Removing 22 bidding entities from the list of winning range suppliers (the nine new bidding entities and the 13 bidding entities that indicated they could not expand their capacity) coincidentally leaves 14 bidding entities in the winning range. In order to have successful competitions in the future, the number of contracts awarded and the methodology used to establish the payment amounts made to the contract suppliers must result in total payments to contract suppliers that do not exceed the amounts that would otherwise be paid, after also factoring in the impact of the CBP in reducing fraud, waste, and abuse as discussed in greater detail in section VII.D., titled "Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected."

The goal in this proposed rule is to find the right mix in terms of the number of contracts awarded and how to establish the SPAs using the bid amounts so that contracts are awarded to multiple suppliers but no more than needed to meet beneficiary demand for items and services, and to ensure the DMEPOS CBP will generate total payments to contract suppliers that are less than the total amounts that would otherwise be paid under the standard

payment rules under sections 1834(a)(2) through (7), 1834(h), 1834(z), and 1842(s). As noted previously, CMS must be cognizant of how the SPA methodology and methodology to select the number of awarded contracts can impact whether total payments to contract suppliers that are less than the total amounts that would otherwise be paid under these standard payment rules.

As explained in more detail later in this section, we believe certain changes to how CMS determines the number of awarded contracts and changes to the SPA methodology can increase the likelihood that the DMEPOS CBP program will generate savings. Regarding changes to how CMS determines the number of awarded contracts, we believe data on actual contract supplier capacity from previous rounds of the DMEPOS CBP should be used in lieu of self-reported supplier capacity estimates CMS uses, in accordance with 42 CFR 414.414(e)(2), to determine the number of contracts needed to meet demand for items and services in a CBA.

Three options for determining SPAs are discussed later in this section and address how the number of contract suppliers would need to be limited in order to achieve savings at the median bid level if bid amounts higher than the median bid amounts are used to establish the SPA. These options include using the median of winning bid amounts, using the maximum winning bid amount but limiting the number of contract suppliers so that the maximum winning bid amount is approximately equal to the median of winning bid amounts, or using the 75th percentile of winning bid amounts but limiting the number of contract suppliers so that a maximum winning bid amount is approximately equal to the median of winning bid amounts. In addition to the change described previously, we evaluate how complementary changes to the methodology for calculating number of awarded contracts may or may not affect the competitiveness of the program. One option is to use the median of winning bids (median bid option). The second option is to continue using the maximum winning bid (maximum bid option) and limit the number of contracts awarded so that the maximum winning bid is approximately equal to where the median of winning bids would be under the median bid option. The third option, which we believe is the best approach, is to establish SPAs based on the 75th percentile of winning bids (75th percentile option) and limit the number of contracts awarded so that

the 75th percentile of winning bids is approximately equal to where the median of winning bids would be under the median bid option. Using the 75th percentile approach pays more contract suppliers above their bid amount than below their bid amount, which was a criticism of the median bid option, and is less susceptible to outlier pricing than the maximum bid option.

Conceptually, where the SPA is based on the maximum winning bid rather than the median of winning bids, many contract suppliers are paid using a SPA that is significantly higher than the bid amount they submitted, therefore providing more money for them to furnish additional items and services (that is, to increase their capacity) and resulting in the need for fewer contract suppliers.

Round 2021 was not successful for the 13 product categories included under the CBP from 2011 through 2018 with SPAs calculated based on the median of winning bids in those previous competitions. CMS did not change the methodology for determining the number of contracts to award, continuing the practice of awarding more contracts than needed to meet demand, even though the bid amount used for calculating SPAs was changed from the median of winning bids to the maximum winning bid. If, in addition to adjusting the SPA methodology, CMS had revised the methodology for determining the number of contracts to award so that less contracts were awarded, it would have been more likely that the maximum winning bid amounts would have been closer to the median of winning bid amounts in prior rounds. This is important because the fee schedule amounts for items included in prior competitions had already been adjusted in accordance with section 1834(a)(1)(F) of the Act based on the SPAs calculated using the median of winning bids, becoming the payment amounts that would otherwise be paid in the absence of implementation of the DMEPOS CBP. Under the requirements for awarding contracts under section 1847(b)(2)(A)(iii) of the Act, total payments to contract suppliers based on SPAs must not be expected to exceed the total amount that would otherwise be paid. Contracts could not be awarded under Round 2021 if the SPAs based on the maximum winning bids were significantly higher than the SPAs previously established for the items and services based on the median of winning bids, as this would have resulted in total payments to contract suppliers being greater than the adjusted fee schedule amounts that would

otherwise be paid. As explained later in this section, this problem was further compounded by bidding entities submitting lower capacity estimates than in previous rounds of competition, with very few bidding entities providing estimates that they could increase their volume of business and market share if awarded a contract.

Prior to the opening of the bid window for Round 2021, CMS published a “Capacity and Demand” Fact Sheet to increase transparency regarding the DMEPOS CBP by explaining the methodology that CMS would utilize to calculate projected beneficiary demand for Round 2021, as well as how CMS would determine a bidder’s capacity to meet projected demand. CMS also provided increased transparency by publishing a “Financial Scoring Methodology” Fact Sheet that explained how bidding entities would be evaluated to determine if they met the financial standards mandated by section 1847(b)(2)(A)(ii) of the Act. After receiving this detailed information, some industry consultants created and distributed information encouraging bidding entities to submit very low estimates of their capacity to furnish items if awarded a contract in order to significantly overinflate the total number of contracts awarded and drive up the maximum winning bids and SPAs. For example, when bidding to become contract suppliers for oxygen and oxygen equipment, 56 percent of the bidding entities “estimated” they could furnish less than one percent of the projected first year demand target and 1,496 out of 3,192 (47 percent) bidding entities submitting oxygen bids in Round 2021 “estimated” that they would not be able to provide one additional oxygen concentrator a month beyond what they have historically furnished. Also, 261 out of 3,192 (8 percent) bidding entities submitted an estimated capacity of one concentrator a month. This is the lowest possible capacity number a bidding entity could provide as their estimated capacity because the DMEPOS Bidding System would not allow an estimated capacity entry of zero.

After the Round 2021 bid evaluation processes concluded, we estimated that if payments had been made using SPAs based on the maximum winning bids, this would have resulted in an increase of \$1.2 billion in total payments to contract suppliers above the total amounts that would otherwise have been made over the 3-year contract performance period for Round 2021. As a result, CMS was prohibited from awarding contracts, per section 1847(b)(2)(A)(iii) of the Act, in all

product categories except OTS back braces and OTS knee braces, which saved an estimated \$934 million. The OTS back braces and OTS knee braces product categories were new, and payment using the SPAs based on maximum winning bid amounts did result in lower payments to contract suppliers than would otherwise be made in most of the 130 CBAs. We found as a result of this effort that the practice of providing very low-capacity estimates as part of the bid in order to increase SPAs affects the calculation of the SPA regardless of whether the SPA is based on the maximum winning bid amount or the median of winning bid amounts, but the effect is much more pronounced and subject to outlier bids when the SPA is based on the maximum winning bid. A median is calculated using all bids (low and high), whereas the maximum winning bid is based on one bid amount (the highest) and can change dramatically from one bidding entity to the next as shown in table 38.

Very low bidding entity-reported estimates of their capacity for furnishing items would have resulted in the award of more contracts than needed to meet demand. The combination of the awarding of more contracts than needed to meet demand and the change in determining SPAs to use of the maximum winning bid in Round 2021 resulted in an inability to award contracts for almost all items and services because total payments to contract suppliers would have greatly exceeded payments that would have otherwise been made. It is therefore important to establish a more accurate methodology for determining the number of contract suppliers needed to incentivize competitive bids and meet projected demand for items and services, and to select a methodology for determining SPAs that does not result in situations where total payments to contract suppliers would exceed payments that would otherwise be made. Furthermore, CMS does not have a mechanism to address situations where bidding entities submit capacity estimates that do not accurately reflect their ability to increase their volume of business if awarded a contract. As seen in the bids for Round 2021, this resulted in capacity estimates that were arbitrary and would have resulted in an increase in the number of contracts awarded and thereby drive up the prices paid under the program. In order for pricing to be competitive, especially as markets consolidate and small suppliers may not be expanding their businesses, the number of contracts awarded has to be limited to the degree that large suppliers

face the risk of not being awarded a contract, thereby creating an incentive to bid more competitively. Only a small number of bidders were excluded in past rounds of competition, greatly reducing the incentive for suppliers to bid competitively. Thus, we believe the methodology for determining the number of contracts to award for future rounds of the DMEPOS CBP cannot rely on self-reported capacity estimates from bidding entities as this methodology is not effective in limiting the number of contracts awarded to the number needed to meet projected demand for items and services in accordance with section 1847(b)(4)(A) of the Act.

In order to successfully recomplete contracts for product categories previously bid under the methodology that established SPAs based on the median of winning bid amounts in accordance with section 1847(b)(2)(A)(iii) of the Act, there must be an expectation that total payments to contract suppliers will be less than the total amounts that would otherwise be paid. We have explored and summarized three options, which have been informed by simulations we conducted using bid and contracting information from previous rounds of the DMEPOS CBP. We explain additional details about these simulations in a later discussion.

The first possible option of accomplishing this is to implement the methodology for determining SPAs used under competitions prior to Round 2021 that established SPAs based on the median of winning bid amounts, and award the same number of contracts awarded under those pre-Round 2021 competitions, adjusted based on the percentage change in Medicare Part B enrollment in the CBAs. We refer to this as the “median bid” option.

A second option would be to maintain the current methodology that establishes SPAs based on the maximum winning bid amount. Based on our analysis of past bidding rounds, we believe that to meet the requirements of section 1847(b)(2)(A)(iii) of the Act and maintain the current methodology for determining SPAs based on maximum winning bid amounts, we would need to better ensure that the maximum winning bid amount is closer to the median winning bid amount that would be selected under the first option. We believe this could be achieved by reducing the number of contracts awarded under future competitions by approximately 50 percent below the number of contracts awarded in past bidding rounds. This would reduce the likelihood of basing the SPA on an outlier bid amount and could increase

the likelihood that the SPAs established under this option would be roughly equivalent to the SPAs that would be established under the median bid option. We refer to this as the “maximum bid” option.

A third option would be to implement a methodology that uses the 75th percentile of winning bid amounts to establish a SPA, which is halfway between the median or 50th percentile of winning bid amounts and the maximum winning bid amount or 100th percentile of winning bid amounts. Similar to the process discussed for the second option, based on our analysis of past bidding rounds, we believe that to meet the requirements of section 1847(b)(2)(A)(iii) of the Act we would need to implement a process to better ensure that the selected bid amount is not influenced by outlier bid amounts and remains closer in value to the amount that would be selected under option one. We believe this could be

achieved by reducing the number of contracts awarded under future competitions by approximately 25 percent below the number of contracts awarded in past bidding rounds. This would reduce the likelihood of basing the SPA on an outlier bid amount and better increase the likelihood that the SPAs established under this option would be roughly equivalent to the SPAs that would be established under the median bid option. We refer to this as the “75th percentile” option.

Reducing the number of contracts awarded in proportion to the position in the array of winning contract suppliers used to establish the SPA is necessary in order to comply with the requirements of the statute. Section 1847(b)(3)(B) of the Act requires that contracts be recompeted not less often than once every 3 years, while section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under these competitions unless the total amounts to

be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. Establishing SPAs using bid amounts from suppliers higher in the array of winning contract suppliers than the median of bid amounts increases the chances that the SPA will be based on an outlier price (a bid amount that is significantly higher than other bid amounts for contract suppliers in the winning array), and therefore increases the chances that the competitions will not be successful in generating payments that are less than the amounts that would otherwise be paid for the items and services. These risks must be considered to implement future competitions under the DMEPOS CBP that are successful in generating program savings for competitively priced DMEPOS items and services. Table 39 lists the three options discussed previously and the tradeoffs associated with each option.

TABLE 39: THREE OPTIONS FOR DETERMINING SPAS

SPA	Tradeoffs
Median Bid	• Highest number of winners and choice of contract suppliers and lowest risk of outlier prices • Approximately half of winning contract suppliers with bid amounts below SPA
75 th Percentile	• Lower number of winners and greater risk of outlier prices than median bid option • More contract suppliers paid at or above their bid amount than median bid option
Maximum Bid	• Lowest number of winners and greatest risk of outlier prices • All contract suppliers paid at or above their bid amount

The median bid option offers the highest number of contracts for suppliers, and, therefore, the greatest degree of choice for beneficiaries. Even though this option results in payment amounts that are higher than the bid amounts for approximately half of the suppliers in the winning array of bidding entities, much criticism has been provided by DMEPOS suppliers, manufacturers, and certain economists about the fact that this option results in payment amounts that are lower than the bid amounts for approximately half of the suppliers in the winning array of bidding entities. Despite that criticism suppliers accepted the contracts at the median SPA rates 92 percent of the time and as noted previously, beneficiary access was not compromised, suppliers in non-CBAs adjusted to using these rates, assignment rates remained high, and beneficiary health outcomes remained stable. Nevertheless, as noted previously, we were seeing some pressures in downward trends in regard to suppliers’ willingness to expand capacity, indicating that the current

structure might not have been sustainable for the long term.

The maximum bid option, which would base SPAs on the maximum winning bid amounts coupled with an approximate 50 percent reduction in the number of contracts awarded below past bidding rounds, offers the lowest number of contracts for suppliers, and, therefore, the smallest degree of choice for beneficiaries. While this option results in payment amounts that are equal to or higher than the bid amounts for all of the suppliers in the winning array of bidding entities, even with a reduction in the number of contract suppliers, it also presents the highest risk of establishing a SPA based on an outlier bid, resulting in a SPA that might not meet the statutory requirement for total payments to contract suppliers that are lower than the total amounts that would otherwise be made for the items and services in the CBA. We observed this in Round 2021. We believe the risk of additional unsuccessful competitions using this option is too great.

The 75th percentile option uses the bid amount in the array of winning bid

amounts that is halfway between the median of the winning bid amounts (50th percentile) and maximum winning bid amount (100th percentile) to establish the SPA, and, therefore, serves a “middle ground” option. This option would be coupled with an approximate 25 percent reduction in the number of contracts awarded below past bidding rounds. It therefore results in more contracts and less risk of outlier prices than the maximum winning bid option, but fewer contracts and more risk of outlier prices than the median bid option. It is also an option that has never been attempted under the DMEPOS CBP. This option partly addresses the criticism provided by DMEPOS suppliers, manufacturers, and certain economists about paying contract suppliers less than their bid amount. However, as noted previously, the fact that 92 percent of suppliers accepted contracts at the median bid rates, and these amounts were proven to be adequate for items and services to be furnished with no negative impact on health outcomes, indicates that this criticism may be unfounded. While

there is still a greater risk of outlier prices associated with this option than the median bid option, we believe this option would result in successful competitions, and we are soliciting comments on a proposal that this methodology replace the current maximum bid methodology in the regulations for calculating the SPAs for items and services under the CBP. In order for this option to enable the DMEPOS CBP to meet its statutory objectives, the number of contracts awarded must be reduced by approximately 25 percent from the current methodology so that total payments to contract suppliers based on SPAs equal to the 75th percentile of winning bid amounts are no greater than total payments to contract suppliers based on SPAs equal to the median (or 50th percentile) of winning bid amounts. We continue to maintain that, “One of the purposes of the program is to create a competitive bidding payment structure that is more reflective of a competitive market” (72 FR 18036).

We analyzed the performance of contract suppliers under the previous Round 2 Recompete and Round 1 2017 competitions and identified the number of contract suppliers in each competition that provided at least 5 percent of total contract supplier utilization during these rounds of competition. We believe these numbers represent the number of contract suppliers that made a meaningful contribution toward meeting demand for the items and services in each competition. Under the previous Round 2 Recompete and Round 1 2017 competitions, on average, only 28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished by contract suppliers in each competition. This indicates that the vast majority of contracts awarded under these previous rounds were not necessary to ensure access and that there is sufficient experience and rationale for reducing the number of contracts offered under the DMEPOS CBP to determine a competitive price while maintaining access as mandated by section 1847(b)(4)(A) of the Act.

If under future competitions, the number of contracts awarded for each

competition was limited to the number of contract suppliers that furnished at least 5 percent of the total number of items and services for the competition, this would reduce the number of contract suppliers in the winning array and increase the likelihood that total payments to contract suppliers under future rounds of competition would be lower than the amounts that would otherwise be paid. If we continue awarding the same number of contracts as in past rounds of competition and use the 75th percentile of winning bid amounts rather than the 50th percentile (median) of winning bid amounts to establish the SPAs, the SPAs would be prohibitively higher than they would otherwise be if we had used the median of winning bid amounts to establish SPAs. To counter this, we can reduce the number of contracts awarded so that the 75th percentile of winning bid amounts are more closely aligned to where the median of winning bid amounts would have fallen. Using the competition example under table 38, the 75th percentile of the 36 bid amounts is \$105.00, which is much higher than the median of winning bid amounts of \$82.76. Under this competition, if the number of suppliers in the winning array is reduced by 25 percent from 36 to 27, the 75th percentile of the 27 bid amount amounts is \$89.95, which is only 9 percent higher than the median of winning bid amounts of \$82.76. However, there is no way to know for sure if the contract suppliers in the winning array under future competitions with this type of cap on the number of contracts awarded would have the capacity to furnish all of the items and services needed in the competition. Although larger suppliers should have economies of scale that would allow them to bid lower than smaller suppliers, it is possible that all large suppliers could be outbid by small suppliers that collectively do not have the capacity to meet demand for the items and service covered under their contracts. We are therefore soliciting comments on a proposal to increase the number of contracts awarded to double the number of contract suppliers that previously furnished at least 5 percent of the items and services needed in the competition. This would mitigate the

risk of awarding too few contracts such that the total supplier capacity would not be sufficient to meet the expected beneficiary demand, but would also increase the risk of awarding too many contracts, resulting in situations where total payments to contract suppliers at the 75th percentile of winning bid amounts could be greater than the payments that would otherwise be made based on fee schedule amounts adjusted using information from past rounds of the CBP where SPAs were established based on the median (or 50th percentile) of winning bid amounts rather than the 75th percentile of winning bid amounts.

CMS contracted with the Research Triangle Institute (RTI) to evaluate how the changes in Round 2021 impacted the DMEPOS CBP, and to consider ways in which the DMEPOS CBP can address the issues that occurred in Round 2021. RTI conducted a simulation of the 75th percentile option using bid and contracting information from previous rounds of the DMEPOS CBP. Specifically, RTI used the number of Round 2 Recompete and Round 1 2017 contracts in each of these successful competitions, as well as Round 2 Recompete and Round 1 2017 contract supplier utilization, to determine the number of contract suppliers that furnished at least 5 percent of total contract supplier utilization under each under these previous rounds. These numbers were then doubled to generate the target number of suppliers to include in the winning array in each competition under the simulation. The SPAs for the lead item in each competition were calculated based on the 75th percentile of bid amounts for suppliers in the winning array. If the 75th percentile fell directly on one of the suppliers in the winning array, that bidding entity's bid amount became the SPA for the competition under the simulation. Table 40 provides an example of this calculation. If the 75th percentile fell between 2 bidding entities (that is, there was an odd number of bids in the winning array), the SPA was determined using the amount that is 75 percent between the two bid amounts, rounded to the nearest cent. An example of this calculation is provided in Table 41.

TABLE 40: EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING ON ONE SUPPLIER

Winning Contract Suppliers	Bid Amount
1	\$4.00
2	\$5.00
3	\$5.25
4	\$5.50
5	\$6.00
6	\$6.50
7	\$7.00
8	\$7.50

The 75th percentile falls directly on the sixth winning supplier (8 × 75 percent = 6), resulting in the SPA of \$6.50.

TABLE 41 EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING BETWEEN TWO SUPPLIERS

Winning Contract Suppliers	Bid Amount
1	\$4.00
2	\$5.00
3	\$5.25
4	\$5.50
5	\$6.00
6	\$6.50
7	\$7.00
8	\$7.50
9	\$8.00

The 75th percentile falls between the 6th and 7th winning supplier with bid amounts of \$6.50 and \$7.00, respectively. The SPA is calculated using the amount that is 75 percent of the way between \$6.50 and \$7.00, rounded to the nearest cent, which is \$6.88 ($[(\$7.00 - \$6.50) \times 75 \text{ percent}] + \$6.50$).

After the SPAs were calculated, additional contracts were added for small suppliers, if necessary, to meet the 30 percent small supplier target in each competition.

The last step of the simulation involved a review of the utilization for the suppliers that would be awarded contracts in each competition under the simulation to determine if their combined historic capacity totaled at least 5 percent of the overall utilization for the lead item in the competition. If the suppliers that would be awarded contracts did not collectively provide at least 5 percent of the overall utilization for the lead item in the competition, one additional bidding entity that met all eligibility requirements as stated in the request for bids for the competition and furnished at least 5 percent of the overall utilization in the competition for

the lead item, was awarded, if available. If bidding entities met these criteria, the bidding entity with the lowest bid amount was awarded a contract under the simulation.

The resulting SPAs and total number of contracts awarded under the simulation were then compared to the SPAs and total number of contracts awarded under the previous Round 2 Recompete and Round 1 2017 competitions. In 91 percent of the simulated competitions (1,539 of 1,690), both the SPAs and number of contracts awarded were lower than the SPAs and number of contracts awarded under Round 2 Recompete and Round 1 2017. Of the remaining 151 simulated competitions, 10 competitions resulted in the same number of contracts being awarded under Round 2 Recompete and Round 1 2017 competitions, while three competitions resulted in more contracts being awarded. Additionally, of the 151 simulated competitions, 105 competitions had higher SPAs than the Round 2 Recompete and Round 1 2017 competitions, while 41 competitions had SPAs that were the same as the Round 2 Recompete and Round 1 2017 competitions. Please note that there is

overlap in how the simulation data for the remaining 151 competitions is presented. For example, a simulated competition that resulted in more contracts and a higher SPA compared to a Round 2 Recompete and Round 1 2017 competition could be counted in both the contract and SPA data mentioned previously.

In order to ensure beneficiary access to items and services under the simulation, a floor on the total number of contracts awarded was established, so that the number of contracts awarded under the simulation would be no less than 50 percent of the number of contracts awarded under the previous rounds, rounded up to the nearest whole number. Also, in order to ensure savings under the simulation, a ceiling on the total number of contracts awarded was established, so that the number of contracts awarded under the simulation would be no more than 75 percent of the number of contracts awarded under the previous rounds, rounded down to the nearest whole number. Note that modifications to the methodology for determining the number of contracts to award for product categories that have never been

included under the CBP, as well as the product categories for OTS back braces and OTS knee braces included in Round 2021, are discussed later in this section. The simulation was run again using the floor and ceiling, and the results were analyzed. The simulated SPAs were mostly lower than the SPAs under the previous Round 2 Recompete and Round 1 2017 competitions. For all

product categories and CBAs for both the Round 2 Recompete and Round 1 2017 competitions, the percentage reduction in the number of contracts awarded ranged from 33 percent for enteral nutrients, equipment, and supplies, to 41 percent for standard manual wheelchairs. In addition, the percentage reduction in SPAs ranged from 2.6 percent for hospital beds to

13.8 percent for group 2 support surfaces. To illustrate the results of the simulation, the simulation SPAs and number of contract suppliers is compared to the number of contracts and SPAs for Round 1 2017 for oxygen and oxygen equipment (lead item, HCPCS Level II code E1390) in Table 42.

TABLE 42: ROUND 2017 RESULTS COMPARED WITH SIMULATION RESULTS FOR OXYGEN AND OXYGEN EQUIPMENT (LEAD ITEM HCPCS LEVEL II CODE E1390)

CBA	2017 # of Contracts	2017 SPA	75 th # of Contracts	75 th SPA	Reduction in # of Contracts	Reduction in SPA
Charlotte-Concord-Gastonia, NC	21	\$79.00	14	\$72.33	33%	8%
Chester, Lancaster & York Counties, SC	15	\$70.04	11	\$70.00	27%	0%
Cincinnati, OH	21	\$79.00	12	\$76.21	43%	4%
Cleveland-Elyria, OH	25	\$78.00	16	\$77.42	36%	1%
Covington-Florence-Newport, KY	18	\$72.45	11	\$69.81	39%	4%
Dallas-Fort Worth-Arlington, TX	31	\$76.48	22	\$72.90	29%	5%
Dearborn, Franklin, Ohio & Union Counties, IN	15	\$74.92	9	\$70.09	40%	6%
Kansas City-Overland Park-Ottawa, KS	18	\$79.23	12	\$73.91	33%	7%
Kansas City, MO	19	\$78.53	13	\$73.91	32%	6%
Miami-Fort Lauderdale-West Palm Beach, FL	29	\$90.01	16	\$82.99	45%	8%
Orlando-Kissimmee-Sanford, FL	23	\$79.20	12	\$72.00	48%	9%
Pittsburgh, PA	28	\$77.50	20	\$70.71	29%	9%
Riverside-San Bernardino-Ontario, CA	21	\$79.22	13	\$70.77	38%	11%

Under the simulation, there was a 36 percent average reduction in the number of contracts awarded for oxygen and oxygen equipment in the Round 1 2017 CBAs under the simulation and a 6 percent average reduction in the SPAs. For comparison, the percentage of contract suppliers in each Round 2 Recompete and Round 1 2017 competition that furnished 5 percent or more of total contract supplier utilization was, on average, only 28 percent suggesting that the number of contracts awarded but not needed in a competition in the previous rounds was as high as 72 percent. Thus, we believe a reduction in the number of contracts awarded under the DMEPOS CBP of approximately 36 percent would not result in a shortage of contract suppliers.

We acknowledge the simulation uses supplier bids from past competitions and does not reflect how suppliers may

actually bid in future competitions. However, we believe the balance of achieving savings while ensuring access to items and services under the program would be preserved if these changes are implemented. The suppliers competing for contracts would know that only a limited number of contracts would be offered, and we believe this would increase the level of competition under the program in terms of lower bid amounts that also result in adequate payment for all contract suppliers, while also mitigating some of the concerns of the supplier community associated with using the median winning bid.

If the maximum bid option were used, the reduction in the number of contracts awarded would need to be even greater, such as no more than 50 percent of the number of contracts awarded in the previous rounds of competition. Using the maximum bid option would mean

fewer suppliers would be awarded contracts than under the other two options, providing less choice for beneficiaries and increasing the chances that the amount paid is an outlier price that is significantly higher than the bid amounts of other winning contract suppliers. Using the median bid option would minimize or eliminate the impact of outlier prices but would result in more contract suppliers being paid less than the amount they bid. We are not proposing either of these options, but we are soliciting comments on these two options in addition to the proposed 75th percentile option. A summary of how the number of contracts to award in the next competition for items included in Round 2 Recompete, Round 1 2017, and Round 2021 of the DMEPOS CBP would be determined under the three options is summarized in Table 43.

TABLE 43: THREE OPTIONS FOR DETERMINING SPAS AND NUMBER OF CONTRACTS TO AWARD FOR PRODUCT CATEGORIES AND CBAS INCLUDED IN ROUND 2 RECOMPETE, ROUND 1 2017, AND ROUND 2021 OF THE DMEPOS CBP

SPA	Number of Winning Contract Suppliers for Next Competition
Median Bid Alternative	The number of winning contract suppliers is equal to the total number of contract suppliers from the last successful competition (regardless of the quantity of items furnished by each contract supplier), adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces.
75 th Percentile Proposal	The number of winning contract suppliers is equal to double the number of Round 2 Recompete, Round 1 2017, or Round 2021 contract suppliers that furnished at least 5 percent of the total utilization for the lead item in the competition, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces. The total number of contracts awarded would be no less than 50 percent of the number of contracts in Round 2 Recompete, Round 1 2017, or Round 2021 rounded up to the nearest whole number and no more than 75 percent of the number of contracts in Round 2 Recompete, Round 1 2017, or Round 2021 rounded down to the nearest whole number.
Maximum Bid Alternative	The number of winning contract suppliers is equal to 50 percent of the total number of contract suppliers in Round 2 Recompete, Round 1 2017, or Round 2021 (regardless of quantity of items furnished by each contract supplier), adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces.

As an example of how this would work for the 75th Percentile Proposal, in 2018, CMS had 29 contract suppliers to furnish continuous positive airway pressure (CPAP) items in the Miami, FL competitive bidding area, but only 9 contract suppliers furnished at least 5 percent of the total utilization for CPAP in the Miami, FL CBA. If Part B enrollment for the area has decreased by 5 percent since 2018, the CMS would do the following:

- Double the number of contract suppliers in 2018:
 $9 \times 2 = 18$
- Adjust the result by the 5 percent decrease in Part B enrollment since 2018:
 $18 \times 0.95 = 17.1$ rounded to the nearest whole number, 17.
- Determine the fewest number of contracts to award:
 $29 \times 0.50 = 14.5$ rounded up to the nearest whole number, 15.
- Determine the highest number of contracts to award:
 $29 \times 0.75 = 21.75$ rounded down to the nearest whole number, 21.
- Compare the result in Step 2 to the fewest and highest number of contracts and adjust up or down, if necessary:
 No change needed as 17 is greater than 15 and less than 21.

Result: CMS would award 17 contracts for CPAP in the Miami, FL CBA.

In addition, as explained earlier, we are not proposing any changes to the method of using the lead item to establish pricing under current regulations at 42 CFR 414.416, but are proposing to change the methodology used for determining SPAs for lead

items under § 414.416(b)(1) to replace “maximum bid” with “75th percentile of bids”.

We are also soliciting comments on our proposal to change the way the SPAs are calculated for the non-lead items in a product category. Currently, to calculate the non-lead item, CMS multiplies the lead item SPA by a relative ratio, which is based on the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item. This formula uses average fee schedule amounts, which in some cases results in SPAs for non-lead items being higher than the fee schedule amount that would otherwise be paid because the 2015 fee schedule amounts for some areas are lower than the average of the 2015 fee schedule amounts for all areas. To address this situation for CBAs other than a nationwide or regional CBA, we are soliciting comments on a proposal to calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas. For example, in the Miami/CPAP competition, the lead item SPA for the CPAP product category will be multiplied by a relative ratio, which will be based on the 2015 fee schedule amount for the CPAP non-lead item in Miami divided by the 2015 fee schedule amount for the CPAP lead item in Miami. For nationwide or regional CBAs, we would still need to use the average of the fee schedule amounts since these CBAs would include

multiple areas with different fee schedule amounts.

For all three options, the number of winning contract suppliers for all subsequent competitions would be provided to bidders prior to bidding. For example, based on the Miami/CPAP 75th percentile option example noted previously, we would let bidding entities know that for the initial competition for these items last furnished by contract suppliers in 2018, a total of 17 contracts would be awarded for this competition. The SPA for the lead item would be based on the 75th percentile of the bids for the 17 lowest bidding entities for the CPAP product category in Miami. For subsequent rounds of competition, the number of contracts awarded would be based on the number of winning contract suppliers from the initial competition under the new rules (17 in this example), trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the last contract period. We are soliciting comments on a proposal to slightly modify versions of the methodology discussed previously for determining the number of contracts to award for product categories that have not previously been included under the DMEPOS CBP. For product categories or CBAs that were not included in Round 2 Recompete, Round 1 2017, or Round 2021 of the DMEPOS CBP, the proposed methodology for determining the number of winning contract suppliers in the next competition under the 75th percentile option, as well as the alternative options, are described in table 44.

TABLE 44: DETERMINING SPAS AND NUMBER OF CONTRACTS TO AWARD FOR NEW PRODUCT CATEGORIES AND CBAs PHASED IN TO THE DMEPOS CBP

SPA	Number of Winning Contract Suppliers for Next Competition
Median Bid Alternative	The number of winning contract suppliers is equal to 150 percent of the number of suppliers that furnished at least three percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.
75 th Percentile Proposal	The number of winning contract suppliers is equal to 125 percent of the number of suppliers that furnished at least three percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.
Maximum Bid Alternative	The number of winning contract suppliers is equal to the number of suppliers that furnished at least three percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.

The number of winners for the 75th percentile option would be 25 percent lower than the median option and 25 percent higher than the maximum option, which is in proportion to the percentage increase in the position in the winning array of bid amounts where the SPA would be set using the median option (50th percentile) and the percentage decrease in the position in the winning array of bid amounts where the SPA would be set using the maximum option (100th percentile). The number of winning contract suppliers for competitions following the initial competition under the new rules would be based on the number of winning contract suppliers from the initial competition under the new rules, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the last contract period. For new product categories and CBAs, we use 3 percent of total utilization for the lead item rather than 5 percent as the measure of a contract supplier that made a meaningful contribution toward meeting total demand for the lead item. We believe the measure of meaningful supplier performance should be different for product categories and areas that have never been included under the CBP because there is no limit on the number of suppliers that can furnish items and services; therefore, spreading out overall utilization of the items and services over more contract suppliers. As noted previously, under the previous Round 2 Recompete and Round 1 2017 competitions, on average, only 28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished by contract suppliers in each competition. For new product categories there is no limit on the number of suppliers furnishing items like there is under the DMEPOS CBP and therefore our claims data shows less concentration and a lower average volume of items furnished per

supplier. However, data indicates that generally, there have been the same dominant, local suppliers in the competitive bidding areas providing the majority of DMEPOS, even prior to the implementation of the DMEPOS CBP.

We can illustrate how we would determine the number of contracts to award for new product categories being phased into the DMEPOS CBP using 2023 Medicare claims data. If competitions were held today for a nationwide remote item delivery (RID) CBP as proposed under section F using the 75th percentile methodology, then based on 2023 Medicare claims data for the lead items for the examples of potential future product categories in Table 45 entitled “Categories of Items Furnished from Remote Supplier Locations”, we would award the following numbers of RID CBP contracts: seven for urological supplies; eight for ostomy supplies; nine for class II continuous glucose monitors (CGMs); nine for OTS upper extremity braces; nine for OTS back braces; and 10 for OTS knee braces. By comparison, 11 contracts were awarded for the Round 2 Recompete national mail order CBP for diabetes testing supplies. Five contract suppliers furnished at least 3 percent of total contract supplier utilization (allowed services) for diabetes testing supplies. These five suppliers accounted for 92 percent of total contract supplier utilization (allowed services) from July 1, 2016, through December 31, 2018.

There could be situations where CMS is not able to award enough contracts to meet the target number of contracts in a competition, if for example, the target number of contracts for the competition is 10, but only five entities submitted a bid. In these instances, CMS plans to move forward with awarding contracts to all eligible bidding entities in the competition, as long as there are at least 2 or more eligible bidding entities to award contracts to, and we do not otherwise have data indicating that the

bidding entities that would be awarded contracts would not be able to meet beneficiary demand. Once the competition is implemented, CMS will monitor for any potential access concerns, as it has done continually since 2011 (even during temporary gap periods in the DMEPOS CBP).

Finally, current regulations at 42 CFR 414.414(h) indicate that contracts are generally awarded to at least five suppliers satisfying the conditions for awarding contracts under § 414.414(b) through (f). As the program is implemented in additional areas throughout the United States, we believe that five contract suppliers would be excessive for some areas and product categories. Therefore, in addition to proposing to revise the regulations to include the methodologies described previously for determining the number of contract suppliers needed for each competition, we are proposing to indicate that this number can be no lower than 2 for any competition as the statute mandates multiple contract suppliers (at least 2), per section 1847(b)(4)(B) of the Act. We are soliciting comments on these proposals.

3. Provisions of the Proposed Regulation

In the previous section, we discussed three options to calculate the SPAs for items and services under the CBP (the current maximum bid methodology, the median bid methodology used in prior rounds of the CBP, and a 75th percentile methodology). Based on that discussion we are soliciting comments on our proposal to:

- Change the methodology used for determining SPAs for lead items under the program by revising § 414.416(b)(1) to replace “maximum bid” with “75th percentile of bids,” so that the SPA for the lead item in the product category would be based on the 75th percentile of bid amounts for the lead item that are equal to or below the pivotal bid for the product category.

- Revise § 414.416(b)(1) to indicate that in cases where there is an odd number of winning contract suppliers and the 75th percentile falls between 2 suppliers, the SPA for the lead item would be determined by going 75 percent of the way between the 2 bid amounts, rounded to the nearest cent.
- Change the way the SPAs are calculated for the non-lead items in a product category in CBAs other than a nationwide or regional CBA by revising § 414.416(b)(3). Specifically, the calculation would involve multiplying the lead item SPA by a relative ratio, which would be based on the 2015 fee schedule amount for the non-lead items in the applicable state divided by the 2015 fee schedule amounts for the lead item in the applicable state.
- Change the methodology for calculating the number of contract suppliers sufficient to furnish items and services in a competition by revising § 414.414(h). Specifically, for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services would be at least 2, but no more than double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023. The number of suppliers awarded contracts would not be less than 50 percent of the total number of contract suppliers in 2018 or 2023 rounded up to the nearest whole number, or more than 75 percent of the total number of contract suppliers in 2018 or 2023 rounded down to the nearest whole number. After the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services would be equal to the number of contract suppliers selected the first time a competition is recompeted after 2023, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent contract period.

For competitions not included in the DMEPOS CBP in 2018 or 2023, the first time a competition is conducted after 2023, the number of contract suppliers needed to furnish items and services would be at least 2, but no more than 125 percent of the number of contract suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA

during the most recent calendar year at the time of bidding. For all subsequent recompetes for the competition, the number of contract suppliers needed to furnish items and services would be equal to the number of contracts awarded the first time a competition is held after 2023, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent contract period.

In previous sections we proposed using contract supplier capacity data from previous rounds of the DMEPOS CBP, as opposed to using supplier-reported capacity, to determine the number of contract suppliers needed to meet demand for items and services in a CBA. Therefore, we are proposing to change the methodology for evaluating bids by revising § 414.414(e). Specifically, CMS is proposing to evaluate composite bids submitted for a lead item within a product category by: (1) calculating the number of contract suppliers selected to furnish the items and services in the competition based on the methodology described previously, (2) arraying the composite bids from the lowest composite bid price to the highest composite bid price and (3) selecting the number of contract suppliers and networks that were calculated in #1 that meet basic supplier eligibility, quality standards and accreditation, and financial standards. We are soliciting comments on this proposal.

C. Adjustments to SPAs

CMS recognizes the increased challenge a supplier may have to account for the potential future effects of price increases when formulating its bids. We are soliciting comments on our proposal to apply an annual update factor to SPAs as we believe it would give bidding entities more certainty and confidence in formulating their bids based on their costs at the time of bidding, and would help ensure beneficiary access in the event that costs do increase significantly during a contract performance period.

1. Background

The fee schedule amounts for DME, orthotics, and enteral nutrition are updated by annual update factors specified in sections 1834(a)(14), 1834(h)(4)(A), and 1842(s)(1)(B) of the Act, respectively. The payment amounts for lymphedema compression treatment items are updated on an annual basis in accordance with regulations at 42 CFR 414.1650(c). In general, the annual update factors are established based on the percentage change in the Consumer

Price Index for all Urban Consumers (CPI-U) calculated by the Bureau of Labor Statistics for the 12-month period ending with June of the previous year, although for certain years, the statute has mandated a “freeze” or zero percent update, or other percentage below the percentage change in the CPI-U, for DME, orthotics, and enteral nutrition. In addition, for 2011 and subsequent years, the update factors for DME, orthotics, and enteral nutrition are reduced by a productivity adjustment, which in some years can result in a negative percentage or reduction in the fee schedule amounts.

In the 2006 proposed rule (71 FR 25663), we proposed to apply an annual inflation update to the SPAs established for a CBP (proposed 42 CFR 414.408(b)). Specifically, beginning with the second year of a contract entered into under a CBP, we proposed to update the SPAs by the percentage increase in the CPI-U for the 12-month period ending with June of the preceding calendar year. We stated that using the CPI-U index would be consistent with Medicare using this index to update the DME fee schedule and would obviate the need for the bidding entity to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multiyear contract. We did not finalize the proposal to apply an annual inflation update to SPAs. In the 2007, final rule (72 FR 18005), we stated that we believe it is more appropriate for bidding entities to address the possible effects of inflation or price increases when they formulate their bids because automatic payment adjustments to competitively bid items may result in higher payment amounts than would occur under the DMEPOS fee schedule payment amounts if these amounts are subject to legislative freezes or payment reductions.

2. Current Issues

As a result of the COVID-19 PHE, supply chain disruptions, and recent years’ higher than normal inflation, we believe it would improve the CBP to add an annual inflation update to the SPAs as long as the updates are the same as the updates to the DMEPOS fee schedule amounts, which would prevent the SPAs from becoming higher than the fee schedule amounts during a contract period of 2 or 3 years in length. CMS has recognized the increased challenge a bidding entity may have to account for the potential future effects of price increases when formulating its bids. We believe that adding an annual update factor would address unforeseen changes and inflation as described previously, giving bidding entities more

certainty and confidence in formulating their bids based on their costs at the time of bidding. We believe this would reduce burden for bidding entities since they would no longer need to factor standard inflationary cost increases into their bid calculation. We also believe it would help to better ensure access to items and services under the program in the event that costs do increase significantly during the contract period.

3. Provisions of the Proposed Regulation

We are proposing to amend 42 CFR 414.408 by revising paragraph (b) and its title to adjust the SPAs for the second and third years of a DMEPOS CBP supplier contract performance period by an inflation update equal to the percentage change in the CPI-U for the 12-month period ending 6 months prior to the beginning of the respective second or third year of the DMEPOS CBP supplier contract performance period. We propose that in no case could the updated SPA for an area be greater than the unadjusted fee schedule amount for the state or area that includes the CBA where the SPA is applied or 110 percent of the adjusted fee schedule amount for state or area that includes the CBA where the SPA is applied. We are soliciting comments on this proposal.

D. Bid Limits and Conditions for Awarding Contracts if Savings Are Not Expected

Recognizing that the DMEPOS CBP generates additional savings for Medicare beyond reducing the payments amounts for DMEPOS items and services, we propose that in determining whether the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid, in accordance with section 1847(b)(2)(A)(iii) of the Act, that CMS would not award a contract under the DMEPOS CBP if CMS determines the total amount paid under the DMEPOS CBP would be greater than all payments that would otherwise be made—inclusive of payments made pursuant to improper billing and any other expenses paid under the DMEPOS fee schedules. Accompanying this proposal, we propose to modify under what circumstances CMS would not award a contract for a competition under 42 CFR 414.414(f) and modify the maximum bid amounts allowed for bids under 42 CFR 414.412.

We are soliciting comments on these proposals.

1. Background

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts to any entity unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid under the methodologies set forth in sections 1834 and 1842 of the Act. We emphasize that the language in the statute refers to “total amounts paid” and not to individual payment amounts. Other factors other than the specific dollar amount paid per item can impact the total amounts paid.

In the 2007 final rule (72 FR 18084) CMS implemented the DMEPOS CBP and established that bids submitted for each item in a product category could not exceed the payment that would otherwise be made under the existing fee schedule methodology (42 CFR 414.412(b)(2)). We stated that we would not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach would ensure that the SPA for each item in a product category is equal to or less than our current fee schedule amount for that item. As noted in the rule, we implemented this policy in part out of concern that if contracts were awarded that allowed higher prices for some items while lower prices for others, this could incentivize improperly shifting utilization to the higher-priced items, defeating the intent that the CBP create savings.

Section 1834(a)(1)(F)(ii) and (iii) of the Act requires the Secretary to use information on the payment determined under a DMEPOS competitive bidding program to adjust the DMEPOS fee schedule amounts in areas where competitive bidding is not in effect. Authority for adjusting payment amounts in a similar manner for OTS orthotics, lymphedema compression treatment items, and enteral nutrition is provided by sections 1834(h)(1)(H)(ii), 1834(z)(3)(B), and 1842(s)(3)(B) of the Act, respectively. In the final rule implementing these provisions, published in the **Federal Register** on November 6, 2014, and titled “Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies”, we noted that these adjusted fee schedule amounts would serve as the bid limit for future competitive bidding (79 FR 66120).

In the November 2016 final rule, we established an alternative “lead item” bidding method for submitting bids and determining SPAs for certain groupings of similar items (for example, walkers)

with different features (wheels, folding, etc.) under the DMEPOS CBP. (81 FR 77834). To conform with this change, the bid limit language at 42 CFR 414.412(b)(2) was updated to refer to “lead items.” Along with this change, the rule also changed the bid limit from the adjusted fee schedule amount to the unadjusted fee schedule amount. As the preamble to the rule noted, this change to bid limits was made to address concerns that use of adjusted fees as the bid limit may make the DMEPOS CBP unviable as cost pressures evolve over time (81 FR 77950).

2. Current Issues

As discussed previously, CMS announced that it would not award competitive bidding contracts for 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings. In addition to the changes proposed elsewhere in this rule, we believe that further changes to the bid limit provisions at § 414.412(b)(2) and conditions for awarding contracts at § 414.414(f) are needed to ensure both the continued viability of the DMEPOS CBP and adherence to the requirement for savings laid out in 1847(b)(2)(A)(iii) of the Act. We also believe that differing approaches to bid limits are needed for items that have been included in a previous round of competitive bidding and those that have not because the specific amounts that would otherwise be paid for the former are adjusted based on rates established under previous rounds of the DMEPOS CBP while the specific amounts that would otherwise be paid for the later have not yet been adjusted based on rates established under the DMEPOS CBP.

The expectation of savings has been at the heart of the DMEPOS CBP since its inception for good reason. In examining the first two rounds of bidding, the GAO found that among the products that had been part of the Round 1 Rebid, the Round 1 Recompete, and Round 2, the SPA continued to decrease with each competition for all products except for standard power wheelchairs (which decreased with the first round and remained below the pre CBP payment amount in subsequent rounds). The largest price decrease occurred with the initial round of bidding, with savings ranging from 20 to 50 percent as compared to the previous Medicare fee schedule payment amounts (<https://www.gao.gov/assets/gao-15-63.pdf>). With the Round 2 expansion of the program, SPAs were, on average, 45 percent less than the fee schedule amounts, and SPAs for the national mail

order program for diabetes supplies were, on average, 72 percent less than the previous fee schedule amounts.

However, as explained in section VII.A.1., in addition to the price savings, there are two important benefits of the DMEPOS CBP that must be taken into consideration: guaranteed access for beneficiaries and reductions in improper utilization. Outside of the DMEPOS CBP, Medicare functions as an open network. Suppliers may choose which items to provide, and there is understandable market pressure to focus on more profitable or higher-volume items. Also, despite successful efforts to target waste, fraud, and abuse, it is often difficult to identify bad actors until claims patterns have demonstrated areas of concern. Within the DMEPOS CBP, instances of waste, fraud, and abuse are less likely to occur for two reasons: lower payment amounts reduce the profit to be made from improper payments, and the reduction in number of suppliers and heightened scrutiny and monitoring of contract suppliers makes it more difficult for entities, particularly new entrants, intending to commit fraud to gain access to the program.

While it is difficult to put a dollar amount on the benefit of guaranteed access for beneficiaries, it is possible to quantify the impact the DMEPOS CBP has had on reducing improper utilization. In its study of the DMEPOS CBP Round 1 Rebid, the GAO found that the number of beneficiaries furnished DME items covered by the CBP decreased more in the competitive bidding areas than in non-competitive bidding areas (<https://www.gao.gov/assets/gao-14-156.pdf>), even as monitoring of medical outcomes and beneficiary complaints did not suggest any difficulties in beneficiary access. Although the specific decrease in utilization varied across product categories, this study found decreases of 10 to 20 percent attributable to the CBP. The GAO study of Round 2 found a 17 percent decrease in the number of beneficiaries receiving items covered by the DMEPOS CBP as compared to 6 percent in non-CBP areas (in the context of a broader enforcement program that saw over 580,000 providers lose billing privileges). Similarly to Round 1, this decrease was not accompanied by any evidence that beneficiaries were unable to access needed equipment, and the competitive bidding areas experiencing the largest decreases in utilization were in states with historically high rates of fraud and abuse (<https://www.gao.gov/assets/gao-16-570.pdf>).

Given these findings, it is clear that the historic savings generated by the

DMEPOS CBP come from two sources: the reduction in price that comes from the competitive bidding process and a reduction in improper utilization.

Because the evidence suggests a 10 to 20 percent reduction in waste, fraud, and abuse is associated with the DMEPOS CBP, we believe that it is appropriate and consistent with 1847(b)(2)(A)(iii) of the Act to award contracts in a CBA even if the SPA is 10 percent higher than the adjusted fee schedule payment amount that would otherwise be paid for items included under previous rounds of the DMEPOS CBP, as long as the SPA does not exceed the unadjusted fee schedule amounts for the items and services or the fee schedule amounts in effect prior to the application of the fee schedule adjustments using the methodologies under 42 CFR 414.210(g).

(a) Limits on SPAs

We are soliciting comments on a proposal to modify 42 CFR 414.414(f) to specify that a contract would not be awarded for a competition if the SPA for the lead item would be greater than the lesser of 110 percent of the adjusted fee schedule amount for the lead item, if applicable, or 100 percent of the unadjusted fee schedule amount for the lead item. This proposal is different than the bid limit proposal discussed under “(b) Submissions of bids” because the fee schedule amounts for items and services included under previous rounds of the DMEPOS CBP are adjusted using SPA data from multiple CBAs in different regions of the nation, and in the case of the adjusted fee schedule amounts for items furnished in rural and non-contiguous areas, the adjusted fee schedule amounts include a 50 percent blend of the unadjusted fee schedule rates. As a result, the amount that would otherwise be paid in a CBA at the adjusted fee schedule rates using SPA pricing from multiple CBAs and in some cases updated, unadjusted fee schedule rates could be higher than the previous SPAs established in the specific CBA.

(b) Submission of Bids

For similar reasons, we are soliciting comments on a proposal for several modifications to 42 CFR 414.412 regarding the bid amounts submitted for competitions under a DMEPOS CBP to better ensure that total payments to contract suppliers would be no higher than the total payments that would otherwise be made for the items and services in the CBA.

We are also soliciting comments on a proposal to modify 42 CFR 414.412(b)(2) to expressly specify that the bid submitted for each lead item and

product category included under the DMEPOS CBP for the first time must not exceed the unadjusted fee schedule amount for the lead item.

For items included in a prior competition, we are soliciting comments on a proposal to modify 42 CFR 414.412(b) to require that the bid submitted for each lead item and product category must not exceed, for the same CBA, the lesser of the most recent SPA for the item plus 10 percent or the unadjusted fee schedule amount for the item. If it has been more than one year since the most recent SPA was last paid due to a temporary gap in the CBP, we are proposing that the bid for the lead item must not exceed the lesser of the most recent SPA for the item, adjusted by an inflation factor, plus 10 percent or the unadjusted fee schedule amount for the item. Updating the most recent SPA in this manner allows for the bid limit to address the possible effects of inflation since last paid. We are also soliciting comments on a proposal that the inflation adjustment factor would be based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the 12-month period that the most recent SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the applicable round of competition.

We are soliciting comments on a proposal that the bid submitted for each lead item and product category included in a prior competition but made under a bid for a new CBA must not exceed the lesser of the adjusted fee schedule amount for the lead item plus 10 percent or the unadjusted fee schedule amount for the lead item. For the same reasons noted previously for adding 10 percent to the SPA for the lead item from a previous competition in the same CBA, we are proposing to add 10 percent to the adjusted fee schedule amount for the lead item in this case since the adjusted fee schedule amounts are the amounts that would otherwise be paid and are based on SPAs from previous competitions.

Bidding entities would be educated that they would not be allowed to enter bids that are higher than these proposed limits. The SPAs going from one round to the next would not be able to exceed the 10 percent increase in payments that, as discussed previously, we believe would still allow contracts to be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act.

As discussed in section VII.F.3., OTS back braces and OTS knee braces are currently delivered to beneficiaries from remote supplier locations that on

average are hundreds of miles from the beneficiary's residence. We are therefore soliciting comments on a proposal to establish a nationwide or regional CBA(s) for items such as OTS back braces and OTS knee braces to be phased in at some point in the future. We are soliciting comments on a proposal to amend 42 CFR 414.412(b) to establish bid limits for OTS back braces and OTS knee braces for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). OTS back braces and OTS knee braces were included under the DMEPOS CBP in over 100 CBAs from 2021 through 2023 with SPAs calculated using maximum winning bid amounts. The fee schedule amounts for OTS back braces and OTS knee braces are adjusted based on the prices established under this round of the DMEPOS CBP. In accordance with regulations at 42 CFR 414.210(g)(1), the fee schedule amounts for nonrural areas within the contiguous United States are adjusted based on regional average SPAs limited by a national ceiling and floor. The average of the 2025 fee schedule amounts for nonrural areas for HCPCS level II code L0450 for example is \$124.53. By comparison, the average of the 2025 adjusted fee schedule amounts for these items when furnished to beneficiaries in rural areas within the contiguous United States and areas outside the contiguous United States for HCPCS level II code L0450 is \$184.76. The higher fee schedule amounts established for these areas in accordance with regulations at 42 CFR 414.210(g)(2)(ii) and (iii) account for higher costs of suppliers furnishing items in these areas. However, these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations. The cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area. Additional shipping and handling costs may be incurred in some cases for items that are shipped to an area outside the contiguous United States such as Alaska, Hawaii, or Puerto Rico, but there are very few beneficiaries living in these areas compared to areas within the contiguous United States. We are soliciting comments on a proposal that the bids submitted for an OTS back brace or an OTS knee brace included as a lead item in a product category in a nationwide or regional RID CBP for the first time cannot exceed the average of the nonrural fee schedule amounts that

would otherwise apply to the item under subpart D of this part for the areas included in the nationwide or regional CBP.

While we believe this bid limit for items that have previously been part of competitive bidding is important in terms of balancing the benefits of the DMEPOS CBP with the statutory requirement for savings, we also recognize that it may be possible in the long term that the bid limit as previously described may, in fact, exceed the unadjusted fee schedule amounts for certain items. For this reason, we propose a "fail-safe" to ensure that the bid limit would never exceed the unadjusted fee schedule amount.

3. Provisions of the Proposed Regulation

We are proposing to amend 42 CFR 414.412 to amend paragraph (b)(2) to specify that this paragraph would apply to items included under the DMEPOS CBP for the first time, and to streamline the text by deleting the references to the application of §§ 414.210(g), 414.105, and 414.1690. We are proposing to renumber paragraphs (b)(3) through (b)(5) as (b)(6) through (b)(8), respectively. We are proposing to add a new paragraph (b)(3) to set the bid limit for items that have been previously included under a competition for the same CBA with a SPA used to pay contract suppliers as the lesser of the most recent SPA plus 10 percent or the unadjusted fee schedule amount for the item. We are proposing to add a new paragraph (b)(4) to specify that if it has been more than one year since the most recent SPA was last paid, the amount under (b)(3) would be adjusted by the percentage change in the CPI-U from the mid-point of the 12-month period the most recent SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the current round of competition. Should either the most recent SPA plus 10 percent or the most recent SPA plus 10 percent and the increases for inflation for SPAs that have not been used for payment for more than one year exceed the unadjusted fee schedule amount for the lead item, the bid submitted would be limited to the unadjusted fee schedule amount. We are proposing to add new paragraph (b)(5) to set the bid limit for items that have been previously included under the DMEPOS CBP but are being phased into a CBA where the items have never been bid as the adjusted fee schedule amount for the lead item plus 10 percent. If the adjusted fee schedule amount for the lead item plus 10 percent exceeds the

unadjusted fee schedule amount for the lead item, the bid submitted would be limited to the unadjusted fee schedule amount for the lead item. We are proposing to specify under new paragraph (b)(9) that the bid amounts submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a RID CBP for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the RID CBP divided by 60. We are proposing to specify under new paragraph (b)(10) that the bid amounts submitted for rental of insulin infusion pumps included as a lead item in a product category in a RID CBP for the first time must not exceed the nonrural adjusted fee schedule amount that would otherwise apply to the supplies and accessories for the insulin infusion pump under subpart D of this part for a 1-month period plus the total nonrural adjusted rental fee schedule amounts that would otherwise apply to the rental of the insulin pump for 13 months of continuous use under subpart D of this part divided by 60. We are proposing to specify under new paragraph (b)(11) that the bid amounts submitted for an OTS back brace or OTS knee brace included as a lead item in a product category in a RID CBP for the first time cannot exceed the average nonrural payment amount that would otherwise apply to the item under subpart D of this part, with the application of § 414.210(g), for the areas included in the RID CBP. We are proposing to specify under new paragraph (b)(12) that the bid amounts submitted for all other items included as a lead item in a product category in a RID CBP for the first time must not exceed the average payment amount that would otherwise apply to the item under subpart C, D, or Q of this part for the areas included in the RID CBP.

We are proposing to amend 42 CFR 414.414(f) to state that contracts cannot be awarded for a competition unless CMS determines the SPA to be paid to contract suppliers for the lead item would be no greater than the lesser of 110 percent of the adjusted fee schedule amount for the item, if applicable, or the unadjusted fee schedule amount for the lead item.

We are soliciting comments on these proposals.

E. Revising the Definition of “Item” Related to Medical Supplies

Section 1847(a)(1) of the Act requires that the Secretary phase in all included items and services for competitive bidding. Including items in competitive bidding generates savings for Medicare Part B. Certain items may present a particular risk for improper utilization, and prioritizing these items for competitive bidding may facilitate a reduction in improper utilizations. For these reasons, we are proposing to facilitate the statutorily mandated expansion of the competitive bidding program by clarifying the definition of “medical equipment items”, to include ostomy, tracheostomy, and urological supplies.

1. Background

Section 1847(a)(1)(B) of the Act authorizes the Secretary to phase in CBPs first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

In the 2007 final rule we stated we would rely on several variables in determining the savings potential for specific items or categories of items. Those variables include annual allowed charges, annual growth in expenditures, number of suppliers, savings under the demonstrations, and various reports and studies conducted by CMS and other Federal agencies (72 FR 18025).

We received several comments in the 2007 final rule from commenters who believed that ostomy products and supplies do not meet the definition of DME and, therefore, are not part of the items and services subject to the CBPs described in section 1847(a)(2)(A) of the Act (72 FR 18023). We responded that we believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS CBP because the term “medical supplies” in the section heading could be interpreted either to modify the term “durable medical equipment” (meaning that the medical supplies would have to be associated with the DME to be included), or to be a separate category of items that are not associated with DME. In addition, although the definition of “covered item” in section 1834(a)(13) of the Act means “durable medical equipment (as defined in section 1861(n) [of the Act]), including such equipment described in section 1861(m)(5) [of the Act] . . .,” the term “such equipment” in section 1861(m)(5) of the Act could be interpreted to refer either to the term “durable medical

equipment” or to the term “medical supplies” (which would include ostomy supplies) in that section. In light of these ambiguities, we stated that we believe we have discretion to interpret section 1847(a)(2)(A) of the Act to include or exclude ostomy products and supplies in the competitive bidding programs. We did not exercise our authority to include these items at that time and stated we would continue to review this issue.

Prior to enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Public Law 108–173; section 4319 of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, authorized implementation of up to five demonstration projects of competitive bidding for Medicare Part B items, except physician services. In accordance with section 4319 of the BBA, we planned and implemented the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for DMEPOS. The demonstration was implemented at two sites: Polk County, Florida, and in the San Antonio, Texas, Metropolitan Statistical Area (MSA). The competitive bidding demonstrations, authorized under the BBA, were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program, and offered beneficiaries sufficient access and quality products.

At the first site, Polk County, Florida, we conducted the first of two rounds of bidding in 1999. Five categories of DMEPOS were put up for bidding: oxygen equipment and supplies (required by statute); hospital beds and accessories; enteral nutrition formulas and equipment; urological supplies; and surgical dressings. A total of 16 contract suppliers began providing demonstration products in Polk County on October 1, 1999, and continued for 2 years. The second and final round of bidding in Polk County was conducted in 2001 for the same product categories minus enteral nutrition (Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes). The second set of competitively bid payment amounts took effect in October 2001. As in round one, 16 suppliers were selected, of whom half had participated as winners previously. The new fee schedules developed from the bids in each round replaced the Statewide Medicare DMEPOS fees. The second round of the demonstration in Polk County ended in September 2002. Texas was the second site for the demonstration. In Bexar, Comal, and

Guadalupe counties in the San Antonio MSA, we conducted bidding in 2000 for five kinds of DMEPOS: oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; general orthotics; and nebulizer drugs. Fifty-one suppliers were selected and began serving Medicare beneficiaries under the new fees in February 2001. The San Antonio site ended operations in December 2002, the statutorily required termination date in the BBA.

In each area of evaluation, the data indicated mostly favorable results for the Medicare program. The demonstration led to lower Medicare fees for almost every item in almost every product category in each round of bidding. Fee reductions varied by product category and item, resulting in a nearly 20 percent overall savings at each site. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged. For urological supplies, the estimated savings rate for the first round of the demonstration in Polk County were \$16,409, which were 18 percent, and Round 2 bidding in Polk County resulted in 9 percent savings (72 FR 18078). Our findings from beneficiary surveys in Polk County did not indicate that beneficiaries using urological supplies experienced any negative impact on the quality of their equipment.⁸⁰

Multiple winners were selected in each product category in each round of bidding. In Polk County, non-demonstration suppliers in Round 1 bid successfully in Round 2. However, the falling number of bidders for urological supplies raised questions about the feasibility of bidding for products with low allowed charges. At the time, this product category did not have a single dominant product code, with the items with the highest allowed charges accounting for only 28 percent of total Medicare allowed charges for urological supplies.

2. Current Issues

There have been several reports detailing Medicare’s excessive payment rates for items not included in the DMEPOS CBP. In 2018, the Medicare Payment Advisory Commission (MedPAC) released a report describing how Medicare expenditures for DMEPOS products excluded from the CBP have continued to grow.⁸¹ MedPAC discussed how “. . . some non-CBP

⁸⁰ <https://www.cms.gov/files/document/2rtcappendixpdf>.

⁸¹ https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch6_medpacreport_sec.pdf.

DMEPOS products continue to generate high rates of improper payments, experience high utilization growth, and exhibit patterns of potential fraud and abuse.” In this report, MedPAC looked at ostomy, tracheostomy, and urological supplies (for example, catheters), and found two products for which Medicare’s payment rates were 45 percent and 57 percent higher than private-payer rates. Specifically, intermittent urinary curved tip catheters under HCPCS Level II code A4352 were 57 percent more, whereby Medicare could save \$37 million dollars if Medicare paid the median private-payer rate. Intermittent urinary straight tip catheters (HCPCS Level II code A4351) were 45 percent more, whereby Medicare could save \$41 million dollars if Medicare paid the median private-payer rate.

In August 2022, the HHS Office of Inspector General (OIG) released a report titled, “Reducing Medicare’s Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year” (OEI-04–20–00620).⁸² The report found that, “Medicare and its beneficiaries paid suppliers \$407 million for intermittent urinary catheters in fiscal year 2020, more than three times the suppliers’ estimated acquisition costs of \$121 million.” Based on these findings, OIG recommended that CMS lower Medicare’s payment rates for intermittent urinary catheters. OIG noted that CMS could incorporate such items into the DMEPOS CBP.

We have also seen significant growth in allowed charges for ostomy, tracheostomy, and urological supplies. In 2001, the second year of the demonstration in Polk County, total allowed charges for intermittent urinary curved tip catheter HCPCS Level II code A4352 were \$1,779,928 while total allowed charges for intermittent urinary straight tip catheters HCPCS Level II code A4351 were \$5,753,184. Total allowed charges have increased significantly for these items in 2022, to \$344,012,449 for HCPCS Level II code A4352 and \$153,606,517 for HCPCS Level II code A4351. Medicare allowed charges for ostomy supplies have also grown significantly. For instance, total allowed charges for HCPCS Level II code A4407 for ostomy skin barriers increased from \$12,990,011 in 2003 to \$37,478,467 in 2022. Additionally, prior reviews performed by OIG and CMS contractors have identified high improper payment rates for urological

supplies (including intermittent urinary catheters) that did not meet Medicare requirements.⁸³ We also published in the **Federal Register** on September 27, 2024 a Medicare Shared Savings Program final rule (89 FR 79152), in which we discussed significant, anomalous, and highly suspect (SAHS) billing activity for certain intermittent urinary catheters on Medicare DMEPOS claims in CY 2023. We finalized several proposals as a result of this SAHS billing activity, one of which was to specify in the Shared Savings Program regulations at § 425.670(b) that CMS has determined that the billing of HCPCS codes A4352 (Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each) and A4353 (Intermittent urinary catheter, with insertion supplies) represents SAHS billing activity for CY 2023 that would have caused significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed (89 FR 79158).

Further information about this urinary catheter fraud that CMS identified in 2023 can be found in a CMS case study titled “Urinary Catheter Case Study: CMS’ Swift Action Saves Billions”.⁸⁴ In sum, CMS identified a concerning rise in urinary catheter billings attributed to a small group of 15 DMEPOS supply companies that had recently changed ownership. Through investigative work, CMS determined that people with Medicare did not receive catheters from these DMEPOS companies and were not billed directly, physicians did not order these supplies, and the supplies were not needed. While CMS took swift action to protect people with Medicare and the Medicare program in this situation,⁸⁵ including ostomy, tracheostomy, and urological supplies in the DMEPOS CBP may mitigate such situations in the future.

⁸³ <https://oig.hhs.gov/documents/audit/10169/A-09-22-03019.pdf>.

⁸⁴ <https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf>.

⁸⁵ Using fraud prevention tools, CMS stopped over 99% of the payments to the small group of potential bad actors before they went out the door. There was no impact to legitimate suppliers providing medically necessary services to people with Medicare. CMS revoked enrollment of the 15 potential bad actors from Medicare between late 2023 and 2024, meaning they are no longer able to bill Medicare for services and cannot re-enroll for up to 10 years. CMS also replaced hundreds of thousands of Medicare Beneficiary Identifiers (MBIs) that were used to file the suspicious claims, changed the MBI of the most at-risk people with Medicare, and completed changing all impacted MBI in March 2024.

3. Provisions of the Proposed Regulation

We are soliciting comments on our proposal that the medical equipment set forth at section 1861(m)(5) of the Act, namely home health medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and certain covered osteoporosis drugs) be included in the list of items CMS may subject to the DMEPOS CBP. In general, section 1847(a)(1)(A) of the Act states the Secretary must establish and implement competitive bidding for covered items. In identifying the scope of covered items subject to the DMEPOS CBP, section 1847(a)(2) of the Act relies on section 1834(a)(13) of the Act, which defines covered items as durable medical equipment, as defined at section 1861(n) of the Act (including supplies used in conjunction with durable medical equipment), and certain equipment described in section 1861(m)(5) of the Act used to furnish home health services, such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and certain covered osteoporosis drugs. Consequently, we believe that ostomy, tracheostomy, and urological supplies are included within the scope of section 1847(a)(2)(A) of the Act that CMS may select for competitive bidding. We no longer believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS CBP.

Additionally, the Conference Report for the MMA of 2003 (H. Rept. 108–391) says, “The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, medical supplies, home dialysis supplies, blood products, parental nutrition, and off the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments.”⁸⁶ Here, the second mention of “medical supplies” is a distinct category from “durable medical equipment” and from “drugs and supplies used in conjunction with durable medical equipment”.

We are soliciting comments on a proposal to add equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies to the definition of “Item” under § 414.402(6). We are also soliciting comments on a proposal to

⁸² <https://oig.hhs.gov/oei/reports/OEI-04-20-00620.pdf>.

⁸⁶ <https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf>.

add § 414.408(g)(6) to specify medical equipment, including ostomy, tracheostomy, and urological supplies are purchased items for which the SPA is calculated based on the bids submitted and accepted.

F. Remote Item Delivery (RID) CBP

We are soliciting comments on a proposal to establish definitions for “remote item delivery CBP” and “remote item delivery item.” A remote item delivery CBP is similar to a mail order CBP except that items furnished on a non-mail basis would not be excluded from the remote item delivery CBP as they are under a mail order CBP.

1. Background

In a September 2004 report (GAO–04–765), GAO recommended that we consider using mail delivery for items that can be provided directly to beneficiaries in the home as a way to implement a DMEPOS competitive bidding strategy. The report stated that “Because MMA authorizes CMS to designate the geographic areas for competition for different items, designating the entire country as the competitive area for selected items is a possibility.” The GAO noted that demonstration suppliers provided surgical dressings, urological supplies, and inhalation drugs to beneficiaries by mail.⁸⁷ Additionally, the GAO noted that the MMA states that areas within MSAs that have low population density should not be excluded from competition if a significant national market exists through mail order for a particular item or service. The GAO went on to say that “in contrast to conducting competitive bidding on a piecemeal basis in multiple geographic areas, a consolidated nationwide approach would allow CMS to more quickly implement competitive bidding on a large scale.” The GAO also stated that “this approach would enable companies that provide, or demonstrate the ability to provide, nationwide mail order service to compete for Medicare beneficiaries’ business.” In the report we stated that CMS would explore the feasibility of GAO’s recommendation to consider using mail-order delivery for items that could be provided directly to beneficiaries in the home, as a way to

implement a national competitive bidding strategy.

In response, we have continued to review and evaluate avenues to expand mail delivery for items under the DMEPOS CBP. In the 2006 proposed rule (71 FR 25669), we stated that our data shows that a significant percentage of certain items such as diabetes testing supplies (blood glucose test strips and lancets) are furnished to beneficiaries by national mail order supplier and proposed to establish a nationwide or regional competitive bidding program, effective for items furnished on or after January 1, 2010, for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail order outlet. Specifically, we proposed in § 414.410(d)(2) and § 414.412(f) and (g) to establish a nationwide competitive bidding program or regional competitive bidding programs for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail. We proposed that the national or regional CBAs under the Medicare DMEPOS CBP would be phased in after CY 2009, and payment would be based on the bids submitted and accepted for the furnishing of items through mail order throughout the nation or region. Suppliers that furnish these items through mail order on either a national or regional basis would be required to submit bids to participate in any CBP implemented for the furnishing of mail order items.

In the 2007 final rule (72 FR 18018), we finalized these proposals and specified that our data indicated that over 60 percent of Medicare expenditures for diabetes supplies are for items furnished by nationwide mail order suppliers. In the 2007 final rule (72 FR 18018), we stated that any national or regional mail order CBP that we might choose to implement starting in CY 2010 would be limited to the furnishing of items “through the mail.” The 2007 final rule included the addition of definitions under § 414.402 related to nationwide or regional CBPs.

A national mail order CBP was implemented for diabetes testing supplies (supplies for blood glucose monitors) from July 1, 2013, through

December 31, 2018. Prior to implementing this national mail order program, as part of a final rule published in the **Federal Register** on November 29, 2010, titled “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011” (75 FR 73567), we established definitions for “mail order item” and “non-mail order item” in § 414.402. These definitions were established to clarify that a mail order item is not limited to an item that is literally furnished through the mail (United States Postal Service) and includes any item delivered to the beneficiary, whereas a non-mail order item was an item the beneficiary picked up in person at a local pharmacy or other supplier storefront. The definition for “mail order item” is “any item (for example, diabetes testing supplies) shipped or delivered to the beneficiary’s home, regardless of the method of delivery.” The definition for “non-mail order item” is “any item (for example, diabetes testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront.” Non-mail order diabetes testing supplies were not included under the national mail order program. However, the fee schedule amounts for these items are established based on the payment amounts determined for the items under the national mail order program in accordance with section 1834(a)(H) of the Act.

2. Current Issues

Medicare claims data shows that several high-volume categories of items subject to the DMEPOS CBP are furnished to beneficiaries throughout the nation from remote supplier locations. As shown in table 45, the national average distance between the beneficiary address and supplier location is several hundred miles for the lead items in seven, high volume categories of items. The average delivery distance was measured based on the distance between the beneficiary residence and supplier location for all claims with dates of service in calendar year 2024 for the “lead item” in the category of items, or the item with the highest total nationwide Medicare allowed charges in 2024 of any item in the category.

⁸⁷ <https://www.gao.gov/assets/gao-04-765.pdf>.

TABLE 45: CATEGORIES OF ITEMS FURNISHED FROM REMOTE SUPPLIER LOCATIONS

Category	2024 Allowed Charges for the Category	Lead Item	Average Distance ⁸⁸ (Lead Item)
Class II Continuous Glucose Monitors	\$1.945 million	A4239	813 miles
Urological Supplies ¹	\$1,214 million	A4353	784 miles
Ostomy Supplies ¹	\$436 million	A5057	758 miles
Insulin Pumps	\$151 million	E0784	679 miles
Off-the-shelf Knee Braces	\$138 million	L1852	1047 miles
Off-the-shelf Upper Extremity Braces	\$127 million	L3916	1049 miles
Off-the-shelf Back Braces	\$126 million	L0651	976 miles

¹ Urological supplies and ostomy supplies categories have 9 overlapping HCPCS codes at \$16 million

We are soliciting comments on a proposal that items like those listed in Table 45 that are generally furnished from remote supplier locations should be included under a remote item delivery CBP that does not exclude non-mail order items as is the case under a mail order CBP.

Rather than implementing hundreds of local CBPs and CBAs and placing unnecessary burden on the bidding program and suppliers, we believe the easiest and best way to implement CBPs for remotely delivered items such as these is to include them under product

categories in one nationwide “RID” CBP or several large regional “RID” CBPs, which would consist of all areas where a beneficiary resides or receives covered items under the product categories, with limited exceptions as explained later in this section. This is consistent with the findings of a report from the GAO from September 2004⁸⁹ that discussed the use of national CBAs as a way to streamline the implementation of the CBP. Listed in table 46 are the current HCPCS Level II codes for several product categories we believe should be

included under a future RID CBP(s) because they are typically furnished to beneficiaries from remote supplier locations, or locations that are hundreds of miles on average from the beneficiary residence where the items are delivered. This table is for illustration purposes only. The actual product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means in accordance with existing regulations at § 414.406(d).

BILLING CODE 4120-01-P

⁸⁹ <https://www.gao.gov/assets/gao-04-765.pdf>.

TABLE 46: EXAMPLES OF RID CBP PRODUCT CATEGORIES AND HCPCS CODES

Product Category	HCPCS Level II Code	Short Description
Class II CGMs and Insulin Pumps	A4224	Supply insulin inf cath/wk
Class II CGMs and Insulin Pumps	A4225	Sup/ext insulin inf pump syr
Class II CGMs and Insulin Pumps	A4239	Non-adju cgm supply allow
Class II CGMs and Insulin Pumps	E0784	Ext amb infusn pump insulin
Class II CGMs and Insulin Pumps	E2103	Non-adju cgm receiver/mon
OTS Back Brace	L0450	Tlso flex trunk/thor pre ots
OTS Back Brace	L0455	Tlso flex trnk sj-t9 pre ots
OTS Back Brace	L0457	Tlso flex trnk sj-ss pre ots
OTS Back Brace	L0467	Tlso r fram soft pre ots
OTS Back Brace	L0469	Tlso rig fram pelvic pre ots
OTS Back Brace	L0621	Sio flex pelvic/sacr pre ots
OTS Back Brace	L0623	Sio rig pnl pelv/sac pre ots
OTS Back Brace	L0625	Lo flex l1-below l5 pre ots
OTS Back Brace	L0628	Lso flex no ri stays pre ots
OTS Back Brace	L0641	Lo rig pos pnl l1-l5 pre ots
OTS Back Brace	L0642	Lo sag ri an/pos pnl pre ots
OTS Back Brace	L0643	Lso sag ctr rigi pos pre ots
OTS Back Brace	L0648	Lso sag r an/pos pnl pre ots
OTS Back Brace	L0649	Lso sc r pos/lat pnl pre ots
OTS Back Brace	L0650	Lso sc r ant/pos pnl pre ots
OTS Back Brace	L0651	Lso sag-co shell pnl pre ots
OTS Knee Brace	L1812	Ko elastic w/joints pre ots
OTS Knee Brace	L1830	Ko immob canvas long pre ots
OTS Knee Brace	L1833	Ko adj jnt pos r sup pre ots
OTS Knee Brace	L1836	Ko rigid w/o joints pre ots
OTS Knee Brace	L1850	Ko swedish type pre ots
OTS Knee Brace	L1851	Ko single upright prefab ots
OTS Knee Brace	L1852	Ko double upright prefab ots
OTS Upper Extremity Brace	L3650	So 8 abd restraint pre ots
OTS Upper Extremity Brace	L3660	So 8 ab restr can/web pre ots
OTS Upper Extremity Brace	L3670	So acro/clav can web pre ots
OTS Upper Extremity Brace	L3675	So vest canvas/web pre ots
OTS Upper Extremity Brace	L3678	So hard plas stabili pre ots
OTS Upper Extremity Brace	L3710	Eo elas w/ metal jnts pre ots
OTS Upper Extremity Brace	L3761	Eo, adj lock joint prefab ot
OTS Upper Extremity Brace	L3762	Eo rigid w/o joints pre ots
OTS Upper Extremity Brace	L3809	Whfo w/o joints pre ots
OTS Upper Extremity Brace	L3908	Who cock-up nonmolde pre ots
OTS Upper Extremity Brace	L3912	Hfo flexion glove pre ots
OTS Upper Extremity Brace	L3916	Who nontorsion jnts pre ots
OTS Upper Extremity Brace	L3918	Metacarp fx orthosis pre ots
OTS Upper Extremity Brace	L3924	lifo without joints pre ots
OTS Upper Extremity Brace	L3925	Fo pip dip jnt/springs pre ots
OTS Upper Extremity Brace	L3927	Fo pip dip no jt spr pre ots
OTS Upper Extremity Brace	L3930	Hfo nontorsion jnts pre ots
Ostomy Supplies	A4331*	Extension drainage tubing
Ostomy Supplies	A4357*	Bedside drainage bag

Product Category	HCPCS Level II Code	Short Description
Ostomy Supplies	A4361	Ostomy face plate
Ostomy Supplies	A4362	Solid skin barrier
Ostomy Supplies	A4363	Ostomy clamp, replacement
Ostomy Supplies	A4364	Adhesive, liquid or equal
Ostomy Supplies	A4366	Ostomy vent
Ostomy Supplies	A4367	Ostomy belt
Ostomy Supplies	A4368	Ostomy filter
Ostomy Supplies	A4369	Skin barrier liquid per oz
Ostomy Supplies	A4371	Skin barrier powder per oz
Ostomy Supplies	A4372	Skin barrier solid 4x4 equiv
Ostomy Supplies	A4373	Skin barrier with flange
Ostomy Supplies	A4375	Drainable plastic pch w fcpl
Ostomy Supplies	A4376	Drainable rubber pch w fcplt
Ostomy Supplies	A4377	Drainable plstic pch w/o fp
Ostomy Supplies	A4378	Drainable rubber pch w/o fp
Ostomy Supplies	A4379	Urinary plastic pouch w fcpl
Ostomy Supplies	A4380	Urinary rubber pouch w fcplt
Ostomy Supplies	A4381	Urinary plastic pouch w/o fp
Ostomy Supplies	A4382	Urinary hvy plstc pch w/o fp
Ostomy Supplies	A4383	Urinary rubber pouch w/o fp
Ostomy Supplies	A4384	Ostomy faceplt/silicone ring
Ostomy Supplies	A4385	Ost skn barrier sld ext wear
Ostomy Supplies	A4387	Ost clsd pouch w att st barr
Ostomy Supplies	A4388	Drainable pch w ex wear barr
Ostomy Supplies	A4389	Drainable pch w st wear barr
Ostomy Supplies	A4390	Drainable pch ex wear convex
Ostomy Supplies	A4391	Urinary pouch w ex wear barr
Ostomy Supplies	A4392	Urinary pouch w st wear barr
Ostomy Supplies	A4393	Urine pch w ex wear bar conv
Ostomy Supplies	A4394	Ostomy pouch liq deodorant
Ostomy Supplies	A4395	Ostomy pouch solid deodorant
Ostomy Supplies	A4396	Peristomal hernia supprt blt
Ostomy Supplies	A4398	Ostomy irrigation bag
Ostomy Supplies	A4399	Ostomy irrig cone/cath w brs
Ostomy Supplies	A4402*	Lubricant per ounce
Ostomy Supplies	A4404	Ostomy ring each
Ostomy Supplies	A4405	Nonpectin based ostomy paste
Ostomy Supplies	A4406	Pectin based ostomy paste
Ostomy Supplies	A4407	Ext wear ost skn barr <=4sq"
Ostomy Supplies	A4408	Ext wear ost skn barr >4sq"
Ostomy Supplies	A4409	Ost skn barr convex <=4 sq i
Ostomy Supplies	A4410	Ost skn barr extnd >4 sq
Ostomy Supplies	A4411	Ost skn barr extnd =4sq
Ostomy Supplies	A4412	Ost pouch drain high output
Ostomy Supplies	A4413	2 pc drainable ost pouch
Ostomy Supplies	A4414	Ost sknbar w/o conv<=4 sq in
Ostomy Supplies	A4415	Ost skn barr w/o conv >4 sqi
Ostomy Supplies	A4416	Ost pch clsd w barrier/fltr
Ostomy Supplies	A4417	Ost pch w bar/bltinconv/fltr
Ostomy Supplies	A4418	Ost pch clsd w/o bar w fltr
Ostomy Supplies	A4419	Ost pch for bar w flange/flt
Ostomy Supplies	A4420	Ost pch clsd for bar w lk fl
Ostomy Supplies	A4422	Ost pouch absorbent material
Ostomy Supplies	A4423	Ost pch for bar w lk fl/fltr
Ostomy Supplies	A4424	Ost pch drain w bar & filter
Ostomy Supplies	A4425	Ost pch drain for barrier fl

Product Category	HCPCS Level II Code	Short Description
Ostomy Supplies	A4426	Ost pch drain 2 piece system
Ostomy Supplies	A4427	Ost pch drain/barr lk flng/f
Ostomy Supplies	A4428	Urine ost pouch w faucet/tap
Ostomy Supplies	A4429	Urine ost pouch w bltinconv
Ostomy Supplies	A4430	Ost urine pch w b/bltin conv
Ostomy Supplies	A4431	Ost pch urine w barrier/tapv
Ostomy Supplies	A4432	Os pch urine w bar/fange/tap
Ostomy Supplies	A4433	Urine ost pch bar w lock fln
Ostomy Supplies	A4434	Ost pch urine w lock flng/ft
Ostomy Supplies	A4435	1pc ost pch drain hgh output
Ostomy Supplies	A4436	Irr supply sleev reus per mo
Ostomy Supplies	A4437	Irr supply sleev disp per mo
Ostomy Supplies	A4450*	Non-waterproof tape
Ostomy Supplies	A4452*	Waterproof tape
Ostomy Supplies	A4455*	Adhesive remover per ounce
Ostomy Supplies	A4456*	Adhesive remover, wipes
Ostomy Supplies	A5051	Pouch clsd w barr attached
Ostomy Supplies	A5052	Clsd ostomy pouch w/o barr
Ostomy Supplies	A5053	Clsd ostomy pouch faceplate
Ostomy Supplies	A5054	Clsd ostomy pouch w/flange
Ostomy Supplies	A5055	Stoma cap
Ostomy Supplies	A5056	1 pc ost pouch w filter
Ostomy Supplies	A5057	1 pc ost pou w built-in conv
Ostomy Supplies	A5061	Pouch drainable w barrier at
Ostomy Supplies	A5062	Drnble ostomy pouch w/o barr
Ostomy Supplies	A5063	Drain ostomy pouch w/flange
Ostomy Supplies	A5071	Urinary pouch w/barrier
Ostomy Supplies	A5072	Urinary pouch w/o barrier
Ostomy Supplies	A5073	Urinary pouch on barr w/flng
Ostomy Supplies	A5081	Stoma plug or seal, any type
Ostomy Supplies	A5082	Continent stoma catheter
Ostomy Supplies	A5083	Stoma absorptive cover
Ostomy Supplies	A5093	Ostomy accessory convex inse
Ostomy Supplies	A5102*	Bedside drain btl w/wo tube
Ostomy Supplies	A5120	Skin barrier, wipe or swab
Ostomy Supplies	A5121	Solid skin barrier 6x6
Ostomy Supplies	A5122	Solid skin barrier 8x8
Ostomy Supplies	A5126	Disk/foam pad +or- adhesive
Ostomy Supplies	A5131*	Appliance cleaner
Urological Supplies	A4217	Sterile water/saline, 500 ml
Urological Supplies	A4295	Straigh tip hydrophilic cath
Urological Supplies	A4296	Coude tip hydrophilic cath
Urological Supplies	A4297	Hydrophilic coat insert sup
Urological Supplies	A4310	Insert tray w/o bag/cath
Urological Supplies	A4311	Catheter w/o bag 2-way latex
Urological Supplies	A4312	Cath w/o bag 2-way silicone
Urological Supplies	A4313	Catheter w/bag 3-way
Urological Supplies	A4314	Cath w/drainage 2-way latex
Urological Supplies	A4315	Cath w/drainage 2-way silcne
Urological Supplies	A4316	Cath w/drainage 3-way
Urological Supplies	A4320	Irrigation tray
Urological Supplies	A4322	Irrigation syringe
Urological Supplies	A4326	Male external catheter
Urological Supplies	A4327	Fem urinary collect dev cup
Urological Supplies	A4328	Fem urinary collect pouch

Product Category	HCPCS Level II Code	Short Description
Urological Supplies	A4331*	Extension drainage tubing
Urological Supplies	A4332	Lube sterile packet
Urological Supplies	A4333	Urinary cath anchor device
Urological Supplies	A4334	Urinary cath leg strap
Urological Supplies	A4336	Urethral insert
Urological Supplies	A4338	Indwelling catheter latex
Urological Supplies	A4340	Indwelling catheter special
Urological Supplies	A4344	Cath indw foley 2 way silicn
Urological Supplies	A4346	Cath indw foley 3 way
Urological Supplies	A4349	Disposable male external cat
Urological Supplies	A4351	Straight tip urine catheter
Urological Supplies	A4352	Coude tip urinary catheter
Urological Supplies	A4353	Intermittent urinary cath
Urological Supplies	A4354	Cath insertion tray w/bag
Urological Supplies	A4355	Bladder irrigation tubing
Urological Supplies	A4356	Ext ureth clmp or compr dvc
Urological Supplies	A4357*	Bedside drainage bag
Urological Supplies	A4358	Urinary leg or abdomen bag
Urological Supplies	A4360	Disposable ext urethral dev
Urological Supplies	A4402*	Lubricant per ounce
Urological Supplies	A4450*	Non-waterproof tape
Urological Supplies	A4452*	Waterproof tape
Urological Supplies	A4455*	Adhesive remover per ounce
Urological Supplies	A4456*	Adhesive remover, wipes
Urological Supplies	A5102*	Bedside drain btl w/wo tube
Urological Supplies	A5105	Urinary suspensory
Urological Supplies	A5112	Urinary leg bag
Urological Supplies	A5113	Latex leg strap
Urological Supplies	A5114	Foam/fabric leg strap
Urological Supplies	A5131*	Appliance cleaner
Urological Supplies	A5200	Percutaneous catheter anchor

* HCPCS Level II codes included in product categories for ostomy supplies and urological supplies

BILLING CODE 4120-01-C

Specifically with regard to certain codes for lower volume items under the OTS Upper Extremity Braces and OTS Back Braces product categories, the average delivery distances were less than 100 miles as shown in tables 47 and 48. Although it does not appear that the braces falling under these codes are currently being delivered from remote locations, we still believe that they could be furnished by nationwide or regional contract suppliers. However,

we are soliciting comments on whether there is any reason that these codes should not be furnished on a mail order basis from remote supplier locations and instead should only be furnished on a non-mail order basis. The alternative would be to exclude codes that have a national average delivery distance of less than 100 miles and include them in future nationwide or regional competitions if the delivery distance for these codes increases to more than 100

miles. Excluding the items would mean that contract suppliers would not be required to furnish these braces, and we are concerned that this could potentially affect access to these items. However, contract suppliers would have discretion to furnish the items to beneficiaries on a non-mail order basis in addition to furnishing the items on a mail order basis, but contract suppliers would not be required to furnish the items on a non-mail order basis.

TABLE 47: NATIONAL AVERAGE DELIVERY DISTANCE FOR OTS UPPER EXTREMITY BRACES (2024)

HCPCS Level II Code	Average Distance	Allowed Charges
L3650	111	\$248,236
L3660	489	\$6,072,706
L3670	403	\$15,405,591
L3675	194	\$178,258
L3678	13	\$974
L3710	32	\$50,676
L3761	813	\$11,742,340
L3762	129	\$468,633
L3809	356	\$15,210,077
L3908	275	\$13,311,651
L3912	59	\$21,253
L3916	1,049	\$59,578,443
L3918	160	\$12,113
L3924	263	\$3,989,591
L3925	41	\$100,324
L3927	52	\$112,892
L3930	84	\$10,240

TABLE 48: NATIONAL AVERAGE DELIVERY DISTANCE FOR OTS BACK BRACES (2024)

HCPCS Level II Code	Average Distance	Allowed Charges
L0450	16	\$10,903
L0455	12	\$5,570
L0457	832	\$20,199,134
L0467	4	\$1,911
L0469	4	\$1,629
L0621	221	\$117,797
L0623	1,055	\$13,417
L0625	57	\$46,479
L0628	39	\$11,732
L0641	292	\$131,336
L0642	157	\$3,799,823
L0643	13	\$3,341
L0648	252	\$4,563,082
L0649	146	\$4,401
L0650	179	\$18,004,560
L0651	976	\$79,147,145

In the case of a RID CBP, the bid items would be delivered by the contract supplier to the beneficiary from a remote location, for example, through the mail. Items may be furnished to beneficiaries who come into the local storefront of a contract supplier, but we believe that most contract suppliers would have a limited number of local storefronts and therefore these occurrences would be rare. Again, contract suppliers would have discretion to furnish the items to

beneficiaries on a non-mail order basis in addition to furnishing the items on a mail order basis, but contract suppliers would not be required to furnish the items on a non-mail order basis.

We believe that situations where a beneficiary loses or is temporarily without supplies that Medicare has already paid for are rare. Claims for replacement supplies furnished from a supplier in these situations would be denied because Medicare has already paid for supplies for the time when the

replacement supplies are needed. The supplier of the replacement supplies would likely have the beneficiary sign an Advance Beneficiary Notice of Noncoverage (ABN), form CMS-R-131, making the beneficiary liable for the cost of the replacement supplies in the event the claim is denied. The beneficiary can appeal the denial of the claim for the replacement supplies, indicating the reason why the replacement supplies were needed, and the claim denial could potentially be

overturned on appeal. We are soliciting comment on our proposal that for supplies included under a RID CBP, these situations would continue to be handled the way they are now, through the claim appeals process. We are also soliciting comment on our proposal that obtaining replacement supplies from a local storefront owned by a non-contract supplier in these rare situations would not be a reason to deny a claim if it is determined that paying the claim for the replacement supplies would otherwise be reasonable.

3. Provisions of the Proposed Regulation

We are soliciting comments on our proposal to phase in a nationwide RID CBP or regional RID CBPs, to be defined under § 414.402, for product categories including items such as those listed in table 45 that typically are furnished to beneficiaries from remote supplier locations or locations that are hundreds of miles on average from the beneficiary residence under a future round of the DMEPOS CBP. The term “Remote item delivery competitive bidding program” would be defined under § 414.402 to mean “a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category primarily to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.” The term “Remote item delivery item” would be defined under § 414.402 to mean an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary’s home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person. The product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means in accordance with existing regulations at 42 CFR 414.406(d). Contract suppliers serving a nationwide or regional RID CBP would be responsible for furnishing the items on either a mail order or non-mail order basis under the product category to all Medicare beneficiaries, regardless of where they live in the CBA. If a beneficiary who resides in a CBA receives an item in person at a local supplier storefront, that supplier would need to be a contract supplier for the item.

Items furnished to beneficiaries from remote supplier locations, such as those

listed in table 46 would be furnished in a nationwide RID CBP or regional RID CBPs that include both mail order and non-mail order items, and not under a “mail order” program that only includes mail order items.

G. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

Because CGMs and insulin infusion pumps are subject to rapid technological change, requiring frequent and substantial servicing, we are proposing to reclassify all CGMs and infusion pumps under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, as implemented under § 414.222(a). CMS would pay for all CGMs and insulin infusion pumps on a monthly rental basis under both the DMEPOS CBP and in non-CBAs under the fee schedule payments. The monthly rental payments would include payment for any necessary supplies and accessories. As further discussed later in this section, this would be a departure from how these items are currently paid under the Medicare DMEPOS fee schedule. Under the Medicare DMEPOS fee schedule, we typically pay for the purchase of CGMs, which are classified as routinely purchased equipment. Payment for insulin pumps is made on a capped rental basis, with beneficiaries taking over ownership of the pump after rental payments are made for 13 months of continuous use. In addition, we are proposing to allow contract suppliers to bill for up to 3 months of rental for these items in advance.

Class III devices are statutorily excluded from the DMEPOS CBP per section 1847(a)(2)(A) of the Act. Because certain brands of insulin infusion pumps are used in conjunction with class III CGMs, we propose that insulin infusion pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP. We want to avoid a situation where Medicare payments for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs are grossly excessive compared to Medicare payments for class II CGMs and insulin pumps that are not used in conjunction with class III CGMs. To avoid this, we propose that once class II CGMs and insulin infusion pumps are phased into the DMEPOS CBP, if the rental fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs are more than 15 percent higher than the SPAs established for class II CGMs and insulin infusion pumps under the DMEPOS CBP, then we propose that we would adjust the fee schedule amounts

for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to be equal to the SPAs established for class II CGMs and insulin infusion pumps under the DMEPOS CBP in accordance with the process described in § 405.502.

We are soliciting comments on these proposals.

1. Background

The Medicare Part B benefit for DME is primarily a benefit for rental of durable medical equipment such as wheelchairs, hospital beds, oxygen equipment, and ventilators for use in the beneficiary’s home, including certain institutions used as the beneficiary’s home. Various statutory payment provisions that added an option to purchase certain DME in lieu of rental or that cap total rental payments after a certain number of months or when total payments equal the purchase price for the equipment were phased in beginning in 1968. These statutory rules were intended to save money for the beneficiary and the Medicare program in cases where DME is needed on a long-term basis. However, we are concerned that two types of DME—CGMs and insulin infusion pumps—are classified under statutory provisions that limit beneficiary choice and access to newer technology, thereby limiting options for beneficiaries to improve their health and not accounting for the frequent and substantial servicing these devices require.

Medicare payment for CGM receivers can be made on a lump sum purchase basis or a monthly rental basis, although most Medicare beneficiaries receive the items on a purchase basis. Medicare pays for CGM receivers classified by the Food and Drug Administration (FDA) as class II or class III devices under the Federal Food, Drug, and Cosmetic Act. CGM systems can only be classified under class II if they can meet the requirements to be an integrated CGM system in accordance with Federal regulations at 21 CFR § 862.1355. Class III CGMs are not accurate enough to be classified as an integrated CGM system.

The 2025 average Medicare fee schedule amount for purchase of a new, class II CGM receiver is \$286.03. In addition to receiving payment for the purchase of the CGM receiver, suppliers are allowed to bill for replacement supplies necessary for the operation of the CGM every 90 days for a payment of \$803.76 for supplies used with class II CGMs, with total payments for the ongoing replacement of supplies accounting for over 98 percent of the total CGM costs over 5 years. CMS

issued program instructions on October 19, 2023 (Transmittal 12303; Change Request 13397) instructing Medicare Administrative Contractors (MAC) to allow CGM supplies to be billed in 90 day increments to align with longstanding practices in place for blood glucose monitors. In addition, the DME MAC Local Coverage Determinations for external infusion pumps allow suppliers to dispense up to 3 months of supplies at a time: <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794>.

Medicare payment for insulin infusion pumps is made on a capped rental basis, with beneficiaries taking ownership of the pump after rental payments are made for 13 months of continuous use. The rental payments over 13 months add up to \$5,702.34 for insulin pumps furnished in nonrural areas (metropolitan statistical areas) and \$5,926.87 for insulin pumps furnished in other, rural areas and non-contiguous areas of the United States (Alaska, Hawaii, Puerto Rico, etc.). In addition to receiving payment for rental of the insulin pump, suppliers are allowed to bill for replacement supplies necessary for the operation of the insulin pump every 90 days for a payment of approximately \$403.68 for nonrural areas and \$447.06 for rural and non-contiguous areas, with total payments for the ongoing replacement of supplies accounting for 60 percent of the total insulin pump costs, not including the cost of insulin, over 5 years.

In accordance with the payment rules for DME under section 1834(a) of the Act, DME items are classified under several different payment classes with different payment rules under section 1834(a)(2)(7) of the Act, added by section 4062(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Pub. L. 100–203). In accordance with section 1834(a)(2)(A)(ii) of the Act and regulations at 42 CFR 414.220(a)(2), equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987 is considered routinely purchased equipment and can be paid on a rental or lump-sum purchase basis in accordance with the rules at section 1834(a)(2) of the Act and regulations at 42 CFR 414.220, but total payments for the equipment cannot exceed the purchase price for the item. Therefore, if the equipment is rented, the rental payments would cap at the point where total rental payments equal the Medicare fee schedule amount for purchase of the item. Although Medicare did not start covering CGMs

until 2017, blood glucose monitors, predecessors to the CGM, were acquired by purchase on a national basis more than 90 percent of the time during the period July 1986 through June 1987. As part of the final rule entitled “Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas,” published on December 28, 2021, CGMs were classified as routinely purchased equipment (FR 86 73900).

Since Medicare did not start covering insulin infusion pumps until 1994, they also were not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Other types of external infusion pumps that were covered as DME during the period July 1986 through June 1987 were not acquired by purchase on a national basis at least 75 percent of the time. Therefore, insulin infusion pumps are not classified as routinely purchased equipment in accordance with the statute and regulations and are not inexpensive equipment which can be paid in accordance with the rules at section 1834(a)(2) of the Act and regulations at 42 CFR 414.220. As such, insulin infusion pumps are classified as other covered items of DME and paid for in accordance with the capped rental payment rules at sections 1834(a)(7) and (8) of the Act and regulations at 42 CFR 414.229. Medicare pays a monthly rental amount for capped rental items for a period not to exceed 13 months of continuous use. “Continuous use” is defined in regulations at 42 CFR 414.230. After the 13-month capped rental period is over, the title to the equipment transfers to the beneficiary. In the case of both CGMs and insulin infusion pumps, Medicare makes separate payments on a purchase basis for supplies necessary for the effective use of the CGM or insulin infusion pump using fee schedule amounts calculated in accordance with section 1834(a)(6) and (8) of the Act.

Other than customized items of DME paid for in accordance with section 1834(a)(4) of the Act and regulations at 42 CFR 414.224 and oxygen and oxygen equipment paid for in accordance with section 1834(a)(5) and (9) of the Act and regulations at 42 CFR 414.226, CMS may classify an item as DME requiring frequent and substantial servicing paid

for in accordance with section 1834(a)(3) of the Act and regulations at 42 CFR 414.222 if the item requires frequent and substantial servicing in order to avoid risk to the patient's health. Payment for items falling under this class are made on a monthly rental basis, with rental payments continuing as long as coverage of the equipment under Part B continues and the equipment is being used in the home. The monthly rental amount includes payment for rental of the equipment, including maintenance and servicing of the equipment, and replacement of supplies and accessories necessary for the effective use of the DME. Separate payment is not allowed for supplies and accessories for items falling under this payment class.

We believe payment for CGMs and insulin infusion pumps should be on a continuous rental basis like other DME items requiring frequent and substantial servicing. The class of DME items requiring frequent and substantial servicing is described on page 392 of the House of Representatives Committee on the Budget Report 100–391 that accompanied OBRA 87 as items “that are technologically sophisticated and require frequent monitoring or adjustment in order to make sure they are functioning properly or being properly utilized by the patient. They are also typically quite expensive to purchase and often subject to relatively rapid technological change.” As we discuss in greater detail later in this section, CGMs and insulin infusion pumps are subject to rapid technological change and require frequent servicing by the supplier.

2. Current Issues

While Medicare beneficiaries enrolled under Part B who use CGM equipment generally use it on a long-term basis, making purchase of the equipment seem more practical than rental, the ongoing need to purchase replacement supplies for the equipment continues, and, in accordance with current regulations at 42 CFR 414.210(f)(a), the beneficiary is not able to obtain new, replacement CGMs or insulin pumps for 5 years unless the equipment is lost, stolen, or irreparably damaged. The technology for CGMs and insulin infusion pumps is rapidly evolving to be more accurate and to work in tandem, with combination CGM/insulin pump systems that regulate the administration of insulin based on patient need and even in anticipation of a patient's need. The American Diabetes Association (ADA) has also noted that diabetes technology is rapidly changing, but there is no “one-size-fits-all” approach

to technology use in people with diabetes. Per the ADA, insurance coverage can lag behind device availability, patient interest in devices and willingness to change can vary, and providers may have trouble keeping up with newly released technology.⁹⁰

We believe that the technology for CGMs and insulin infusion pumps, which are often used in conjunction with CGMs, will continue to change very rapidly in future years. In the CY 2022 DMEPOS final rule, commenters noted the rapid pace in changes in technology for CGMs and diabetes equipment in general. We discussed how glucose monitoring technology is changing rapidly, and the Medicare fee schedule amounts for this equipment should not be limited solely to the technology that is currently on the market (86 FR 73901). Rickson et al. (2023) have noted that seventeen new CGM devices have been introduced to the market during the past decade.⁹¹ Rickson et al. (2023) have also noted that the time between innovation and market launch for diabetes technologies is relatively short. New models with new features come onto the market often and physicians who treat patients with diabetes are frequently monitoring the patient's needs and whether they are properly utilizing their glucose monitoring and insulin infusion equipment. CGMs are used to alert the patient about dangerous glucose levels and to set insulin delivery rates or shut off insulin delivery via their infusion pumps, if necessary. Thus, it is vital that patients are using equipment with the latest features and technology to ensure that the measuring and displaying of glucose levels is as accurate as possible, so that the best information is available for both patient activated and equipment activated changes in diet and insulin.

Both CGMs and insulin pumps require software updates to ensure they are functioning properly and are protected from hacking or cyberattacks. Klonoff (2019) has noted the need for diabetes devices to meet established, sound security baselines in design and throughout the product's lifecycle.⁹² Klonoff (2015) also notes that everything about the importance of robust cybersecurity that is true for medical devices in general is particularly true for diabetes devices. Thus, software updates are often necessary to ensure the cybersecurity of diabetes devices

and prevent adverse events.⁹³ The FDA, for instance, in 2019 warned patients and health care providers that certain insulin pumps were being recalled due to potential cybersecurity risks, and recommended that patients using these models switch their insulin pump to models better equipped to protect against these potential risks.⁹⁴ The FDA noted that the cybersecurity vulnerabilities could allow a person to over deliver insulin to a patient, leading to low blood sugar (hypoglycemia), or to stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis (a buildup of acids in the blood). For this recall, the manufacturer did not update the software, and instead opted to replace the device. However, Klonoff (2019) noted in response to this recall that insulin pump manufacturers should carefully review the cybersecurity of their products already on the market and provide software patches or updates when possible. Klonoff (2015) notes that patients with diabetes have a special need for impeccable data fidelity when they access their current glucose levels, glucose trend data, predictive data, insulin dosing records, hypoglycemia alerts, hyperglycemia alerts, blood pressure records, calorie information exercise records, and various reminders and timely notifications.

If beneficiaries are using rented CGM and/or insulin pump equipment, then the supplier of the rented equipment is responsible for making sure the equipment has the latest software updates and that the beneficiary is educated on how to use any updated software or features on the rented equipment. As the technology for these devices is rapidly changing and becoming more complex, beneficiaries may require more technical support from their supplier for any hardware or software issues. If either a CGM or insulin pump were to malfunction, for example provide inaccurate glucose measurements or insulin dosage, it would present an immediate health risk requiring urgent intervention. Suppliers of CGMs and insulin pumps must also adhere to frequent supply delivery schedules, as the supplies for these devices require frequent replacement so beneficiaries can maintain proper use of their equipment. Thus, we believe it is in the best interest of the beneficiary to classify CGMs and insulin pumps as items requiring frequent and substantial servicing.

We also believe that classifying CGMs and insulin pumps as items requiring frequent and substantial servicing, which would pay on a monthly rental basis in accordance section 1834(a)(3) of the Act under the fee schedule payment rules and under the DMEPOS CBP in accordance with regulations at 42 CFR 414.408(h)(8) and (j)(2)(iii), would have the additional benefit of allowing greater access to the latest technology equipment. This would eliminate beneficiary-ownership of the CGMs or insulin pumps for new patients but allow flexibility to switch to newer technology equipment and supplies more often than once every 5 years. The beneficiary would no longer be locked into the same CGM device or insulin pump technology for 5 years. Moreover, this would prevent the concerning scenario where beneficiaries rely on CGM or insulin pump technology that has lost manufacturer support, resulting in reduced software updates, discontinued security patches, or obsolete components. Such outdated technology poses significant risks to patient safety, data security, and therapeutic efficacy. By reclassifying these devices under the frequent and substantial servicing payment class, Medicare would ensure beneficiaries maintain access to current, fully supported technology that meets evolving safety and performance standards, which could ultimately reduce the potential for outdated device complications. The contract supplier of the rented equipment would be responsible for updating the software (including supporting the beneficiary with appropriately updating the software) and performing any other necessary maintenance and servicing of the equipment. The contract supplier would also be responsible for addressing recalls of the rented equipment and furnishing replacement equipment as necessary. As evidenced previously, the risk of recalls for this technology is real and serious if it were to occur. Under the DMEPOS CBP, the contract supplier would be required to furnish the CGM receiver or insulin pump ordered by the beneficiary's physician for use in treating diabetes, with the physician now being able to order changes in the equipment more frequently so that the beneficiary is able to take advantage of the latest equipment features and technology for managing diabetes. Over 98 percent of the cost of the CGM over 5 years is attributed to the frequent replacement of supplies and over 70 percent of the cost of the insulin pump over 5 years is

⁹⁰ <https://diabetes.org/sites/default/files/2023-09/dc22s007.pdf>.

⁹¹ <https://pubmed.ncbi.nlm.nih.gov/37306447/>.

⁹² <https://pmc.ncbi.nlm.nih.gov/articles/PMC6955451/>.

⁹³ <https://pmc.ncbi.nlm.nih.gov/articles/PMC4667325/>.

⁹⁴ <https://www.fda.gov/news-events/press-announcements/fda-warns-patients-and-health-care-providers-about-potential-cybersecurity-concerns-certain>.

attributed to the frequent replacement of supplies.

As discussed in section VII.F. of the preamble of this proposed rule, these items are currently delivered to beneficiaries from remote supplier locations that on average are hundreds of miles from the beneficiary's residence. In this section of the preamble of this proposed rule, we are proposing to establish a nationwide or regional CBP(s) for items such as CGMs and insulin pumps that may be phased in under future competitions. We are proposing to phase in payment on a monthly rental basis for CGMs and insulin pumps and all related supplies and accessories under the DMEPOS CBP. The monthly rental payments would continue as long as Medicare Part B coverage for the items continue. We are proposing to amend 42 CFR 414.412(b) to establish bid limits for CGMs and insulin infusion pumps for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). For CGMs, we are proposing that the bids submitted for rental of CGMs included as a lead item in a product category in a RID CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies for the CGM under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the CGM for the areas included in the RID CBP divided by 60 for the number of months over a 5-year period because the purchase fee schedule amount for the CGM receiver would cover use of the device for 5 years. Using 2025 fee schedule amounts to demonstrate how the bid limits would be calculated, for a nationwide CBP, the monthly fee schedule amount for the supplies for a non-adjunctive CGM (HCPCS level II code A4239) is \$267.92. The average of the 2025 fee schedule amounts for the purchase of a new, non-adjunctive CGM (HCPCS level II code E2103) with a reasonable useful lifetime of 5 years is \$286.03, which when divided by 60 generates a monthly payment of \$4.77. The 2025 bid limit for the bundled nationwide monthly rental payment for non-adjunctive, class II CGMs would therefore be \$272.69 (\$267.92 + \$4.77). Bidding entities competing to be a nationwide contract supplier for these items and other items in the same product category would need to submit bids that are lower than the bid limit (\$272.69 in this example) to be considered. Not factoring in reduced pricing under the DMEPOS CBP, beneficiary coinsurance payments would be the same as they are now for

the CGM receiver and monthly supplies, but the coinsurance payments for the CGM receiver would now be lower and spread out over 60 months rather than paid all at once in one lump sum.

Insulin infusion pumps were included under the DMEPOS CBP in nine CBAs from 2014 through 2016 as part of the product category for external infusion pumps. The fee schedule amounts for insulin infusion pumps and related supplies and accessories are adjusted based on the prices established under this round of the DMEPOS CBP. In accordance with current regulations at 42 CFR 414.210(g)(3), the fee schedule amounts for nonrural areas within the contiguous United States are adjusted based on 110 percent of the unweighted average of the nine SPAs in effect in 2016, which are updated on an annual basis in accordance with inflation update factors specified under 42 CFR 414.210(g)(4). The current nonrural 2025 fee schedule amount for rental of an insulin infusion pump (HCPCS level II code E0784) is \$543.08. The current nonrural 2025 fee schedule amount for the weekly supplies for an insulin infusion pump (HCPCS level II code A4224) is \$25.19, and the current nonrural 2025 fee schedule amount for one sterile syringe type cartridge supply for an insulin infusion pump (HCPCS level II code A4225) is \$3.38. By comparison, the 2025 adjusted fee schedule amounts for these items when furnished to beneficiaries in rural areas within the contiguous United States and areas outside the contiguous United States are much higher. The average of the 2025 fee schedule amounts for these areas is \$565.51 for HCPCS level II code E0784, \$28.50 for HCPCS level II code A4224, and \$3.54 for HCPCS level II code A4225. The higher fee schedule amounts established for these areas in accordance with regulations at 42 CFR 414.210(g)(2)(ii) and (iii) account for higher costs of suppliers furnishing items in these areas. However, these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations. The cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area. Additional shipping and handling costs may be incurred in some cases for items that are shipped to an area outside the contiguous United States such as Alaska, Hawaii, or Puerto Rico, but there are very few beneficiaries living in these areas compared to areas within the contiguous United States.

For insulin pumps, we are soliciting comments on our proposal that the bids submitted for rental of insulin infusion pumps included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under subpart D of this part for nonrural areas for a one month period plus the total rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part for nonrural areas divided by 60. The payment amount that would otherwise apply to the supplies and accessories for insulin pumps would be calculated using the nonrural weekly fee schedule amount for supplies paid using HCPCS level II code A4224 multiplied by four plus the nonrural fee schedule amount for nine sterile, syringe type cartridges paid using HCPCS level II code A4225. In 2024, Medicare paid for seven to nine units of A4225 per month on average for beneficiaries using insulin infusion pumps (HCPCS code E0784). We are soliciting comments on our proposal to use nine units for the one-month supply calculation as this represents the upper range currently being paid for by Medicare on a monthly basis and therefore builds in sufficient payment to ensure this quantity of supplies can continue to be furnished. Using 2025 fee schedule amounts to demonstrate how the bid limits would be calculated, for a nationwide CBP, the weekly nonrural 2025 fee schedule amount for the supplies for an insulin infusion pump (HCPCS level II code A4224) is \$25.19 and the monthly allowance is \$100.76 (\$25.19 multiplied by four). The nonrural 2025 fee schedule amount for one sterile syringe type cartridge for an insulin infusion pump (HCPCS level II code A4225) is \$3.38 and the monthly allowance is \$30.42 (\$3.38 multiplied by nine). The total nonrural 2025 rental payments for the insulin infusion pump over 13 months is \$5,702.34 and the monthly allowance is \$95.04 (\$5,702.34 divided by 60 for the number of months over 5 years). The 2025 bid limit for the bundled nationwide monthly rental payment for insulin pumps would therefore be \$226.22 (\$100.76 + \$30.42 + \$95.04). Bidding entities competing to be a nationwide contract supplier for these items and other items in the same product category would need to submit bids that are lower than the bid limit (\$226.22 in this example) to be considered. Not factoring in reduced pricing under the DMEPOS CBP, for beneficiaries that begin using insulin

pumps once the new rules would take effect, coinsurance payments would be approximately the same as they are now for the insulin pumps and monthly supplies and accessories, but the coinsurance payments for the insulin pump would now be lower and spread out over 60 months rather than over 13 months. For beneficiaries who own their insulin infusion pump, coinsurance payments would remain approximately the same unless they elect to obtain a new insulin pump, which would result in new monthly coinsurance payments that include payment for the pump as well as the supplies and accessories for the pump. For beneficiaries who are in the middle of the 13-month capped rental period at the time the pumps are phased into the DMEPOS CBP and the new rules would take effect, their coinsurance payments would increase since they would transition to the new monthly payments with coinsurance payments which would not be reduced by the amounts attributed to the monthly rental payments already made under the capped rental rules. However, the payments made overall should be reduced under the DMEPOS CBP and therefore the net change in beneficiary coinsurance after factoring in the competitive bidding price reductions should be a reduction in cost sharing across the board.

We are soliciting comments on our proposal to make corresponding changes to the regulations for determining competitive bidding payment amounts for non-lead items at 42 CFR 414.416(b) to reflect how to use the bid amounts to calculate the monthly payments for the non-lead items. We are soliciting comments on our proposal that the SPAs for the rental of a non-lead item in a product category including CGMs and insulin infusion pumps would be established in a manner that is consistent with how SPAs are established currently for non-lead items in accordance with § 414.416(b). Currently the SPA for a non-lead item is equal to the SPA for the lead item multiplied by the ratio of the 2015 fee schedule amount for the non-lead item for each area to the 2015 fee schedule amount for the lead item for the same area. Our methodology for calculating SPAs for non-lead items is based on the difference in the unadjusted fee schedule amounts for the lead item compared to the non-lead item. We use the 2015 fee schedule amounts for this purpose as this was the last year the DMEPOS fee schedule amounts were not adjusted based on pricing from the DMEPOS CBP. The fee schedule amounts for insulin pumps

were adjusted using pricing from the DMEPOS CBP. Given the possibility that CGMs and insulin pumps would be included in the same product category (with CGMs being the lead item), we are proposing to calculate what the unadjusted fee schedule amounts for CGMs would have been in 2015 so we can compare that to the unadjusted fee schedule amounts for insulin pumps from 2015 for the purpose of calculating the non-lead item SPAs for the insulin pumps. We are soliciting comments on our proposal that the 2015 fee schedule amounts for the monthly rental of a class II CGM would be calculated using the 2025 fee schedule amounts and removing the fee schedule update factors from 2016 through 2025 to convert the 2025 fee schedule amounts to 2015 fee schedule amounts. We are also soliciting comments on our proposal to then add the 2015 fee schedule amount for the monthly supplies for a class II CGM to the average of the 2015 fee schedule amounts for the purchase of a new class II CGM divided by 60 for the areas included in the CBA. The conversion of the fee schedule amounts to 2015 fee schedule amounts is necessary because the methodology under § 414.416(b) uses the ratio of unadjusted fee schedule amounts from 2015 (the year before the DMEPOS CBP was implemented) between the non-lead item and the lead item multiplied by the SPA for the lead item to establish the SPA for the non-lead item and because Medicare did not start paying for class II CGMs until after 2015.

We are soliciting comments on our proposal that the 2015 fee schedule amounts for the monthly rental of an insulin infusion pump would be calculated using the average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the nonrural areas included in the RID CBP, and then adding the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the nonrural areas included in the RID CBP plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by four for the nonrural areas included in the RID CBP. The average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 equals the total rental payments made over the 13-month capped rental period.

DME items that are class III devices under the Federal Food, Drug, and Cosmetic Act are excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act. Federal Food, Drug, and

Cosmetic Act classifies medical devices into three classes based on the level of control needed to ensure their safety and effectiveness. Class I devices are considered low risk and are subject to general controls. Class II devices are considered moderate risk and are subject to general controls and special, device-specific controls. Class III devices are considered high risk and are subject to general controls and premarket approval, the most stringent device marketing application required by the FDA. Class III CGMs are excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act. In addition, there are some insulin infusion pumps that are approved by the FDA for use in conjunction with a class III CGM. In instances where an insulin infusion pump that has been approved by the FDA for use in conjunction with a class III CGM is being used in conjunction with a class III CGM, we believe the insulin pumps should be excluded from the DMEPOS CBP as well. We are soliciting comments on this proposal to exclude insulin pumps used in conjunction with a class III CGM from the DMEPOS CBP under these circumstances.

a. Medicare Part B Payment for Class III CGMs and Insulin Pumps Used in Conjunction With Class III CGMs

Because class III CGMs are excluded from the DMEPOS CBP by statute and we are proposing that insulin infusion pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP, we believe it is necessary to use the authority at section 1842(b)(8) of the Act to limit the payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to the level established for class II CGMs and insulin infusion pumps that are used alone or in conjunction with a class II CGM under the CBP.

As discussed previously, class III CGMs are statutorily excluded from the DMEPOS CBP and are less accurate than class II CGMs. We believe that lowering the Medicare payment amounts for class II CGMs and class II insulin infusion pumps under the DMEPOS CBP and maintaining higher payments for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs under the Medicare fee schedule for DME would encourage a shift from more accurate class II CGMs and insulin pumps to less accurate class III CGMs and insulin pumps. To prevent this from happening, we are therefore proposing to adjust the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class

III CGM to equal the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP.

In order to make proposals to use the authority at section 1842(b)(8) of the Act to adjust the fee schedule payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs, the process mandated by section 1842(b)(9) of the Act and its implementing regulations at 42 CFR 405.502(g) and (h) apply. We expect that reductions in the payment amounts for class II CGMs and insulin pumps under the DMEPOS CBP would result in payment amounts for these items that are more than 15 percent below the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. We are proposing that in situations where the Medicare bundled monthly rental payment amounts for class II CGMs and/or insulin pumps under the DMEPOS CBP are more than 15 percent lower than the Medicare bundled monthly rental fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs, that the Medicare bundled monthly rental fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs would be adjusted so that they are equal to the bundled monthly rental payment amounts established under the DMEPOS CBP for the class II CGMs and insulin pumps.

b. Medicare Part B Fee Schedule Payments for Class II CGMs and Insulin Pumps

We are not proposing to utilize the inherent reasonableness authority at 42 CFR 405.502(g) and (h) to adjust the prices of class II CGMs or insulin infusion pumps paid under Medicare Part B. In accordance with section 1834(a)(1)(F)(i) of the Act, the payment basis for class II CGMs and insulin infusion pumps furnished in a CBA is the payment basis determined under the CBP. In accordance with section 1834(a)(1)(F)(ii) and (iii) of the Act, we soliciting comments on our proposal that the fee schedule amounts for class II CGMs or insulin infusion pumps would be adjusted based on information on the payment determined under the CBP for the rental of the equipment using the methodology established in regulations at 42 CFR 414.210(g). For the same reasons discussed previously for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs, in any situation where payment for class II CGMs or insulin infusion pumps not used in conjunction with class III CGMs are paid for in

accordance with the fee schedule payment basis at section 1834(a)(1)(B) of the Act in an areas that is not a CBA following the phase in of these items under the DMEPOS CBP, these items would be classified as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act.

3. Provisions of the Proposed Regulation

a. Payment for CGMs and Insulin Pumps Furnished by Contract Suppliers Under the DMEPOS CBP and by Grandfathered Suppliers

We are soliciting comments on our proposal to make payment on a monthly rental basis for CGMs and insulin pumps furnished by contract suppliers under the DMEPOS CBP and by non-contract, grandfathered suppliers in accordance with section 1847(a)(4) of the Act, which allows rental agreements for covered CGMs and insulin pumps entered into before the application of the DMEPOS CBP to be continued once the items are phased in under the program, on a bundled monthly rental basis in accordance with regulations at 42 CFR 414.408(h)(8) and (j)(2)(iii), respectively. Payment would be based on SPAs for the bundled, monthly rental of the items for both the contract suppliers and non-contract grandfathered suppliers. Separate payment for supplies and accessories for the equipment would no longer be made and contract suppliers would retain ownership of the rental equipment.

b. Bids Submitted for Class II CGMs or Insulin Pumps Included as a Lead Item in a Product Category for the First Time

We are soliciting comments on our proposal to amend the regulations at 42 CFR 414.412 to specify that the bids submitted for rental of CGMs included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies for the equipment under subpart D plus the average of the purchase fee schedule amounts that would otherwise apply to the CGM (HCPCS level II code E2103) for the areas included in the CBA divided by 60.

We are also soliciting comments on our proposal to amend the regulations at 42 CFR 414.412 to specify that the bids submitted for rental of insulin infusion pumps included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under subpart D of this part for nonrural areas for a one month

period plus the total rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part for nonrural areas divided by 60. The payment amount that would otherwise apply to the supplies and accessories for insulin pumps would be calculated using the nonrural weekly fee schedule amount for supplies paid using HCPCS level II code A4224 multiplied by four plus the nonrural fee schedule amount for nine sterile, syringe type cartridges paid using HCPCS level II code A4225.

c. Separate Payment for Replacement of Supplies and Accessories for Class II CGMs and Insulin Pumps Owned by the Beneficiary at the Time These Items Are Phased in Under the DMEPOS CBP for the First Time in a CBA

We are soliciting comments on our proposal that separate payment can continue to be made under the DMEPOS CBP for replacement of supplies and accessories necessary for the effective use of a CGM or insulin pump owned by the beneficiary at the time these items are phased in under the DMEPOS CBP for the first time in a CBA. The beneficiary would continue to own the CGM or insulin pump and would receive replacement supplies and accessories for the CGM or insulin pump from a contract supplier for the CBA where they reside. This is a temporary transition rule that would phase out once all beneficiary-owned CGMs or insulin pumps are replaced by rented equipment after they are lost, stolen, irreparably damaged, have been in use for the equipment's 5-year reasonable useful lifetime. During this transition period, SPAs for the monthly supplies and accessories for a beneficiary-owned CGM or insulin pump would be established in accordance with the payment rules for non-lead items under proposed regulations at 42 CFR 414.416(b)(4) summarized in section VII.G. As noted previously, we are proposing that the beneficiary would have the option to transition from the use of the equipment they own to use of a rented CGM and/or insulin pump from a contract supplier at any time.

d. Calculating SPAs for Class II CGMs, Insulin Pumps, and Supplies and Accessories for Beneficiary-Owned Class II CGMs and Insulin Pumps Furnished as Non-Lead Items in a Remote Item Delivery CBP

We are soliciting comments on our proposal to amend existing regulations at 42 CFR 414.416(b) by adding paragraph (4) to establish the

methodologies for calculating the SPAs for items furnished as non-lead items under product categories in a RID CBP for the monthly rental of class II CGMs, the monthly rental of insulin infusion pumps, the monthly supplies for a beneficiary-owned class II CGM, and the monthly supplies and accessories for a beneficiary-owned insulin infusion pump in a manner consistent with existing regulations at 42 CFR 414.416 which bases the SPAs for the lead item in a product category and CBA on the bids submitted and the SPAs for each non-lead item in the same product category and CBA based on the 2015 fee schedule amount for the non-lead item divided by the 2015 fee schedule amount for the lead item multiplied by the SPA for the lead item.

We are also soliciting comments on our proposed methodologies for calculating the 2015 fee schedule amounts for the monthly rental of class II CGMs, the monthly rental of insulin infusion pumps, the monthly supplies for a beneficiary-owned class II CGM, and the monthly supplies and accessories for a beneficiary-owned insulin infusion pump under paragraphs (i) through (iv) of § 414.416(b)(4) as follows:

- The 2015 fee schedule amounts for the monthly bundle that includes a CGM and supplies are calculated using the 2025 fee schedule amounts and removing the fee schedule update factors from 2016 through 2025, and then adding the 2015 fee schedule amount for the supplies to the average of the 2015 fee schedule amounts for the purchase of a new CGM divided by 60 for the areas included in the RID CBP.
- The 2015 fee schedule amount for the monthly supplies for a CGM owned by a beneficiary is calculated using the 2025 fee schedule amount and removing the fee schedule update factors from 2016 through 2025.
- The 2015 fee schedule amounts for the monthly bundle that includes an insulin infusion pump and supplies and accessories are calculated using the average 2015 nonrural fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the areas included in the RID CBP, and then adding the average 2015 nonrural fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the areas included in the RID CBP plus the average 2015 nonrural fee schedule amounts for the weekly insulin pump supplies multiplied by four for the areas included in the RID CBP.
- The 2015 fee schedule amounts for the monthly bundle that includes the supplies and accessories for an insulin

infusion pump owned by a beneficiary is calculated using the average 2015 nonrural fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the areas included in the RID CBP plus the average 2015 nonrural fee schedule amounts for the weekly insulin pump supplies multiplied by four for the areas included in the RID CBP.

e. Insulin Infusion Pumps Used in Conjunction With Class III CGM

We are soliciting comments on our proposal that in instances where an insulin infusion pump that has been approved by the FDA for use in conjunction with a class III CGM is being used in conjunction with a class III CGM, both the insulin pump and the class III CGM would be excluded from the DMEPOS CBP.

f. Payment Reclassification of CGMs and Insulin Infusion Pumps

We are soliciting comments on our proposal to reclassify all CGMs and insulin infusion pumps paid for in accordance with the rules at section 1834(a) of the Act as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act and regulations at 42 CFR 414.222 for the reasons highlighted in section VII.A.

g. Special Payment Limits for Class III CGMs and Insulin Infusion Pumps Used in Conjunction With Class III CGMs

With regard to class III CGMs excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act and insulin infusion pumps used in conjunction with class III CGMs, we are soliciting comments on our proposal to use the authority at section 1842(b)(8) of the Act to establish special payment limits for these items if the bundled monthly rental amounts for class II CGMs and/or insulin infusion pumps established under the DMEPOS CBP are at least 15 percent below the bundled monthly rental fee schedule amounts for the class III CGMs and related supplies and insulin infusion pumps and related supplies established in accordance with section 1834(a)(3) of the Act. In accordance with § 405.502(g)(1)(ii), a payment amount can be considered grossly excessive and can be adjusted using the authority under section 1842(b)(8) of the Act and process outlined in section 1842(b)(9) of the Act and regulations at § 405.502(g) if it is determined that an overall payment adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount. We believe it is realistic to conclude that suppliers

of class III CGMs and insulin pumps used in conjunction with class III CGMs would be able to furnish class III CGMs and insulin pumps at the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP. We believe the bids obtained for class II CGMs and insulin pumps under the DMEPOS CBP that are determined to be bona fide is valid and reliable data for use in establishing realistic payment amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. We believe it would not be equitable to pay more for a class III CGM and/or insulin pump than a class II CGM and/or insulin pump because class III CGMs are less accurate than class II CGMs. We believe that a reduction in payment for class II CGMs and/or insulin pumps under the DMEPOS CBP of greater than 15 percent indicates that the fee schedule amounts for these items were grossly excessive. We believe that if the fee schedule amounts for class III CGMs and/or insulin pumps used in conjunction with class III CGMs are more than 15 percent higher than the payment amounts established for class II CGMs and/or insulin pumps under the DMEPOS CBP, that the fee schedule amounts for class III CGMs and/or insulin pumps used in conjunction with class III CGMs are grossly excessive. We believe that similar conclusions can be made regarding supplies and accessories used in conjunction with class III CGMs and insulin pumps used in conjunction with class III CGMs owned by the beneficiary at the time class II CGMs and insulin pumps are phased in under the DMEPOS CBP. We believe it is realistic and equitable to establish the payment amounts for these supplies and accessories based on the payment amounts established under the DMEPOS CBP for supplies and accessories used in conjunction with beneficiary-owned class II CGMs and insulin pumps. Separate payment for supplies and accessories for beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs would no longer be made once the 5-year reasonable useful lifetime for the beneficiary-owned equipment has expired. Medicare payment for class II CGMs and insulin pumps would be established under the DMEPOS CBP and therefore the fee schedule amounts for these items would not be adjusted using the authority under section 1842(b)(8) of the Act. We are also soliciting comments on our proposal that the monthly rental fee schedule payment amounts for class III CGMs would be limited to the monthly rental SPAs established for class II CGMs under the

DMEPOS CBP. We are proposing that the monthly rental fee schedule payment amounts for insulin pumps used in conjunction with class III CGMs would be limited to the monthly rental SPAs established for insulin pumps under the DMEPOS CBP. We are soliciting comments on our proposal that the monthly fee schedule payment amounts for supplies used in conjunction with beneficiary-owned class III CGMs would be limited to the monthly SPAs established for supplies used in conjunction with beneficiary-owned class II CGMs under the DMEPOS CBP. We are also soliciting comments on our proposal that the monthly fee schedule payment amounts for supplies and accessories used in conjunction with beneficiary-owned insulin pumps that are used in conjunction with class III CGMs would be limited to the monthly SPAs established for supplies and accessories used in conjunction with beneficiary-owned insulin pumps under the DMEPOS CBP.

In accordance with section 1842(b)(8)(C)(ii) of the Act, we believe that the payment amounts for class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used in conjunction with beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs do not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs. If the fee schedule payment amounts for class II CGMs and insulin pumps are reduced by more than 15 percent under the DMEPOS CBP, then this is an indication that the cost of furnishing these items is significantly lower than the fee schedule amounts for these items. We believe the same would also be true for class III CGMs and insulin pumps used in conjunction with class III CGMs as we believe the acquisition and production costs of class III CGMs and insulin pumps used in conjunction with class III CGMs are similar to the acquisition and production costs of class II CGMs and insulin pumps that are not used in conjunction with class III CGMs. The equipment is used for the same purpose and includes the same covered features of continuous glucose monitoring and pumping of insulin. In the case of CGMs, manufacturers of class II CGMs have invested in making the equipment more accurate and therefore the acquisition and production costs of class II CGMs may be higher than the acquisition and production costs of class III CGMs. Insulin pumps used in

conjunction with class III CGMs perform the same covered function as insulin pumps that are not used in conjunction with class III CGMs. We believe it is therefore realistic and equitable to pay no more for a class III CGM or insulin pump used in conjunction with a class III CGM than the payment amount established under the DMEPOS CBP for a class II CGM or insulin pump.

In accordance with section 1842(b)(9)(A) of the Act, the Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under section 1842(b)(8)(B) of the Act to reduce payment for the item or service by more than 15 percent for a year. The corresponding regulations at 42 CFR 405.502(g)(3) require CMS to publish in the **Federal Register** proposed and final notices announcing a special payment limit before it adopts the limit. Regarding special payment limit adjustments greater than 15 percent of the payment amount, 42 CFR 405.502(h)(3) requires that before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consult with representatives of the supplier industry likely to be affected by the change in the payment amount. CMS must publish in the **Federal Register** the proposed and final notices of a special payment limit before it adopts the limit. Therefore, as part of this proposed rule, we are soliciting comments from representatives of suppliers or other individuals who furnish class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used in conjunction with beneficiary-owned class III CGMs or beneficiary-owned insulin pumps used in conjunction with class III CGMs on the proposed payment reductions for these items and services.

In accordance with section 1842(b)(9)(B)(iii) of the Act and the corresponding regulations at 42 CFR 405.502(h), when the proposed special payment limit adjustments are greater than 15 percent of the payment amount within a year, CMS must consider in a proposed and final notice the potential impacts of the proposed payment reductions on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates. We propose that the payment amounts for class III CGM suppliers and manufacturers would be reduced, but at the same rate as class II CGM suppliers and manufacturers, avoiding the potential impact of

providing a financial incentive to increase access to less accurate class III CGMs and decrease access to more accurate class II CGMs. We are soliciting comments on the proposed reductions in payment and believe they would level the playing field and avoid providing class III CGM suppliers and manufacturers with an unfair advantage. The quality of CGMs in general would not be impacted and if anything would be preserved since contract suppliers would not have a financial incentive to furnish class III CGMs in place of class II CGMs. Class III CGMs currently make up about 25 percent of total allowed charges for CGMs under Medicare and so any impact resulting from the proposed reductions in payment for class III CGMs would be significantly less than any impact resulting from payment reductions for class II CGMs under the DMEPOS CBP. We therefore believe the proposed payment special payment limits and special payment method for class III CGMs and insulin pumps would have a minimal impact on the CGM and insulin pump industry in general. The impact on access to CGMs in general as a result of the special payment limit and method of payment would also therefore be minimal. Beneficiary cost-sharing for class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used with beneficiary-owned class III CGMs and insulin pumps would be reduced as a result of the special payment limit and method. Program savings would also be achieved for these items. Assignment rates and participation rates would likely not be affected as a result of the proposed special payment limits and payment method as payment for the cost of furnishing class III CGMs and insulin pumps on assignment-related basis would be based on the payment established under the DMEPOS CBP based on bids submitted by bidding entities for furnishing class II CGMs and insulin pumps on an assignment-related basis for all beneficiaries under the DMEPOS CBP. Under the DMEPOS CBP, contract suppliers of class II CGMs and insulin pumps are required to accept assignment of all claims for furnishing these items by section 1847(b)(5)(C) of the Act. Suppliers of class III CGMs know that if they do not accept assignment of the claims for the class III CGMs or insulin pumps used in conjunction with class III CGMs, their customers could switch to a class II CGM supplier or supplier of an insulin pump that is not used in conjunction with a class III CGM to avoid the

financial liability associated with unassigned claims.

h. Advance Billing for Three Months of Rental

Payment for supplies and accessories used with a beneficiary-owned class II or class III CGM or a beneficiary-owned

insulin infusion pump is currently made for these items in quantities necessary for a 90-day period. We are soliciting comments on a proposal to allow contract suppliers to bill for up to 3 months of rental for CGMs and insulin infusion pumps in advance to be consistent with this policy.

i. Summary of Proposed Provisions

The following is a summary list of the proposed provisions under this section for which we are soliciting comments:

BILLING CODE 4120-01-P

Proposed Payment Rules for Class II CGMs and Insulin Infusion Pumps that are not used in Conjunction with Class III CGMs and are Furnished under the DMEPOS CBP

- Payment would be on a continuous rental basis with payment for use of the equipment and all necessary supplies and accessories included in monthly rental payments made for up to 3 months in advance. Contract suppliers retain ownership of the rented equipment.
- Payment for replacement of supplies and accessories only for beneficiary-owned equipment at the start of the program in a CBA would continue to be made as separate items under the product category until the beneficiary-owned equipment is replaced because it is lost, stolen, irreparably damaged, has exceeded the reasonable useful lifetime (as defined at 42 CFR 414.210(f)(1)), or in cases where the beneficiary elects to obtain newer equipment. Beneficiaries who own their equipment and want to replace the equipment with new equipment would have the option to obtain new rented equipment from a contract supplier at any time.
- Rental agreements for equipment in place at the time the new rules are phased in under a CBA may be continued under the existing grandfathering rules for items requiring frequent and substantial servicing. Payment to grandfathered suppliers would be based on the monthly rental payment amounts established under the DMEPOS CBP.
- If the class II CGM is the lead item in the product category the first time the new payment rules are implemented in a CBA, the bid limit would be established based on the monthly fee schedule amount for the replacement supplies plus the average purchase new fee schedule amount for the CGM for the areas included in the CBA divided by 60.
- If the insulin pump is the lead item in the product category the first time the new payment rules are implemented in a CBA, the bid limit would be established based on the average weekly fee schedule amount for the replacement supplies and accessories for the areas included in the CBA multiplied by four, plus the average fee schedule amount for the syringe type cartridge for the areas included in the CBA multiplied by nine, plus the average of the total rental fee schedule amounts over 13 months for the insulin pump for the areas included in the CBA divided by 60.

Proposed Payment Rules for Class III CGMs and Insulin Infusion Pumps used in Conjunction with Class III CGMs (to be effective on the date the new rules for Class II CGMs and Insulin Pumps are Implemented)

- All CGM and insulin pump equipment would be classified as items requiring frequent and substantial servicing for the purposes of implementing the payment rules under section 1834(a) of the Act. Payment would be on a continuous rental basis with payment for use of the equipment and all necessary supplies and accessories included in monthly rental payments made for up to 3 months in advance. Contract suppliers retain ownership of the rented equipment.
- Special payment limits would be established in accordance with regulations at 42 CFR 405.502(g) and sections 1842(b)(8) and (9) of the Act to limit payment for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs as well as supplies and accessories for beneficiary owned class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to the payment amounts established for class II CGMs and insulin infusion pumps as well as supplies and accessories for beneficiary owned class II CGMs and insulin infusion pumps under the DMEPOS CBP.
- Payment for replacement of supplies and accessories only for beneficiary-owned equipment would continue to be made as separate items after the implementation date of the CBP until the beneficiary-owned equipment is replaced because it is lost, stolen, irreparably damaged, is more than 5 years old, or in cases where the beneficiary elects to obtain newer equipment.

BILLING CODE 4120-01-C

H. Revising the Submission of Financial Document Requirements for the DMEPOS CBP

1. Background

Section 1847(b)(2) of the Social Security Act (Act) outlines the conditions for awarding a DMEPOS CBP supplier contract. Section 1847(b)(2)(A)(ii) of the Act specifies that CMS may not award a contract to any entity under the competition conducted in a competitive acquisition area unless the Secretary finds that the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

Section 1847(a)(1)(F) of the Act applies to supplier feedback on missing financial documentation. Section 1847(a)(1)(F)(iv) of the Act defines a covered document as “a financial, tax, or other document required to be submitted by a bidding entity as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.” If a covered document is submitted to CMS by the CDRD and one or more covered documents is missing, per section 1847(a)(1)(F)(i)(I) of the Act, the

Secretary is required to provide notice no later than 45 days (in the first round of competition acquisition program as described in subparagraph (B)(i)(I)) or 90 days (in subsequent rounds of such programs) after the CDRD. Per section 1847(a)(1)(F)(ii)(I) and (II) of the Act, the CDRD is the date that is 30 days before the final date specified by the Secretary for submission of bids under the program or the date that is 30 days after the first date specified by the Secretary for submission of bids under the program.

Section 1847(a)(1)(F)(i)(II) of the Act specifies that the Secretary may not reject the bid submission on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidding entity is submitted to the Secretary no later than 10 business days after the date of such notice. Per the limitations of this process in section 1847(a)(1)(F)(iii)(I)–(IV) of the Act, it applies only to the timely submission of covered documents, does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether the documents meet applicable requirements, shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II) of section 1847(a)(1)(F) of

the Act, and shall not be construed as permitting a bidding entity to change bidding amounts or to make other changes in a bid submission.

In the 2006 proposed rule (71 FR 25675), CMS proposed that, as part of the bid selection process, the Request for Bids (RFB) will identify the specific information CMS requires to evaluate bidding entities, which may include: a bidding entity’s bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency.

In the 2007 final rule (72 FR 18037), CMS responded to comments acknowledging that the proposed financial documentation would be too burdensome, particularly for small suppliers. Additionally, the final rule (72 FR 18037) stated that in order to obtain a sufficient amount of information about each bidding entity, while minimizing the burden on both bidding entities and the bid evaluation process, CMS would require, for the initial round of competition (what is referred to as the Original Round 1), bidding entities to submit certain schedules from its tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the

supplier is publicly traded), certain specified financial statement reports such as cash flow statements, and a copy of its current credit report with a numerical credit score and/or rating, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian, Equifax, or TransUnion.

The covered documents described in the 2007 final rule were also outlined in the Original Round 1 RFB in accordance with 42 CFR 414.414(d), which states that each bidding entity must submit along with its bid⁹⁵ the applicable covered documents specified in the RFB. For all subsequent rounds after the Original Round 1 (Round 1 Rebid through Round 2021), the covered documents were specified in the RFB for each applicable round, which included the tax return, income statement, balance sheet, statement of cash flows, and a credit report with a numerical credit score and/or rating.

On January 16, 2009 we published in the **Federal Register** an interim final rule titled “Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)” (hereafter referred to as the “2009 interim final rule”) (74 FR 2876) that codified the process for reviewing covered documents aforementioned in § 414.414(d)(2).

Additionally, the 2006 proposed rule (71 FR 25675) and the 2007 final rule (72 FR 18037) stated that applying financial standards would assist CMS in assessing the expected quality of bidding entities, estimating the total potential capacity of winning contract suppliers, and ensuring that winning contract suppliers are able to continue to serve market demand for the duration of their contracts. We also stated that we would generally require that bidding entities submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a supplier is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period (72 FR 18037).

2. Current Issues

CMS is soliciting comments on a proposal to reduce the number of covered documents that bidding entities are required to submit during the bid window and modify how CMS will evaluate and determine the financial standards for each bidding entity, while still ensuring that a bidder offered a contract is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. We believe a bidding entity's credit score is an up-to-date, reliable, and sufficient measure of the entity's ability to serve market demand for the duration of the contract performance period because data from Round 2021 shows that only 1.7 percent of bidding entities' Tax Identification Numbers (TINs) had a lower credit score, and 21.1 percent of those bidding entities' TINs no longer had an active location (otherwise known as a Provider Transaction Access Number (PTAN)) as of December 28, 2023—the specifics for how these percentages were calculated are described later in this section. This proposal would also align with CMS's focus on continuous process improvement and increase operational and policy efficiency and effectiveness for all aspects of the DMEPOS CBP, while ensuring the integrity of the program is not compromised.

Specifically, CMS is soliciting comments on a proposal to reduce the burden of submitting financial documentation from bidding entities by no longer requiring the submission of a tax return extract, income statement, balance sheet, and statement of cash flows. However, CMS would still require bidding entities to submit a credit report with a numerical credit score or rating from one of the approved credit reporting agencies during the bid window. This proposal will significantly reduce the burden on bidding entities as they will only be required to submit a credit report with a numerical credit score or rating.

To further clarify, CMS is soliciting comments on a proposal to require a bidding entity submit a business credit report with a numerical credit score or rating. However, there may be instances where the bidding entity does not have a business credit report with a numerical credit score or rating if the entity has not been in operation long enough to generate a numerical score or rating. Bidding entities that are unable to generate a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score, in

addition to a personal credit report with a numerical credit score or rating from the supplier's Authorized Official or Delegated Official listed in CMS' PECOS. If the individual's name on the credit report is not an Authorized Official or Delegated Official listed in PECOS, CMS will deem the personal credit report with a numerical credit score or rating unacceptable, and the supplier will not be eligible for a DMEPOS CBP supplier contract.

Commonly owned and/or commonly controlled bidding entities are prohibited from competing against themselves when submitting bids in the same competition. Therefore, when registration opens, commonly owned and/or commonly controlled bidding entities must register one time with a primary Provider Transaction Access Number (PTAN) which designates the primary location in the bidding system and identifies the entity responsible party for all contractual requirements (that is, the bidding entity). When the bid window opens, the bidding entity must submit one bid that includes all commonly owned and/or commonly controlled locations that would furnish the lead item and all non-lead items in the same competition. The legal business name (LBN) for the primary location will auto-populate in the bidding system on the Business Organization section of Form A. This LBN must be the same LBN on your bid surety bond(s). If awarded a contract, CMS will contract with the legal business entity identified by the LBN for the primary location.

Given the longstanding policy as specified in the Request for Bid Instructions, commonly owned and/or commonly controlled supplier organizations that submit separate bids for the same competition will have their bids for the competition disqualified.

Similarly, as specified in the Request for Bid Instructions the bidding entity must attest in the bidding system that it is submitting one bid that includes all commonly owned and/or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

The bidding entity must upload a copy of its business' credit report showing a numerical credit score or rating, the entity's name, the entity's name, and the date that the credit report was prepared not earlier than 90 calendar days prior to the opening of the bid window in a form and manner specified by CMS. If the numerical credit score or rating is generated separately from the credit report, the bidding entity's name and the date it was prepared must be shown on both

⁹⁵ Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

the credit report and the numerical credit score or rating.

Bidding entities that are unable to generate either a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score or rating, and would be further required to submit a personal credit report with a numerical credit score or rating from the supplier's Authorized Official or Delegated Official listed in CMS' PECOS.

This proposal would also reduce the resources needed to review the submissions of covered documents and will streamline the evaluation of financial standards, while ensuring that the entities that are awarded a contract are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. In addition, bidding entities may have improved opportunity to receive a contract offer because they will no longer be disqualified due to errors in their submitted financial statements and tax return extracts, which would disqualify a bidding entity in previous rounds.

CMS analyzed all credit reports with a numerical credit score or rating from bidding entities that submitted a complete bid⁹⁶ in the most recent round of the DMEPOS CBP (Round 2021), as well as Medicare supplier enrollment data, that indicated if a bidding entity's credit report with a numerical credit score or rating is sufficient in determining the financial stability of a bidding entity and if they can fulfill its contractual obligations for the duration of the contract performance period. Specifically, CMS first determined

which bidding entities submitted a complete bid for all product categories competed in Round 2021 (the analysis was not limited to the bidding entities that submitted a complete bid for the OTS Back Brace and OTS Knee Brace product categories that were included in Round 2021) to determine how many bidding entities (identified by TIN) were included on the submission of a complete bid. CMS identified 1,153 bidding entities' TINs and first determined how many of them were still in business as of December 28, 2023, by utilizing data from PECOS.

CMS found that 88.2 percent (1,017 of 1,153) of bidding entities' TINs still had at least one PTAN as of December 28, 2023. Because the Round 2021 bid window was open from July 16, 2019, through September 18, 2019, this means that 88.2 percent of the 1,153 Round 2021 bidding entities had at least one PTAN that was still active/enrolled as a Medicare-enrolled supplier more than 4 years later, supporting the fact that most DMEPOS CBP suppliers are able to stay in business for the duration of a DMEPOS CBP supplier contract performance period which cannot exceed 3 years. CMS would like to note that this timeframe was during the COVID-19 pandemic indicating that companies that submit a bid to participate in the DMEPOS CBP appear to typically be financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period as most were able to stay in business during/after the pandemic.

Additionally, CMS analyzed the numerical credit score and/or rating on the credit report for each bidding entity's TIN to determine where the majority of bidding entities fell within CMS' five-tier credit scoring system. Table 49 outlines the 5-tier credit scoring system, and table 50 provides a description of each business credit report, which were both included in the

Round 2021 Financial Scoring Methodology Fact Sheet. Table 49 (Credit Report Scoring List) contains a list of credit reports and credit scores or ratings, as well as the associated tiers and scoring. All bidding entities were required to submit a credit report with a numerical credit score and/or rating on the Credit Report Scoring List and depending on the bidding entity's credit score or rating, the bidding entity fell within a specific tier and received a correlating score of either 4, 8, 12, 16, or 20 points, where a score of 4 is the worst and 20 is the best. Historically, a bidding entity could receive a maximum score of 20 points from its credit report with a numerical credit score or rating and the remaining 80 points (equating to 100 total points) from its tax return extract, income statement, balance sheet, and statement of cash flows, which will no longer be applicable in future rounds of the DMEPOS CBP per this proposal. Specifically, the remaining 80 points were determined by computing each standard accounting ratio for each bidding entity and arraying the bidding entities from the best to worst ratio. Bidding entities in the bottom 10 percent of the array for a specific ratio received a score of 1 (worst) and suppliers in the top 10 percent of the array for a specific ratio received a score of 7.6 or 9.6 (best). The remaining bidding entities' (that is, those falling in-between the top and bottom 10 percent) scores were prorated between 1 and 7.6/9.6. Of the 10 standard accounting ratios, eight have a maximum score of 7.6, while two have a maximum score of 9.6. This information was contained in the Round 2021 Financial Scoring Methodology Fact Sheet.

Table 49 includes a detailed description of each business credit report to help suppliers understand the difference between the business credit reports.

⁹⁶ A complete bid is defined as a supplier submitting an approved Form A and a certified Form B in the DMEPOS Bidding System, as well as uploading at least one bid surety bond and at least one of the required financial documents in the DMEPOS CBP's secure portal, by the close of the window.

TABLE 49: CREDIT REPORT SCORING LIST

Credit Report Name	Tiers and Scoring				
	20	16	12	8	4
Business Credit Reports					
Equifax - Business Payment Index	100-90	89-80	79-60	59-40	39-1
Equifax - Business Credit Risk Score	992-697	696-649	648-575	574-492	491-101
Equifax - Business Delinquency Score	662-477	476-446	445-400	399-347	346-101
Equifax - Business Failure Risk Score	1610-1488	1487-1366	1365-1244	1243-1122	1121-1000
Experian - Intelliscore Credit Ranking Score/Business Credit Score	100-76	75-51	50-26	25-11	10-1
Experian - Financial Stability Risk Class	1	2	3	4	5
Dun & Bradstreet - Delinquency Predictor Risk Class	1	2	3	4	5
Dun & Bradstreet - Commercial Credit Score	670-580	579-530	529-481	480-453	452-101
Dun & Bradstreet - Supplier Evaluation Risk Rating	1-2	3-4	5-6	7-8	9
Dun & Bradstreet - Paydex	100-80	79-62	61-46	45-32	31-1
Dun & Bradstreet - Financial Stress Class	1	2	3	4	5
Standard & Poor's	AAA	A	BBB	BB	CC
	AA			B	C
				CCC	D
Personal Credit Reports					
Experian - Plus Score	830-721	720-681	680-630	629-480	479-330
Equifax - Score	850-760	759-725	724-660	659-560	559-280
Transunion - Score	850-781	780-661	660-601	600-501	500-300
FICO SCORE - Experian, Equifax, TransUnion	850-781	780-661	660-601	600-501	500-300
Vantage	850-781	780-661	660-601	600-501	500-300

TABLE 50: BUSINESS CREDIT REPORTS WITH DETAILED INFORMATION ON SCORING OR RATING

Approved Credit Reporting Agency	Acceptable Credit Score or Rating	Detailed Description of the Credit Score or Rating
Equifax	Business Payment Index	The Payment Index is a dollar-weighted indicator of a business's payment performance based on the most recently reported financial and non-financial payment experiences.
Equifax	Business Credit Risk Score	The Business Credit Risk Score predicts the likelihood of a business incurring greater than 90 days severe delinquency or charge-off within a 12-month period.
Equifax	Business Delinquency Score	The Business Delinquency Score predicts the likelihood of severe delinquency (91 days or greater), charge-off or bankruptcy within the next 12 months.
Equifax	Business Failure Risk Score	The Business Failure Score predicts the likelihood of business failure through either formal or informal bankruptcy within the next 12 months.
Source: www.equifax.com		
Experian	Intelliscore Credit Ranking Score/Business Credit Score	The Intelliscore Credit Ranking Score predicts the likelihood of delinquency within the next 12 months. Predicts seriously derogatory payment behavior.
Experian	Financial Stability Risk Class	The Financial Stability Risk Class quickly identifies the highest risk businesses and avoid bankruptcy risk and accounts likely to default.
Source: www.experian.com		
Dun & Bradstreet	Delinquency Predictor Risk Class	The Delinquency Predictor Risk Class predicts the likelihood that a company will pay its bills late or on time over the next 12 months.
Dun & Bradstreet	Commercial Credit Score	The Commercial Credit Score predicts the likelihood of an account becoming severely delinquent within the next 12 months.
Dun & Bradstreet	Supplier Evaluation Risk Rating	The Supplier Evaluation Risk Rating predicts the likelihood that a supplier will cease business operations or become inactive over the next 12 months-predicts whether the business will deliver goods and services as promised.
Dun & Bradstreet	Paydex	The Paydex score indicates how quickly a company pays its bills based on the payment experiences in the D&B credit file.
Dun & Bradstreet	Financial Stress Class	The Financial Stress Class predicts the likelihood that a business will experience financial distress or failure over the next 12 months.
Source: www.dnb.com		
Standard & Poor's	S&P Ratings	An S&P credit rating is a forward looking opinion on the creditworthiness of an obligor to meet its overall financial commitments, or financial commitments with respect to specific issues/programs.
Source: www.standardandpoors.com		

The Round 2021 data showed that only 1.7 percent (19 out of 1,133) of suppliers' TINs received a credit score or rating of 8 or lower. Please note that CMS was not able to calculate a score for 20 bidding entity TINs (1,153 – 1,133), mainly due to the following reasons:

- The credit report submitted was not for the entity that submitted the bid.
- There was no date on the credit report indicating when it was generated (credit reports were required to be generated no earlier than 90 calendar days prior to the opening of the bid window).

- A bidding entity that filled a tax return (Form 1120) as a regular "C" corporation submitted a personal credit report instead of a business credit—all were requirements outlined in the Round 2021 RFB.

CMS analyzed the 19 suppliers' TINs that received a score of 8 or lower aforementioned and found that 21.1 percent (4 of the 19) of those bidding entities' TINs did not have an active PTAN as of December 28, 2023, supporting our experience that there is a strong correlation between a bidding entity that has a poor credit score and a supplier no longer being enrolled with Medicare.

CMS is soliciting comments on a proposal to continue requiring each bidding entity to submit a credit report with a numerical credit score or rating that is on the CMS Credit Report Scoring List. This list cannot be finalized until closer to when the bid window opens as credit reporting agencies occasionally update the names of their credit reports, as well as the credit score or rating ranges, so CMS is also soliciting comments on a proposal to include the list that is applicable for each round in the round-specific RFB or a Financial Scoring Methodology Fact Sheet, so bidding entities have plenty of time to obtain the applicable information and submit it prior to the close of the bid window.

CMS is also soliciting comments on a proposal to continue using the same 5-tier scoring system, so bidding entities will continue to receive a score of 4, 8, 12, 16, or 20 for their credit report with a numerical credit score or rating as it was successful in Round 2021 per the aforementioned data. Because the credit report with a numerical credit score or rating will be the only covered document submitted, CMS is soliciting comments on a proposal to deem a bidding entity that receives a minimum score of 12 or higher as passing—meets financial sustainability threshold and be financially eligible for a potential contract offer. We believe that a score of

12 or above would be indicative of the bidding entity being financially stable enough to furnish DMEPOS items during the contract performance period. If deemed as "passing," the bidding entity will continue to be evaluated for a potential contract offer. Because the Credit Report Scoring List as well as the tier and scoring information will be published prior to the bid window opening, bidding entities will be able to determine if they meet CMS's financial standards prior to submitting its bid(s).

Furthermore, CMS is soliciting comments on a proposal to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand. Specifically, CMS has historically used the bidding entity's financial score, as well as a few other factors, to determine if it can provide more than what it has historically provided to beneficiaries—the details of this process are outlined in the "Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP" proposal where CMS is proposing to use a methodology to establish the target number of contracts to award in each competition, so the financial score is no longer applicable for this process.

Lastly, CMS has historically utilized a bidding entity's tax return extract to determine if the entity is a small supplier and has attempted to have at least 30 percent of contract suppliers be small suppliers in each competition to align with section 1847(b)(6)(D) of the Act. For competitive bidding purposes, a small supplier is a supplier that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue. However, because CMS is proposing to no longer require the submission of the tax return extract and the gross revenue is typically not shown on a credit report, CMS is soliciting comments on a proposal to add a field in the bidding system requiring the bidding entity included on the bid have a gross revenue that is under the small supplier threshold. Additionally, before a bidding entity submits its bid(s) in the bidding system, the entity will be required to attest in the bidding system that the information entered into the bidding system is true, correct, and complete—just as bidding entities have done in prior rounds. All bidding entities will also continue to be presented with the "Penalties for Falsifying Information" in the bidding system prior to submitting bid(s).

CMS intends to review Medicare fee-for-service claims data for bidding entities that indicate in the DMEPOS

Bidding System that they are a small supplier to confirm accuracy. Bidding entities that falsify the small supplier status in the bidding system may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program in accordance with 42 CFR

414.412(g)(4)(i). Additionally, bidding entities that falsify the small supplier status will be referred to the Office of Inspector General and Department of Justice for further investigation.

3. Provisions of the Proposed Regulation

a. Required Covered Documents

CMS is proposing that each bidding entity submit a business credit report with a numerical credit score or rating, unless the bidding entity does not have a business credit report with a numerical credit score or rating because the entity has not been in operation long enough to generate a numerical score or rating. Bidding entities that are unable to generate a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score or rating, in addition to a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS.

The bidding entity must upload a copy of its business' credit report showing a numerical credit score or rating, the bidding entity's name, and the date that the credit report was prepared no earlier than 90 calendar days prior to the opening of the bid window. If the numerical credit score or rating is generated separately from the credit report, the bidding entity's name and the date it was prepared must be shown on the credit report and included with the numerical credit score or rating. We are soliciting comments on this proposal.

b. Financial Scoring Methodology

CMS is proposing to continue publishing a Credit Report Scoring List and utilize the same five-tier credit report scoring system used in prior rounds of the DMEPOS CBP. The report will be published in the round specific RFB and/or a fact sheet prior to the opening of the bid window, and will contain the same credit reports with numerical scores or ratings, unless: a credit reporting agency discontinues, changes the name of a credit report, and/or revises the numerical score/rating ranges.

CMS is proposing to continue using the 4, 8, 12, 16, or 20 scoring system

when evaluating a bidding entity's credit report with a numerical credit score or rating. CMS is proposing to deem a bidding entity that receives a minimum score of 12 or higher as passing—meets financial sustainability threshold. If deemed as passing, the bidding entity will continue to be evaluated for a potential contract offer.

CMS is proposing to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand.

CMS is proposing to add a field in the bidding system requiring the bidding entity to verify that all the bidding entities included on the bid has a gross revenue that is under the small supplier threshold. We are soliciting comments on this proposal.

I. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

1. Background

If a bidding entity submits at least one covered document by the CDRD and one or more covered documents are missing, per section 1847(a)(1)(F)(i)(I) of the Act the Secretary is required to notify the bidding entity no later than 45 days (in the first round of competition acquisition program as described in subparagraph (B)(i)(I)) or 90 days (in subsequent rounds of such programs) after the CDRD of any missing covered document(s).

Section 1847(a)(1)(F)(i)(II) of the Act specifies that the Secretary may not reject the bid submission on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidding entity are submitted to the Secretary no later than 10 business days after the date of such notice. Per the limitations of this process in section 1847(a)(1)(F)(iii)(I) through (IV) of the Act, section 1847(a)(1)(F)(i)(I) and (II) of the Act— (1) applies only to the timely submission of covered documents; (2) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether the documents meet applicable requirements; (3) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II) of section 1847(a)(1)(F) of the Act; and (4) shall not be construed as permitting a bidding entity to change bidding amounts or to make other changes in a bid submission.

Per section 1847(a)(1)(F)(ii)(I) and (II) of the Act, the CDRD is the later of the date that is 30 days before the final date

specified by the Secretary for submission of bids under the program or the date that is 30 days after the first date specified by the Secretary for submission of bids under the program.

The 2009 interim final rule codified the CDRD process, which is outlined in 42 CFR 414.414(d)(2) (74 FR 2876 through 2877).

2. Current Issues

Since the inception of the DMEPOS CBP, within either 45 (for Round 1 bids) or 90 days (for subsequent round bids) after the CDRD, CMS has notified bidding entities that submitted at least one covered document by the CDRD, if a covered document was missing by the CDRD and by the close of the bid window. The first step has been identifying the universe of bidding entities that submitted a covered document by the CDRD. The next step has been to determine if each bidding entity with a complete bid has any missing documents covered by the CDRD and the closing of the bid window. If a covered document is identified as missing by the CDRD, CMS then determines if the covered document was received or not by the close of the bid window. Once the analysis is completed, CMS has communicated its findings to the applicable bidding entity within 45 or 90 days after the CDRD, as applicable. CMS specifies in each bidding entity's notification, to the extent applicable, if: (1) a covered document(s) was missing by the CDRD and was still missing by the close of the bid window, (2) a covered document(s) was missing by the CDRD date but was received by the close of the bid window, (3) covered documents were missing by the CDRD but at least one of the missing covered documents was received by the close of the bid window while the other covered document(s) was still missing by the close of the bid window, or (4) no covered document(s) was missing by the CDRD.

CMS is proposing to streamline the evaluation and notification processes by only informing bidding entities if a covered document was missing by the close of the bid window. Each bidding entity would receive a notification stating if: (1) a covered document(s) was missing by the close of the bid window; or (2) no covered document(s) was missing by the close of the bid window. CMS believes that this proposal aligns with the intent of statute as bidding entities would continue to be notified of any missing covered documents (as long as they submit at least one covered document by the CDRD) and would continue to be able to submit any

missing covered documents within 10 business days of receiving the notification.

This proposal would also reduce CMS workload in determining if/when a covered document is missing for bidding entities that submitted at least one covered document by the CDRD. Specifically, CMS is proposing to identify the universe of bidding entities that submitted at least one covered document by the CDRD and then determines if they have a missing covered document(s) by the close of the bid window. CMS would notify bidding entities if they have missing covered documents or if all covered documents were submitted, so CMS will only have to send two different types of notifications compared to the four different notifications previously mentioned. Additionally, due to the simplification of the notifications, bidding entities would have an easier time understanding which covered documents they may need to submit in response to their notification. We are soliciting comments on this proposal.

3. Provisions of the Proposed Regulation

CMS is proposing to streamline the evaluation and notification processes for missing covered document(s). Under this proposal, CMS would no longer evaluate if a bidding entity was missing a covered document(s) by the CDRD and by the close of the bid window, and would only determine if a bidding entity had a missing covered document by the close of the bid window. Once the evaluation is completed, CMS is proposing to continue notifying bidding entities, within 90 days of the CDRD, of the specific covered document(s) that was missing or provide confirmation that all applicable covered documents had been received by the close of the bid window. Bidding entities would continue to have 10 business days from receiving their notification to submit the missing covered document(s). We are soliciting comments on this proposal.

J. Bid Surety Bond Review Process

1. Background

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–101) (MACRA), requires a bid surety bond for bidders. We believe that a bid surety bond would help address the fact that the bids submitted under the DMEPOS CBP are not binding, which can encourage the practice of bidders submitting “low-ball” bids. Requiring a bid surety bond was also believed to reduce the number of bad actors submitting bids in the

DMEPOS CBP, while imposing a penalty for a bidder that doesn't accept a contract that they won.

If a bidder is offered a contract for a competition and its bid is at or below the median composite bid rate for all bidders included in the calculation of the SPA, and it does not accept the contract offer, the bidder's bid surety bond would be forfeited for that CBA. Bidders that accepted the contract offer, or those bids that are above the median composite bid rate, would have the bid surety bond liability returned.

In 2016, CMS published 81 FR 77966 which finalized the regulations at 42 CFR 414.412(g) for setting the requirements for bid surety bonds. Additionally, CMS is proposing to correct a technical error in 42 CFR 414.412(g) that happened as a result of a previous paragraph re-designation in 83 FR 57072.

2. Current Issues

This proposal codifies how CMS handles situations where at least one of the bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i) and (ii) is not properly met after a bidder submits its bid surety bond(s) during the bid window. Specifically, if CMS determines that a bid surety bond requirement is not met, the bidder would be notified by CMS and would be provided with an opportunity to correct the deficiency on the bid surety bond via a bid surety bond rider. A bid surety bond rider is a change or amendment to the original bid surety bond. It is the only legal way of modifying or updating information on a bid surety bond which is still in effect, and it can only be issued by the authorized surety agency that issued the original bid surety bond. Allowing bidders to submit a bid surety bond rider would provide bidders that have a bid surety bond deficiency(s) an opportunity to correct the deficiency(s) instead of the bid(s) for the applicable CBA(s) being disqualified in the early stages of the bid evaluation process. Bids that are disqualified for a bid surety bond deficiency are not included in other bid evaluation processes that are necessary to determine if a bid is eligible for a contract offer.

CMS applied the bid surety bond rider process during bid evaluation for Round 2021 of the DMEPOS CBP, and is now proposing to codify this process in regulation. Additionally, CMS is proposing correcting a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph re-designation in 83 FR 57072.

3. Provisions of the Proposed Regulation

CMS proposes correcting a technical error created in 83 FR 57072 where CMS re-designated paragraphs (e) through (h) as paragraphs (d) through (g), respectively. The re-designated paragraph (g)(3)(ii) still contained a reference to the paragraph (h)(3)(i), which, with the re-designation, was deleted in its entirety. This proposed correction would revise existing paragraph (g)(3)(ii) by removing the reference to "(h)(3)(i)" and replacing it with "(g)(3)(i)". All other parts of paragraph (g)(3)(ii) remain unchanged with this proposal. We are soliciting comments on this proposal.

In 2015, Congress passed section 522(a) of MACRA, which required a bid surety bond for bidders. In 2016, CMS published 81 FR 77967 which finalized the regulations at 42 CFR 414.412(g) for setting the requirements for bid surety bonds. Round 2021 of the DMEPOS CBP was the first round that required bid surety bonds. As a result, CMS reviewed all bids to ensure a bid surety bond was uploaded to the DMEPOS CBP's secure portal by the deadline for bid submission for each CBA in which a bid was submitted, and that it met all bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i)–(ii). During the Round 2021 bid evaluation, CMS was able to identify bid surety bonds that had deficiencies with the bid surety bond requirements, and allowed certain deficiencies to be corrected via a bid surety bond rider.

Round 2021 had 1,338 bidders and 43 were identified as having at least one bid surety bond with a minimum of one deficiency that was able to be corrected via a bid surety bond rider. These 43 bidders were provided with the opportunity to submit a bid surety bond rider from its surety within a 10-business day timeframe rectifying all deficiencies. Of the 43 bidders, 40 responded within the allotted timeframe; however, only 36 out of the 40 bidders submitted a bid surety bond rider that properly corrected the deficiencies. After successful implementation of the process for Round 2021, CMS is proposing to include this process in all future rounds of the program.

Each bid surety bond requirement, described in 42 CFR 414.412(g)(2)(i)–(ii), is listed later in this section followed by an example(s) of the type of deficiency that could be corrected by a bid surety bond rider, which is a change or amendment to the original bid surety bond, that can only be issued by the authorized surety, at its discretion, that issued the original bid surety bond:

- The name of the bidder as the principal/obligor: If a bidder submits a bid surety bond that contains a name of a different entity other than the Legal Business Name entered in the Business Organization section of Form A in the DMEPOS Bidding System, for example using its "doing business as" name or the name is missing the "LLC" at the end, then the error can be corrected by a bid surety bond rider.

- The name and the National Association of Insurance Commissioners (NAIC) number of the authorized surety: If a bidder submits a bid surety bond with a missing or illegible name or NAIC number, or the NAIC number does not match the name on the Treasury Department's list of authorized sureties, these issues can be corrected with a bid surety bond rider.

- CMS as the named obligee: If a bidder submits a bid surety bond without naming CMS as obligee or names another agency or department as obligee, this error can be corrected by a bid surety bond rider.

- The conditions of the bid surety bond as specified in § 414.412(g)(3), which is forfeiture of the bid surety bond language: If a bidder submits a bid surety bond that is missing part or all of the pertinent language on forfeiture of the bid surety bond, then the omission of bid surety bond forfeiture language can be corrected by a bid surety bond rider.

- The CBA covered by the bid surety bond: If a bidder submits a bid surety bond with an incorrect or missing CBA name, then the CBA name can be corrected by a bid surety bond rider.

- The bid surety bond number: If a bidder submits a bid surety bond with a missing or illegible bid surety bond number, then the bid surety bond number can be corrected by a bid surety bond rider.

- The date of issuance: If a bidder submits a bid surety bond with a missing or illegible date of issuance, then the date of issuance can be corrected by a bid surety bond rider.

- The bid surety bond value of \$50,000.00: If a bidder submits a bid surety bond for a value other than \$50,000.00, then the bid surety bond value can be corrected by a bid surety bond rider.

The following are examples of the type of deficiencies that a bidder may have on its bid surety bonds that cannot be corrected by a bid surety bond rider:

- Late Bid Submissions: CMS will not review any bid surety bonds that are submitted after the deadline for bid submission. The Social Security Act clearly states that bidders must provide "proof of having obtained" a bid surety

bond by the “deadline for bid submission.” Submission of a bid surety bond rider will not rectify a bid(s) from a bidder that is disqualified for having a bid surety bond failure, if the failure was for not submitting a bid surety bond prior to the deadline for bid submission. This would also include a bidder that submitted a document other than a bid surety bond (for example, a Medicare enrollment bond, or a Certificate of Liability Insurance). No notice would be provided to a bidder in this situation.

- **Missing Bid Surety Bonds:** If a bidder submitted bids in two different CBAs, but the bidder uploaded the same bid surety bond for both CBAs, then the bidder will not be notified that there is a deficiency for the bid for the CBA in which the bid surety bond that was never uploaded, as a bid surety bond rider cannot correct the issue of a missing bid surety bond, and the bidder did not provide proof of having a bid surety bond for the one CBA by the deadline for bid submission. For example, this could occur by error, where the bidder accidentally uploaded the same bid surety bond for both CBAs, despite having two bid surety bonds; or this could occur by a mistaken understanding of the bidder that one bid surety bond should be sufficient for both CBAs.

Bidders would be notified by CMS of the deficiency (that is, the incorrect, incomplete, or missing requirement), and would be permitted to obtain the bid surety bond rider within a certain timeframe to submit to CMS in order for its bid(s) to remain eligible for further review during bid evaluation. CMS proposes sending the notification to bidders and having bidders provide the bid surety bond riders via the DMEPOS CBP’s secure portal. CMS will not notify bidders of deficiencies that are not correctable with a bid surety bond rider during this review process.

CMS is proposing to provide bidders with a single, 10-business day timeframe to obtain and submit a bid surety bond rider correcting the deficiencies on the bid surety bond. A 10-business day timeframe was utilized for Round 2021, which provided bidders ample time to obtain a bid surety bond rider from the authorized surety that issued the original bid surety bond and submit the bid surety bond rider via the DMEPOS CBP’s secure portal. Additionally, we anticipate the 10-business day timeframe will run concurrent with other bid evaluation processes, and extending this timeframe would result in some bid evaluation processes being delayed until the bid surety bond rider review process is complete, impacting CMS’s ability to

continue evaluating all bids submitted and ultimately awarding contracts in a timely manner. Lastly, CMS believes that bidders have the resources (for example, fact sheets, bid surety bond template) available, and that it is the responsibility of the bidder to submit a bid surety bond that meets all bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i)–(ii). For these reasons, CMS believes a single, 10-business day opportunity to rectify the deficiency is sufficient. We are soliciting comments on this proposal.

K. Tribal Exemption From Participating in the DMEPOS CBP

1. Background

There is a special government-to-government relationship between the federal government and federally recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders, and the U.S. Constitution. This government-to-government relationship forms the basis for federal health services to American Indians/Alaska Natives (AI/AN) in the U.S. In 1976, the Indian Health Care Improvement Act (IHCA) (Pub. L. 94–437, September 30, 1976) amended the Act to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and Tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services may be furnished by IHS operated facilities and programs, and Tribally operated facilities and programs, under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA) (Pub. L. 93–638, January 4, 1975) to AI/ANs. The IHS healthcare delivery system currently consists of 46 hospitals, with 22 of those hospitals operated by the IHS and 24 of them operated by Tribes under the ISDEAA, as well as 380 health centers, 50 operated by IHS and 417 operated by Tribes under the ISDEAA.

The Act prohibits Medicare payment to non-contract suppliers under the DMEPOS CBP. Specifically, section 1847(b)(6) of the Act states that, “payment shall not be made for items and services described in section 1847(a)(2) furnished by a contractor and for which competition is conducted under this section unless: (i) the contractor has submitted a bid for such items and services under this section; and (ii) the Secretary has awarded a contract to the contractor for such items and services under this section.”

However, section 1862(a)(17) of the Act carves out an exception to this rule. Section 1862(a)(17) of the Act states,

“Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a)) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary.”

2. Current Issues

Tribes that operate health facilities or suppliers under the ISDEAA have approached CMS requesting an exception from the DMEPOS CBP to allow Medicare payment for competitively bid items provided to AI/AN Medicare beneficiaries, who reside in a CBA, but who receive services from an IHS or Tribally operated facility or supplier, which can be located 60 or 90 minutes outside the CBA. Many of these AI/AN Medicare beneficiaries receive primary care services at a Tribally operated facility, and, as a result of this visit, might be provided DMEPOS by the facility or a Tribally operated supplier. Without an exception, the IHS or Tribally operated facility or supplier would not be paid by Medicare when providing competitively bid DMEPOS to eligible AI/AN Medicare beneficiaries during an active round of the DMEPOS CBP.

In addition, under the Indian Health Care Improvement Act (IHCA), AI/ANs who are eligible for services from the IHS, in general do not pay coinsurance for DMEPOS they receive from an IHS supplier or facility. However, under an active round of the DMEPOS CBP, AI/AN Medicare beneficiaries residing in a CBA must receive DMEPOS from a competitive bidding contract supplier in their CBA and pay a 20 percent coinsurance, even in cases where they receive care at a Tribally operated facility outside their CBA. This creates added expenses for AI/AN Medicare beneficiaries.

3. Provisions of the Proposed Regulation

CMS is proposing to use the authority at section 1862(a)(17) of the Act to add an exception to § 414.408(e)(2) that would allow Medicare payment to IHS or Tribally operated facilities and suppliers that furnish competitively bid items and services to AI/AN Medicare beneficiaries who reside in a CBA so that the AI/AN Medicare beneficiaries can retain the benefits described

previously when receiving DMEPOS items and services from a Tribal supplier. We are soliciting comments on this proposal.

L. Addition of a Termination Clause for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) Supplier Contracts

1. Background

As previously discussed, an important benefit of the DMEPOS CBP is that it ensures access to covered DMEPOS items and services. Current regulations at 42 CFR 414.422 establishing the terms of each DMEPOS CBP contract state that contract suppliers must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. CMS implemented these regulations pursuant to section 1847(b)(3)(A) of the Act, which states that the Secretary may specify the terms and conditions of a DMEPOS CBP contract. In the 2006 proposed rule (71 FR 25682), CMS proposed adding a unilateral contract termination for convenience clause to the DMEPOS CBP supplier contracts. After receiving multiple public comments challenging the termination for convenience clause, per the 2007 final rule (72 FR 18054—18055), CMS decided not to finalize the proposal.

2. Current Issues

Since the inception of the DMEPOS CBP, CMS has never verified an instance where all contract suppliers for a competition were not able to meet beneficiary demand for the competition, even during a PHE. For example, after the Secretary of HHS declared PHEs after major hurricanes, contract suppliers were able to replace damaged DMEPOS and furnish competitively bid DMEPOS items to beneficiaries without any access concerns. CMS believes this can be attributed to the fact that not all contract suppliers for a CBA are physically located within the impacted CBA. Also, Medicare requires Medicare-enrolled DMEPOS suppliers to “have a contingency plan that enables it to respond to emergencies and disasters, or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as a result of an emergency or disaster” (see section 1.F of the CMS DMEPOS Quality Standards). CMS has experienced that contract suppliers are prepared to promptly resume operations, and remain in compliance with the terms of the DMEPOS CBP supplier contract,

without a need for any contract action by CMS. Additionally, there is an already established network of agencies and organizations at the federal, state, and local levels that are integral in responding to the immediate needs, including DMEPOS needs, during a PHE. For instance, CMS works closely with HHS’s Administration for Strategic Preparedness and Response (ASPR) that leads the nation’s medical and public health preparedness for, response to, and recovery from disasters and other PHEs.

Nevertheless, we are concerned that, in the event of a PHE, contract suppliers may be unable to fulfill their obligations under DMEPOS CBP supplier contracts to furnish certain required items and services to beneficiaries in CBAs or defined area(s) within CBAs specified in the contracts and affected by the PHE (the PHE-impacted area). In the event that CMS determines that, due to a PHE, contract suppliers are unable to furnish items and services to beneficiaries in a PHE-impacted area specified in their DMEPOS CBP contracts, we believe it is prudent for CMS to have the authority to unilaterally terminate or modify each applicable contract to exclude the requirement to furnish such items and services in the PHE-impacted area from the scope of the DMEPOS CBP. If the items and services in the PHE-impacted area to be removed from the DMEPOS CBP encompasses all competitions referenced in a DMEPOS CBP contract, CMS would unilaterally terminate the contract supplier’s entire contract. If the items and services in the PHE-impacted area to be removed from the DMEPOS CBP encompass only a portion of the items and services and areas referenced in a DMEPOS CBP supplier contract, CMS would unilaterally modify the contract to exclude the requirement to furnish the applicable items and services in the PHE-impacted area. Upon modification, the contract supplier would no longer be obligated under the terms of the contract to furnish the specified items and services in the PHE-impacted area, and CMS would no longer provide payment under the contract for furnishing those items and services in that area. Depending on the PHE, such area may be a specific CBA or a defined area within a CBA. A DMEPOS CBP supplier contract modified to exclude the requirement to furnish certain items and services in the PHE-impacted area would continue to remain in effect for all other items and services and all other geographic areas that are within the scope of the contract. Upon the termination and/or modification of each DMEPOS CBP

supplier contract impacted by the PHE, any Medicare enrolled DMEPOS supplier would be able to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area.

CMS would reserve the right to unilaterally terminate or modify every DMEPOS CBP supplier contract impacted by a PHE in accordance with the above if the following conditions are met: (1) the Secretary of HHS declares a PHE, (2) CMS determines the PHE has created an access concern for beneficiaries receiving items and services under the DMEPOS CBP in certain CBAs or defined area(s) within CBAs, (3) CMS determines that awarding additional CBP contracts, per 42 CFR 414.414(i), would not address the access concerns, and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude those specific areas from the DMEPOS CBP would alleviate access concerns.

To determine whether or not a PHE has created an access concern, CMS would review information obtained directly from the contract supplier(s) impacted by a PHE, along with data obtained through CMS’s monitoring system (complaints, claims data, beneficiary health outcomes, assignment rates, etc.) and from other agencies and organizations at the federal, state, and local levels. CMS would continue to remain in communication with affected contract suppliers throughout a PHE. CMS would share all relevant information from contract suppliers with applicable emergency response partners to aid in the response efforts. We would also be analyzing the information to determine the scope and length of the challenges being experienced to assess whether it is necessary to terminate an entire DMEPOS CBP supplier contract, terminate a competition(s), or terminate a defined area(s) within a CBA. For example, if the Secretary of HHS declares a PHE due to a pandemic and the President of the United States enacts the Defense Production Act to assist with furnishing essential medical supplies, CMS would communicate with contract suppliers to determine if they are able to continue furnishing the competitively bid DMEPOS item to beneficiaries in the CBA under existing conditions. The information and data obtained from contract suppliers would be combined with relevant information gathered from other agencies and organizations at the federal, state, and local levels that are integral in responding to the PHE. We are soliciting comments on this proposal.

In a form and manner to be determined by CMS, CMS would announce the exclusion of the PHE-impacted area from the scope of the DMEPOS CBP to all applicable contract suppliers and would further notify each applicable contract supplier if the DMEPOS CBP supplier's contract, based on this announcement, will be terminated or unilaterally modified.

Any termination or modification made in accordance with this proposal would remain in effect for the remainder of the DMEPOS CBP supplier contract term, even if the PHE ends before the contract's expiration date.

CMS would apply a high degree of prudence when making an informed decision to terminate and/or modify a DMEPOS CBP supplier contract to exclude areas impacted by a PHE. CMS would not consider a situation that does not meet the qualifying criteria previously mentioned. Even if a PHE meets the qualifying criteria, CMS would not terminate and/or modify a DMEPOS CBP supplier contract if the body of evidence and information determines that there is sufficient capacity from remaining contract suppliers, or if CMS is able to award additional contracts to meet the existing market demands for the competition(s) or defined area(s) within a CBA. For example, if most contract suppliers for a competition say that they are unable to furnish an item to beneficiaries, but there are at least two contract suppliers that provide evidence that they can meet the demand for the competition, CMS may decide that there is sufficient capacity remaining from a contract supplier. We are soliciting comments on this proposal.

3. Provisions of the Proposed Regulation

If CMS determines that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS is proposing in § 414.422 to have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. Depending on the geographic extent of the PHE, a PHE-impacted area may refer to entire CBA(s) or only certain areas within a CBA.

If the items and services in the PHE-impacted area identified encompass all competitions referenced a DMEPOS CBP supplier contract, CMS is proposing in

§ 414.422 to unilaterally terminate the DMEPOS CBP supplier contract.

If the items and services in the PHE-impacted area identified encompass only a portion of the items and services and geographic areas referenced in a DMEPOS CBP supplier contract, CMS is proposing in § 414.422 to unilaterally modify the DMEPOS CBP supplier contract to remove the contract supplier's obligation to furnish specified items and services in the PHE-impacted area, as well as CMS's obligation to pay for those items and services under the DMEPOS CBP supplier contract.

After termination and/or modification of all applicable DMEPOS CBP supplier contracts, CMS is proposing in § 414.422 to revert back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA. As a reminder, fee-for-service (Medicare enrolled) DMEPOS suppliers are not required to furnish DMEPOS to beneficiaries in the CBA, nor are they required to accept assignment, unless they are already participating suppliers with Medicare. We are soliciting comments on this proposal.

CMS is proposing in § 414.422 to have the option to remove items and services furnished in a PHE-impacted areas from the DMEPOS CBP when all of the following qualifying criteria are met: (1) the Secretary declares a PHE; (2) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA; (3) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns. We are soliciting comments on this proposal.

M. Technical Change to § 414.408(h)(8)

In the 2007 final rule we added § 414.408(h)(7), which set the payment amounts for rented DME requiring frequent and substantial servicing (72 FR 18032). We added § 414.408(h)(7)(i), which referred to paragraph (h)(7)(ii) of this section. Subsequently, we published in the **Federal Register** a final rule in 2011 titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 73170). In this rule we added paragraph § 414.408(h)(2). As a result of this

addition, what used to be § 414.408(h)(7), became § 414.408(h)(8). However, § 414.408(h)(8)(i) was inadvertently not updated to refer to paragraph (h)(8)(ii), and it still refers to paragraph (h)(7)(ii). We are therefore making a technical change to the regulation text at § 414.408(h)(8)(i) so that it will refer to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii). We are soliciting comments on this proposal.

N. Definitions of "Competition" and "Adjusted Fee Schedule Amount" and "Unadjusted Fee Schedule Amount" Under § 414.402

The Medicare fee schedule amounts for enteral nutrition furnished in non-CBAs are adjusted using information from the DMEPOS CBP in accordance with § 414.105. The Medicare fee schedule amounts for DME and medical supplies and OTS orthotics furnished in non-CBAs are adjusted using information from the DMEPOS CBP in accordance with § 414.210(g). The Medicare payment amounts for lymphedema compression treatment items are adjusted using information from the DMEPOS CBP in accordance with § 414.1690. For the purposes of streamlining the language under this subpart, we are proposing to add definitions for "Adjusted fee schedule amount" and "Unadjusted fee schedule amount" under § 414.402. We propose that *Adjusted fee schedule amount* means the payment amount established for the item under Subpart C of this part, with the application of § 414.105; Subpart D of this part, with the application of § 414.210(g); or Subpart Q of this part, with the application of § 414.1690. We propose that *Unadjusted payment amount* means the payment amount established for the item under Subpart C of this part, without the application of § 414.105; Subpart D of this part, without the application of § 414.210(g); or Subpart Q of this part, without the application of § 414.1690.

Similarly, for the purpose of streamlining regulation text, rather than continuing to write out "competitive bidding area and product category combination," we are proposing to add a definition for "Competition" under § 414.402 to read *Competition* means a competitive bidding area and product category combination where bids are submitted by suppliers in an attempt to be awarded contracts for furnishing competitively priced items and services within the product category in the competitive bidding area. The contracts must be recomputed not less often than once every 3 years. We are soliciting comments on this proposal.

VIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

B. Information Collection Requirements (ICRs)

In this HH PPS rule, we are soliciting public comment on each of these 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. As we noted in the CY 2018 HH PPS final rule (82 FR 52738 through 51740), we believe the reconsideration requirements, and the associated burden would be incurred subsequent to 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. We have, however, provided detailed cost burden estimates in section VIII. of this proposed rule. We welcome public comments on the accuracy of the cost estimate assigned to this administrative burden.

1. ICRs for HH QRP

As discussed in section III.D.3. of this proposed rule, we are proposing to remove four items as standardized patient assessment data elements beginning with the CY 2026 HH QRP. The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities as outlined in section III.D.5. of this proposed rule. All elements discussed will be collected at the start of care and resumption of care timepoints. To clarify, home health episodes begin with either a start of care or a resumption of care, corresponding

to admission in other PAC settings. We assumed the Living Situation and Utilities data elements require 0.3 minutes each of clinician time to complete. We assume the Food Runs Out and Food Doesn't Last data elements require 0.15 minutes each of clinician time to complete. Therefore, we estimated that there will be a decrease in clinician burden per OASIS assessment of 0.9 minutes at the start of care and resumption of care. We also propose to remove the patient COVID-19 vaccination item beginning with the CY 2026 HH QRP. This item is collected at the transfer of care, death at home, and discharge assessment timepoints of the OASIS and requires 0.3 minutes of clinician time to complete at each of these time points.

The net effect of these proposals is a decrease in four data elements collected at the start of care one data element at transfer of care, death at home, and discharge for the OASIS implemented on April 1, 2026.

For purposes of calculating the costs associated with the information collection requirements, we obtained median hourly wages for these from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). To account for other indirect costs such as overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in table 54.

TABLE 54: U.S. BUREAU OF LABOR STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefit (100%) (\$/hr)	Adjusted Hourly Wage (\$/hr)
Administrative Services Manager	11-3012	\$52.11	\$52.11	104.22
Registered Nurse (RN)	29-1141	\$45.00	\$45.00	\$90.00
Physical therapists (PT)	29-1123	\$48.57	\$48.57	\$97.14
Speech-Language Pathologists (SLP)	29-1127	\$45.87	\$45.87	\$91.74
Occupational Therapists (OT)	29-1122	\$47.28	\$47.28	\$94.56
Miscellaneous Health Technologists and Technicians	29-2090	\$23.84	\$23.84	\$47.68

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2023 show that the SOC/ROC OASIS is completed by RNs (approximately 75.42 percent of the time), PTs (approximately 23.71 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.87 percent of the time). Based on this analysis, we

estimated a weighted clinician average hourly wage of \$91.72, inclusive of fringe benefits, using the hourly wage data in table 55 $(0.7542 \times \$90.00 + 0.2371 \times \$97.14 + 0.0087 \times \$93.15 = \$91.72)$. Individual providers determine the staffing resources necessary.

For purposes of estimating burden, we compare the item-level burden estimates for the OASIS that will be released on April 1, 2026, to the OASIS that was expected to be implemented as of

January 1, 2027, and finalized in CY 2024 HH PPS final rule (88 FR 77763 through 77768). The first component needed to calculate burden is the total estimated assessments for each year in question. Table 55 shows the total number of OASIS assessments that HHAs completed in CY 2023 at the start of care and resumption of care. It also outlines the estimated assessments that are expected to be collected in 2027 based on a 30 percent increase in

completed assessments required for all
payer data submission requirements for
(CY 2023 assessment total + CY 2023

assessment total * 0.3 = Estimated CY

2027 Assessment total based on all
payer data collection).

BILLING CODE 4120-01-P

**TABLE 55. START OF CARE/RESUMPTION OF CARE OASIS SUBMISSIONS
BASED ON CY 2023 & CY 2025 ESTIMATED OASIS DATA**

Time Point	CY 2023 OASIS Assessments Completed	Estimated CY 2027 OASIS Assessments Based on All-Payer Data Collection
Start of Care	6,627,912	8,616,286
Resumption of Care	911,245	1,184,618
Transfer of Care	1,818,914	2,364,588
Death at Home	48,398	62,917
Discharge	5,389,311	7,006,104
Total Assessments	14,795,780	19,234,513

The totals from table 55 are used to calculate the hourly burden estimates in table 56 based on the following calculations:

START OF CARE		
Estimated time spent per each 2027 OASIS SOC Assessment/Patient = 57.3 clinician minutes		
204 data elements x (range of 0.15 to 0.3) minutes per data element = 57.3 minutes of clinical time spent to complete data entry for the OASIS SOC assessment.		
23 data elements counted as 0.15 minutes/data element (3.45 minutes).	9 data elements counted as 0.25 minutes/ data element (2.25 minutes).	172 data elements counted as 0.30 minutes/ data element (51.6 minutes).
Clinician Estimated hourly burden for all HHAs (11,904) for 2027 OASIS SOC assessments = 8,228,553 hours		
57.3 clinician minutes per SOC assessment x 8,616,286 assessments = 493,713,188 minutes/60 minutes per hour = 8,228,553 hours for all HHAs		
Clinician Estimated hourly burden for all HHAs (11,904) for 2027 OASIS SOC assessments = 8,228,553 hours		
Estimated time spent per each 2026 OASIS SOC Assessment/Patient = 56.4 clinician minutes.		
200 data elements x (range of 0.15 to 0.3) minutes per data element = 56.4 minutes of clinical time spent to complete data entry for the OASIS-E1 SOC assessment.		
21 data elements counted as 0.15 minutes/data element (3.15 minutes).	9 data elements counted as 0.25 minutes/data element (2.25 minutes).	170 data elements counted as 0.30 minutes/data element (51 minutes).
Clinician Estimated hourly burden for all HHAs (11,904) for 2026 OASIS SOC assessments = 8,099,309 hours		
56.4 clinician minutes per SOC assessment x 8,616,286 assessments = 485,958,530 minutes/60 minutes per hour = 8,099,309 hours for all HHAs.		

RESUMPTION OF CARE

Estimated time spent per each **2027** OASIS ROC Assessment/Patient = 48 minutes

172 data elements x (range of 0.15 to 0.3) minutes per data element = 48 minutes of clinical time spent to complete data entry for the OASIS ROC assessment

• 21 data elements counted as 0.15 minute/data element (3.15 minutes)

• 9 data elements counted as 0.25 minute/data element (2.25 minutes)

• 142 data elements counted as 0.30 minute/data element (42.6 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS ROC assessments = 947,694 hours

48 clinician minutes per ROC assessment x 1,184,618 ROC assessments = 56,861,664 minutes/60 minutes = 947,694 hours for all HHAs

Estimated time spent per each **2026** OASIS-E1 ROC Assessment/Patient = 47.1 minutes

168 data elements x (range of 0.15 to 0.3) minutes per data element = 47.1 minutes of clinical time spent to complete data entry for the OASIS-E1 ROC assessment

• 19 data elements counted as 0.15 minute/data element (2.85 minutes)

• 9 data elements counted as 0.25 minute/data element (2.25 minutes)

• 140 data elements counted as 0.30 minute/data element (42 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS-E1 ROC assessments = 823,310 hours

47.1 clinician minutes per ROC assessment x 1,184,618 ROC assessments = 55,795,508 minutes/60 minutes = 929,925 hours for all HHAs

TRANSFER OF CARE

Estimated time spent per each **2027** OASIS TOC Assessment/Patient = 6.9 minutes

23 data elements x 0.3 minutes per data element = 6.9 minutes of clinical time spent to complete data entry for the OASIS TOC assessment

• 23 data elements counted as 0.3 minutes/ data element (6.9 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS TOC assessments = 271,927 hours

6.9 clinician minutes per TOC assessment x 2,364,588 TOC assessments = 16,315,657 minutes/60 minutes = 271,927 hours for all HHAs

Estimated time spent per each **2026** OASIS TOC Assessment/Patient = 6.6 minutes

22 data elements x 0.3 minutes per data element = 6.6

• 22 data elements counted as 0.3 minutes/data element (6.6 minutes)

Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS TOC assessments = 260,105 hours

6.6 clinician minutes per TOC assessment x 2,364,588 TOC assessments = 15,606,281 minutes/60 minutes=260,105 hours for all HHAs

DEATH AT HOME		
Estimated time spent per each 2027 OASIS-E1 DAH Assessment/Patient = 3 minutes		
10 data elements x 0.3 minutes per data element = 3 minutes of clinical time spent to complete data entry for the OASIS DAH assessment		
• 10 data elements counted as 0.3 minutes/data element (3 minutes)		
Clinician Estimated Hourly Burden for all HHAs for 2027 OASIS DAH assessments = 3,146 hours		
3 clinician minutes per DAH assessment x 62,917 DAH assessments = 188,751 minutes/60 minutes=3,146 hours for all HHAs.		
Estimated time spent per each 2026 OASIS-E1 DAH Assessment/Patient = 2.7 minutes		
• 9 data elements counted as 0.3 minutes/data element (2.7 minutes)		
Clinician Estimated Hourly Burden for all HHAs for 2026 OASIS DAH assessments = 2,831 hours		
2.7 clinician minutes per DAH assessment x 62,917 DAH assessments = 169,876 minutes/60 minutes=2,831 hours for all HHAs		

DISCHARGE		
Estimated time spent per each 2027 OASIS DC Assessment/Patient = 40.2 minutes		
146 data elements x (range of 0.15 to 0.3) minutes per data element = 40.2 minutes of clinical time spent to complete data entry for the OASIS-E1 DC assessment		
• 21 data elements counted as 0.15 minutes/data element (3.15 minutes)	• 9 data elements counted as 0.25 minutes/data element (2.25 minutes)	• 116 data elements counted as 0.30 minutes/data element (34.8 minutes)
Clinician Estimated Hourly Burden for all HHAs for 2027 OASIS DC assessments = 4,694,090 hours		
40.2 clinician minutes per DC assessment x 7,006,104 DC assessments = 281,645,381 minutes/60 minutes =4,694,090 hours for all HHAs		
Estimated time spent per each 2026 OASIS DC Assessment/Patient = 39.9 minutes		
145 data elements x (range of 0.15 to 0.3) minutes per data element = 39.9 minutes of clinical time spent to complete data entry for the OASIS DC assessment		
• 21 data elements counted as 0.15 minute/data element (3.15 minutes)	• 9 data elements counted as 0.25 minute/data element (2.25 minutes)	• 115 data elements counted as 0.30 minute/data element (34.5 minutes)
Clinician Estimated Hourly Burden for all HHAs for 2026 OASIS DC assessments = 4,659,059 hours		
39.9 clinician minutes per DC assessment x 7,006,104 DC assessments = 279,543,550 minutes/60 minutes = 4,659,059 hours for all HHAs		

BILLING CODE 4120-01-C

Table 56 summarizes the estimated clinician hourly burden for the OASIS that would be implemented in 2026 with this proposed rule's changes of a decrease in four data elements at start of care and resumption of care and a

decrease in a data element at transfer of care, death at home, and discharge compared to the anticipated 2027 OASIS burden if these reductions were not implemented. This is calculated by multiplying the total number of assessments by the decrease in

assessment time required. We calculate the 2027 and 2026 burden estimates in minutes and then calculate hourly burden estimates shown in Table 56. We estimated a net decrease of 194,181 hours of clinician burden across all

HHAs or 16.31 hours (194,181/11,904) for each of the 11,904 active HHAs.

TABLE 56. SUMMARY OF ESTIMATED CLINICIAN HOURLY BURDEN FOR CY 2027 AND CY 2026 OASIS

OASIS Assessment Type	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2027	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2026	Total Decrease in Hours
Start of Care	8,228,553	8,099,309	-129,244
Resumption of Care	947,694	929,925	-17,769
Transfer of Care	271,927	260,105	-11,822
Death at Home	3,146	2,831	-315
Discharge	4,694,090	4,659,059	-35,031
Totals	14,145,410	13,951,229	-194,181

Table 56 summarizes the estimated clinician costs for the 2027 OASIS and the 2026 OASIS with the net reduction of four data elements at start of care and resumption of care and one data element removed from transfer of care, death at home, and discharge using CY 2024 BLS wage inputs. Total clinician cost for 2027 and 2026 is estimated by multiplying total hourly burden for each year as reported in table 43 by the weighted clinician average hourly wage of \$91.72. Then we calculate the difference in clinician-estimated costs between 2027 and 2026. This calculates the estimated decrease in costs

associated with adding the four data elements at the start of care and resumption of care and removing a data element at transfer of care, death at home, and discharge. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of \$4,326,249 or \$363 (\$4,326,249/11,904) for each of the 11,904 active HHAs. For the four SDOH data elements removed at the start of care or resumption of care, we estimate a decrease in clinician cost of \$13,484,033 or \$1,132 (\$13,484,033/11,904) for each of the 11,904 active HHAs. For all proposals, we estimate a

decrease in clinician costs of \$17,786,980 between 2027 and 2026 related to the implementation of the proposals outlined in this proposed rule across all HHAs or a \$1,494 decrease (– \$17,786,980/11,904) for each of the 11,904 active HHAs. This decrease in burden will begin with the April 1, 2026, OASIS assessments.

The burden estimates detailed in this section will be submitted for OMB review and approval as part of revision of the information collection request currently approved under OMB control number 0938–1279.⁹⁷

TABLE 57. SUMMARY OF ESTIMATED CLINICIAN COSTS FOR CYs 2027 AND 2026

OASIS Assessment Type	Clinician Estimated Cost – OASIS 2027	Clinician Estimated Cost – OASIS-E1 2026	Total Cost Increase
Start of Care	\$754,722,881	\$742,868,621	-\$11,854,260
Resumption of Care	\$86,922,494	\$85,292,721	-\$1,629,773
Transfer of Care	\$24,941,144	\$23,856,831	-\$1,084,313
Death at Home	\$288,551	\$259,659	-\$28,892
Discharge	\$430,541,935	\$427,328,891	-\$3,213,044
Totals	\$1,297,417,005	\$1,279,606,723	-\$17,810,282

2. ICRs for the Expanded HHVBP Model
a. ICRs for the Proposed Changes to the Measure Removal Factors

The proposed changes to the measure removal factors, proposed changes to the HHVBP applicable measure set, and the RFI for the expanded HHVBP Model included in section IV. of this proposed rule do not result in an increase in costs to HHAs. Section 1115A(d)(3) of the Act

exempts Innovation Center model tests and expansions, which include the expanded HHVBP Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

b. ICRs for the Proposed Modification of the HHCAHPS Survey

Beginning with the CY 2027 Public Reporting Period/CY 2028 Payment Determination as described in section III.H. of this proposed rule, we are proposing to modify the HHCAHPS Survey measure beginning in April 2026. Specifically, the updated measures include updates to the Care of Patients and Communication between

⁹⁷ The currently approved OASIS information collection request expires 12/31/2027. [https://](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202406-0938-007)

www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202406-0938-007.

Providers and Patients measures, and removal of Specific Care Issues measure and replacing this measure with three single-item measures related to reviewing home safety, reviewing medications and discussing side effects of medications. As part of these changes, the HHCAHPS Survey is being reduced by 8 survey items. Under OMB control number 0938–1066,⁹⁸ we estimate the time to complete the current HHCAHPS Survey to be approximately 12 minutes per respondent and approximately 1,043,447 respondents would complete and submit the HHCAHPS Survey as part of the Home Health Quality Reporting Program annually. We estimate the combination of survey removals and additions would result in a decrease of 3 minutes (.05 hour) per respondent to complete the updated version of the HHCAHPS Survey. Therefore, we estimate the updated time to complete the shorter HHCAHPS Survey would be 9 minutes per respondent (0.15 hour) at \$32.66 per hour.⁹⁹ Our estimate is based on the written length of the survey and CMS's experience with the revised survey during the mode experiment (CMS 10784, OMB control number 0938–1404). In aggregate, we estimate a burden of 153,884 hours (1,025,894 patients (updated estimated of number of patients) × 0.15 hr.) at a cost of \$5,025,851 (153,884 hr. × \$32.66/hr.) or \$4.90 per survey (\$5,025,851/1,025,894 patients). The burden estimates detailed in this section will be submitted for OMB review and approval as part of revision of the information collection

request currently approved under OMB control number 0938–1066.

3. ICRs for Updates to the Home Health Agency CoPs To Align With the OASIS All-Payer Submission Requirements

As discussed in section V. of this proposed rule, we are proposing technical revisions to the HH CoPs to further clarify that the existing requirement for reporting OASIS information applies to all HHA patients receiving skilled services. This technical change seeks to provide clarity by creating alignment between the terminology used in the CoPs and requirements for data collection and submission to OASIS for purposes of the HH QRP. It does not propose any revisions to the specific requirements for submitting data to OASIS and does not have any bearing on the change to expand the data collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). Therefore, this technical change would not result in an increase in costs for HHAs. For a review of the burden and operational costs associated with the transition to the OASIS all-payer submission requirements we refer readers to the CY 2023 HH PPS final rule "Collection of Information" section (88 FR 66877) and to the CY 2024 HH PPS final rule for the latest burden estimates (88 FR 77676).

4. Medicare and Medicaid Provider Enrollment

As discussed in section VI.A. of this proposed rule, we are proposing several changes to our Medicare provider enrollment regulations, with one minor

revision to a Medicaid provider enrollment provision in 42 CFR part 455, subpart E. Except as otherwise explained in this section VIII. of this proposed rule, we do not believe that any of our proposed provider enrollment provisions implicate an ICR burden.

a. Submission of Additional Documentation

We are proposing to add new paragraph (C) to § 424.510(d)(2)(iii) such that CMS could require a provider or supplier to submit any documentation (that is, documentation beyond that currently required under § 424.510(d)(1)) to verify and confirm the information furnished on the enrollment application; this includes, but is not limited to, documentation regarding the provider's or supplier's ownership or management. We cannot predict the number or types of providers and suppliers that would be requested to provide such documentation or the specific documentation involved, for it would vary widely by provider and supplier. Nonetheless, we believe a general estimate, solely for purposes of this ICR section, is possible.

In terms of cost, it has been our experience that Form CMS–855 applications are completed by the provider's or supplier's office staff. Accordingly, we would use the following wage category and hourly rate from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (<https://data.bls.gov/oes/#/industry/000000>).

TABLE 58: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES – PROVIDER ENROLLMENT

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28

We anticipate that: (1) most of the requested documentation would be that which helps validate the provider's or supplier's ownership and management; (2) 5,000 providers and suppliers per year would have to secure and submit it; and (3) it would take the provider or

supplier 15 minutes (0.25 hr) to do so. This results in an annual burden of 1,250 hours and \$55,350 (\$44.28 × 5,000 × 0.25).

b. DMEPOS Liability Insurance

To enroll and maintain enrollment in the Medicare program, DMEPOS suppliers under § 424.57(c)(10) must have a comprehensive liability insurance policy of at least \$300,000

⁹⁸ The currently approved HHCAHPS information collection request expires July 31, 2026.

⁹⁹ To derive the average costs for individuals, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for our salary estimate

(www.bls.gov/oes/current/oes_nat.htm). We believe that the burden will be addressed under All Occupations (occupation code 00–0000) at \$32.66/hr. since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of

employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage (see below), we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

that covers the supplier's place of business, customers, and employees. We are proposing to revise § 424.57(c)(10) such that an "authorized official" of the DMEPOS supplier (as that term is defined in § 424.502) must sign the liability insurance policy. We do not have data indicating the number of DMEPOS suppliers whose liability insurance policies are signed by: (1) an authorized official; or (2) someone of equivalent status within the organization who nonetheless may not be listed as an authorized official on the supplier's application. Therefore, we are unable to project any ICR burden associated with our proposed change. However, we solicit comment from the DMEPOS supplier community on the possible burden.

c. Miscellaneous

We are also proposing in § 424.516 to reduce the timeframe in which a provider or supplier must report an adverse legal action to CMS from 90 days to 30 days. We wish to clarify for stakeholders that we do not believe this would result in a change in provider burden. This is because regardless of the reporting timeframe involved, the change must be reported; that is, only

the timeframe for disclosure is changing, not the burden.

5. DMEPOS Supplier Accreditation Organizations (AOs)

Section 424.57 requires that DMEPOS suppliers be accredited by a CMS-approved AO to enroll in and bill the Medicare program. The main purpose of accreditation is to confirm—typically via a survey of the DMEPOS supplier's location—that the supplier meets detailed quality standards involving, for example, its administration, financial management, customer service, and DMEPOS product safety. Section 424.58, which was promulgated in 2006, outlines some of the components and requirements of the DMEPOS accreditation program, which CMS oversees but the AOs largely operate. These components include but are not limited to: (1) the process via which an organization can apply to become an AO; and (2) AO submission of accreditation data to CMS. However, two core concerns have arisen regarding aspects of the DMEPOS accreditation program. First, Medicare fraud, waste, and abuse among DMEPOS suppliers has continued notwithstanding the accreditation requirement. Second, we believe that the current provisions in

§ 424.58 must be strengthened to help ensure that AOs are adequately executing their DMEPOS accreditation activities. In our view, and as explained in section VI.B. of this proposed rule, we believe additional requirements are needed and are proposing a number of them. This section VIII. of this proposed rule outlines the estimated ICR burden associated with several of these data categories. Other costs would be addressed in the regulatory impact analysis (RIA) of this proposed rule. We note that only those categories that involve a new burden—that is, above and beyond the current provisions of § 424.58—would be addressed.

a. Submission of Data During AO Initial Application and Reapproval Application

Current § 424.58(b) (which would become new paragraphs (c) and (d)) outlines information that organizations must submit when applying or reapplying to become a DMEPOS AO. We are proposing additional data that must be provided in these situations. These data elements are outlined in Table 59, which also lists our estimated hour burden of compiling, preparing, drafting, and submitting this information.

TABLE 59: NEW DATA SUBMISSION ELEMENTS IN PROPOSED § 424.58(c) AND (d)

Regulatory Citation in Revised § 424.58(c)	Data Element	Estimated Hour Burden Per Submission
(c)(1)(iii)	Description of survey and other accreditation processes	4
(c)(1)(iii)(G)	How AO determines whether to perform survey (including sampling methodology)	2
(c)(1)(vii)(D)	Policies/procedures for avoiding conflicts of interest (including consulting firewall policies)	2
(c)(1)(vii)(E)	Policies/procedures for ensuring adequate number of surveyors	2
(c)(1)(viii)	Process for identifying/addressing deficiencies within its accreditation program	3
(c)(1)(ix)	How AO uses data to ensure compliance with Medicare program requirements	3
(c)(1)(x)(A) and (B)	Outline of steps AO would take in reviewing complaints and determining compliance	3
(c)(xvi)	Information demonstrating AO's DMEPOS knowledge/expertise/experience	2
(c)(xvii)	Information on AO's ability to conduct timely application reviews	2
(c)(xviii)	Description of decision-making process (including approving/denying/terminating a DMEPOS supplier's accreditation and the reasons for denial or termination)	4
(c)(xix)	Policies/procedures for determining whether/when survey is performed and ensuring unannounced surveys	2
(c)(xx)	Policies/procedures for when CAP applied	4
(c)(xxi)	Explanation of what AO deems and defines as deficiency and levels thereof	2
(c)(xxii)	Processes for detecting/reporting fraud, waste, and abuse	3
(c)(xxiii)	Signed statement/agreement	6
(c)(2)	Submission of additional application information per CMS request	8
Total Hour Burden Per Application Submission		52

As we believe that clinicians (such as nurses) and AO managers would be

most likely to prepare and submit the application, we propose to use the

following May 2024 BLS median wage categories:

TABLE 60: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurses	29-1141	45.00	45.00	90.00
Medical and Health Services Managers	11-9111	56.71	56.71	113.42
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28
General and Operations Managers	11-1201	49.50	49.50	99.00

The aforementioned statement in § 424.58(c)(1)(xxiii) must be signed by the AO's chief executive officer (CEO) or someone with equivalent authority within the AO. To account for this task, we would also use May 2024 BLS median wage category of "Chief Executives" (Occupation Code 11-1011). The wage amount is \$99.24; with fringe benefits and overhead, it is \$198.48.

There are currently 8 CMS-approved DMEPOS AOs. For purposes of this ICR estimate only, we would assume that all 8 would apply for reapproval sometime within the next 3-year timeframe (which is the standard OMB approval period) and that 2 organizations would initially apply for AO approval. This would result in a total hour burden for this period of 520 hours (52 hours $\times$ 10 organizations). Of these 520 hours, 10 hours (or 1 hour for each of the 10 AOs) would involve the CEO's review and signature of the statement, resulting in a cost of \$1,985 (10 $\times$ \$198.48). As for the remaining 510 hours, we believe that nurses and the aforementioned managers would be equally involved in preparing the application. We would hence use a midpoint wage estimate of \$101.71 ((\\$90.00 + \\$113.42)/2). This results in a total 3-year cost of \$53,857 ((\\$101.71 $\times$ 510 hours) + \$1,985), with an annual burden of 173 hours and \$17,952.

Except as otherwise noted, we would use the \$101.71 wage figure for the remainder of our DMEPOS accreditation ICR estimates.

b. Monthly Submission of Data

Existing § 424.58(c)(1) (proposed new paragraph (e)(1)(i)) requires AOs to submit certain data to CMS on a monthly basis (for example, notice of accreditation decisions). We are proposing in new paragraph (e)(1) that each AO must also—as part of its monthly submission to CMS—furnish notice of: (1) the instances where the AO had the discretion to perform a survey but decided not to (including the reason for the AO's decision); and (2) all

currently resolved deficiencies among its DMEPOS suppliers.

Although we cannot determine how many DMEPOS AOs there would be over the next 3 years, we would—for purposes of this ICR only—use the current number of 8 AOs.

We estimate it would take an AO a total of 6 hours each month to compile and submit the data in (1) and (2). (That is, about 3 hours for each task.) This would result in an ICR burden over 3 years of 1,728 hours (6 hours $\times$ 8 AOs $\times$ 12 months $\times$ 3 years) at a cost of \$175,755 (1,728 hours $\times$ \$101.71), with the annual burden being 576 hours and \$58,585.

c. CMS Ad-Hoc Data Requests

Proposed new paragraph (e)(1)(ii) would state that CMS may at any time request the AO to submit any of the information described in paragraph (e)(1)(i); this data must be furnished to CMS within 3 business days of the request. We cannot predict the number of instances where CMS would request this data or the specific information that would be solicited. However, solely for purposes of this ICR, we estimate that we would request paragraph (e)(1)(i) data from each AO 3 times per year and that it would take the AO 3 hours to accumulate data for each request. This would result in a 3-year burden of 216 hours (3 hours $\times$ 3 requests $\times$ 8 AOs $\times$ 3 years) and \$21,969 (216 $\times$ \$101.71). The annual burden would be 72 hours and \$7,323.

d. Notice to CMS of Changes to the AO's Accreditation Standards, Requirements, or Survey Process

Among the monthly data the AO must submit under current paragraph (c)(1)(v) is notice of any changes to the AO's accreditation standards, requirements, or survey process. We are proposing to remove this provision from the monthly reporting requirement and instead in new paragraph (e)(2) require the AO to: (1) report such changes to us 60 days before the planned effective date; and (2) submit detailed information about the changes, the rationale for them, and

an accompanying crosswalk. We do not expect the 60-day requirement to impose an additional burden since the changes would still be reported to us, but we believe the additional information in (2) that must be furnished would.

Per our experience, each AO undertakes and reports these program revisions to us about twice per year. We estimate that the additional details that must be submitted would take 2 hours for the AO to compile. The resulting 3-year burden would thus be 96 hours (2 per year $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) and \$9,764 (96 $\times$ \$101.71), with the annual burden being 32 hours and \$3,255.

e. Submission of Complaint Data

AOs under existing § 424.58(c)(1)(iii) must report to CMS each month all complaints related to DMEPOS suppliers. We are proposing to remove this requirement from § 424.58(c)(1)(iii) and establish a new paragraph (e)(3) devoted exclusively to complaints. There are two new proposed ICR-related provisions therein. Specifically—

- Upon receipt of a complaint, the AO must notify CMS in writing of the complaint within 5 calendar days of receiving it.
- Notify CMS in writing of the result of its review of the complaint, the result of the survey, or of any action the AO took against the supplier.

The more frequent reporting of complaints to CMS—as well as notice of the results of the AO's investigation—would constitute an additional ICR burden. Given the number of complaints currently reported to us on a monthly basis, we estimate that each AO would annually report 50 complaints to us and, in turn, submit 50 investigation reports to us. We project that the former would take 1 hour to complete and submit and the latter 3 hours, for an average of 2 hours. This results in a 3-year burden of 4,800 hours ((50 complaint reports + 50 investigation reports) $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) at a cost of \$488,208 (4,800 $\times$ \$101.71), with the annual burden being 1,600 hours and \$162,736.

f. Corrective Action Plans (CAPs)

New paragraph (e)(4) would require AOs to notify CMS in writing of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. The notice must include: (1) the reason for the decision; (2) a detailed explanation and justification as to why the AO applied a CAP instead of revoking the supplier's accreditation; and (3) the details of the supplier's CAP. We believe that each AO would submit approximately 75 such notices to CMS per year and that each notice would take 2 hours to complete. The 3-year burden would therefore be 3,600 hours (75 submissions $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) and \$366,156 (3,600 $\times$ \$101.71). The annual burden would be 1,200 hours and \$122,052.

g. Denials and Terminations of DMEPOS Supplier's Accreditation

Under proposed § 424.58(e)(5)(i), the AO must notify CMS in writing of any decision to deny accreditation to (or terminate the accreditation of) a DMEPOS supplier within 5 calendar days of the decision; the notification must include the reason for the denial or termination. While AOs are currently required under § 424.58(c)(1)(iv) to report DMEPOS supplier terminations to CMS on a monthly basis, new paragraph (e)(5) would increase the frequency with which this information must be provided. We project that each AO would submit approximately 100 such reports to CMS each year. Each report would take 2 hours to prepare and submit. This would result in a 3-year burden of 4,800 hours (100 reports $\times$ 8 AOs $\times$ 3 years $\times$ 2 hours) and \$488,208 (4,800 $\times$ \$101.71) and an annual burden of 1,600 hours and \$162,736.

Proposed § 424.58(e)(5)(ii)(A)(5) would require an AO to deny or terminate a DMEPOS supplier's accreditation if directed by CMS. The AO under § 424.58(e)(5)(ii)(B)(2) would also have to notify CMS in writing that it has taken the directed action. We estimate that each year an AO would submit roughly 20 notices to CMS and that it would take 0.5 hours for the AO to do so each time. The total 3-year burden would thus be 240 hours (20

reports $\times$ 0.5 $\times$ 8 AOs $\times$ 3 years) and \$24,410 (240 hours $\times$ \$101.71). The annual burden would be 80 hours and \$8,137.

h. Voluntary Terminations

New § 424.58(g) would outline procedures via which an AO can voluntarily withdraw from the DMEPOS accreditation program. Part of this process involves: (1) notifying CMS in writing of its decision; and (2) provide written notice to each of its accredited DMEPOS suppliers. For purposes of this ICR only, we estimate that 1 DMEPOS AO over a 3-year period would voluntarily terminate its accreditation and that the tasks in (1) and (2) would take the AO 6 hours combined to complete (mostly involving the second task, which we believe would be done via a listserv message to all suppliers) at a cost of \$610 (1 $\times$ 6 hours $\times$ \$101.71). The annual burden would be 2 hours and \$203.

i. Involuntary Terminations

New § 424.58(h)(4) would require a terminated AO to provide written notice of the termination to each of its accredited DMEPOS suppliers. As with voluntary terminations, we estimate that 1 DMEPOS AO over a 3-year period would have its CMS approval terminated. We estimate it would take the AO 6 hours to notify its DMEPOS suppliers of the termination via a listserv message. This would result in a 3-year burden of 6 hours at a cost of \$610. The annual burden would be 2 hours and \$203.

j. Acknowledgement of Suspension and Lifting Thereof

New § 424.58(i) states that if CMS notifies the AO that its accreditation program has been suspended, the AO must send CMS a written acknowledgment of CMS' notice. Likewise, the AO must notify CMS in writing of its acknowledgment of a CMS notification that the suspension has been lifted. We project that 1 AO over a 3-year period would be suspended and that each of the two acknowledgments would take 1 hour to complete and submit. The 3-year burden would hence be 2 hours (1 hour $\times$ 2 acknowledgments) at a cost of \$203. The

annual burden would be 0.667 hours and \$68.

k. Conflicts of Interest and Consulting

New § 424.58(m) and (n) would establish requirements regarding AO consulting services and conflicts of interest, respectively. There are two principal ICR aspects of these requirements:

- The AO's submission of a report upon CMS request regarding any consulting activities it has engaged or is engaging in (paragraph (m)(4)).
- Preparation and submission to CMS (upon the latter's request) of the AO's written consulting firewall policies (paragraph (m)(5)).

(These documents must also be submitted with an AO's request for initial approval or reapproval of its DMEPOS accreditation program, though the burden associated with this is included in the ICR calculations for AO initial and reapproval applications.)

We project that the report in paragraph (m)(4) would take an AO 2 hours to complete and submit and that CMS would request it twice per year. This would result in a 3-year burden of 96 hours (2 reports per year $\times$ 2 hours $\times$ 8 AOs $\times$ 3 years) and \$9,764 (96 $\times$ \$101.71), or 32 hours and \$3,255 annually. Regarding the firewall policies and procedures, we estimate that it would take the AO 2 hours to prepare and submit these policies and that CMS would request them once a year. The 3-year burden of this activity would be 48 hours (2 hours $\times$ 1 request per year $\times$ 8 AOs $\times$ 3 years) and \$4,882, or 16 hours and \$1,627 per year. The combined annual ICR burden of the requirements of paragraph (m) are 48 hours (32 + 16) and \$3,973 (\$3,255 + \$1,627).

l. AO Changes of Ownership

We are proposing in new § 424.58(o) procedures for which a DMEPOS AO can undergo a change of ownership. Said procedures would be those outlined in § 488.5(f). The latter section contains several actions that we believe would have ICR implications for an AO changing its ownership. Table 61 outlines these actions and the estimated time burden of completing each of them:

TABLE 61: NEW DATA SUBMISSION ELEMENTS IN PROPOSED § 424.58(o)

Regulatory Citation in § 488.5(f)	Action	Estimated Hour Burden Per Action
(f)(1)	DMEPOS AO contemplating or negotiating a change of ownership must notify CMS in writing.	2
(f)(2)(iii)	Prospective AO buyer must submit detailed data in its request for approval of transfer of AO's current approval to the buyer (that is, identifying information, financial statements, transition plan, policies to avoid conflicts of interest)	135
(f)(3) and (4)(ii)	Prospective AO buyer's submission of written acknowledgments to CMS.	2
(f)(4)(i) *	All parties to the transaction must notify all affected DMEPOS suppliers of any CMS approval of the transfer.	12
(f)(5)	Prospective AO buyer notifies CMS in writing that the change of ownership has occurred.	1
TOTAL		152

* Takes into account the aforementioned 6-hour supplier notification burden for voluntary and involuntary terminations.

Regarding the 135-hour burden for § 488.5(f)(2)(iii), we note that we published a final rule in the April 29, 2022, **Federal Register** on titled “Medicare Program; Accrediting Organizations—Changes of Ownership” (87 FR 25413). This final rule added new requirements processes for AO changes of ownership. The estimated burden therein for the activity in § 488.5(f)(2)(iii) was 135 hours, and the material to be submitted would be prepared by individuals in the BLS wage categories of Registered Nurse, Medical or Health Services Manager, and Accountant or Auditor (Occupation Code 13–2011). Therefore, we would use this hour burden for paragraph (f)(2)(iii) (as applied to DMEPOS AO ownership changes) and a combined average wage for these three BLS categories. We previously mentioned the wages for the first two categories, \$90.00 and \$113.42. For accountants and auditors, the median wage with fringe benefits and overhead is \$78.54. The average of these three figures is \$93.99.

We would assume for purposes of this ICR that 1 DMEPOS AO over a 3-year period would undergo a change of

ownership. Using our total hour burden from table 62, this would result in a 3-year burden of 152 hours and \$14,286. The annual burden would be 51 hours and \$4,762.

m. DMEPOS Supplier Change in Majority Ownership

We are proposing in new § 424.551 that a DMEPOS supplier that undergoes a change in majority ownership (CIMO) (as that term is defined in § 424.551) that does not qualify for an exception under that section must enroll in Medicare as an initial DMEPOS supplier, obtain a new accreditation, and receive an accreditation survey. This would require completion of an initial Form CMS–855S Medicare Enrollment Application—Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers,¹⁰⁰ OMB No.: 0938–1056).

We are projecting in section IX. of this proposed rule that an average of 3,768 DMEPOS suppliers each year have a CIMO. We currently require any DMEPOS supplier undergoing a change of ownership involving a new tax identification number to enroll in Medicare as a new supplier. Since these

suppliers already have to complete a new enrollment application, there would be no change in their Form CMS–855S information collection burden. Although we do not have concrete estimates as to what portion of the above 3,768 suppliers fall into this category, we believe it is roughly 400–500. We will therefore base our Form CMS–855S burden projections on an estimated 3,300 affected suppliers.

Per previous projections, completion of an initial Form CMS–855S application takes approximately 4 hours, resulting in an annual time burden of 13,200 hours (3,300 hours × 4). In terms of costs, office and administrative support workers (BLS median wage of \$44.28) complete the application for a 3.5-hour burden, and a general and operations manager (\$99.00 wage) spends 0.5 hours reviewing and signing the form. This results in an annual cost burden of \$674,784 ((3.5 hours × 3,300 × \$44.28) + (0.5 hours × 3,300 × \$99.00)).

n. Totals

Table 62 outlines the annual ICR burdens associated with our proposed DMEPOS accreditation provisions:

¹⁰⁰ The currently approved CMS–855S information collection request expires 12/31/2025.

TABLE 62: ANNUAL ICR BURDEN ESTIMATES FOR DMEPOS AO REQUIREMENTS

	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$) (includes 100% fringe benefits)	Total Cost (\$)
Submission of Additional Initial Application and Reapproval Application Data	0938-New	4	4	Varies	173	101.71	17,596
Submission of Additional Monthly Data	0938-New	8	96	6	576	101.71	58,585
Ad-Hoc CMS Data Requests	0938-New	8	24	3	72	101.71	7,323
Notice of Changes in AO's Standards/Requirements	0938-New	8	16	2	32	101.71	3,255
Complaint Reports	0938-New	8	800	2 (average)	1,600	101.71	162,736
CAPs	0938-New	8	600	2	1,200	101.71	122,052
Denials/Terminations of Supplier's Accreditation Reports to CMS	0938-New	8	800	2	1,600	101.71	162,736
Notice to CMS that AO Denied/Terminated Supplier's Accreditation Per CMS Direction	0938-New	8	160	0.5	80	101.71	8,137
Voluntary Terminations – Notice to CMS and Suppliers	0938-New	0.333	0.333	6	2	101.71	203
Involuntary Termination – Notice to Suppliers	0938-New	0.333	0.333	6	2	101.71	203
Acknowledgment of Suspension and Lifting Thereof	0938-New	0.333	0.333	1	0.333	101.71	34
Consulting Data	0938-New	8	24	Varies	48	101.71	4,882
AO Changes of Ownership	0938-New	0.333	0.333	Varies	51	93.99	4,793
Completion of Initial Form CMS-855S	0938-1056	3,300	3,300	4	13,200	Varies	674,784
TOTALS (Rounded to Nearest Whole Dollar)	N/A	3,369	5,825	Varies	18,636	Varies	1,227,319

The costs of our DMEPOS accreditation proposals to DMEPOS suppliers—as well as additional costs to DMEPOS AOs—are addressed in section IX.C.6. of this proposed rule.

We solicit comment from stakeholders regarding any potential DMEPOS accreditation ICR burdens that may not have been addressed in this section VIII.B.5. of this proposed rule. The burden estimates detailed in this section 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.

6. ICRs for Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(ii))

We propose to add technical language to § 414.234(c)(1) that provides for the exemption process in § 414.234 (c)(1)(ii). We also propose to exempt a supplier from the mandatory prior authorization process (OMB Control No. 0938–1293) in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS withdraws the exemption. In proposed § 414.234 (c)(1)(ii)(B), we would provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we propose to provide 60-day notice if an exemption is withdrawn. We would exempt suppliers that achieve a prior authorization provisional affirmation threshold of at

least 90 percent during a periodic assessment. If the rate of prior authorizations with non-affirmations submitted becomes higher than 10 percent during an annual assessment, we would consider withdrawing exemption for the specific noncompliant supplier, until the following periodic assessment.

We estimate there would be savings for compliant suppliers who meet the 90 percent affirmation threshold. We based our savings estimates on presumptions, which we would discuss herein, and internal data obtained from the DME MACs. Compliant suppliers would not have to submit prior authorization requests (PARs). The burden associated with submitting prior authorization requests is the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the MAC for review. CMS expects that this information would generally be maintained by suppliers as a normal course of business and that this information would be readily available. The documentation submitted must support medical necessity for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare benefit eligibility, and meet all other applicable Medicare statutory and regulatory requirements.

a. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics'

(May 2024 Occupational Employment Statistics report) to find the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. Based on the Bureau of Labor Statistics report (Healthcare Support Occupations), we estimate an average hourly rate of \$19.06 with a loaded rate of \$38.12.

The process of submitting, and unit cost of reviewing expedited prior authorization requests is the same for standard review. Items on the Required Prior Authorization List are rarely used in emergent situations, consequently, we expect the request for expedited reviews to remain low.

In addition to mail, suppliers can submit documentation through fax, electronic portals, and esMD, so supplier burden should not be affected by the method of submission. CMS estimates that the average time for office clerical activities associated with this task to be 30 minutes. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the BLS.

We based the estimated number of responses for Year 1 on the number of prior authorization requests for the DMEPOS items currently on the Required Prior Authorization List for Calendar Year 2024. We estimate a 3 percent increase in the number of PARs received in CYs 2024, 2025, and 2026. In Year One (CY 2026) we anticipate that there would be 232,836 initial requests and 57,017 resubmissions.

We estimate around 30,000 initial prior authorization requests for DMEPOS items that could potentially be added to the Required Prior Authorization List in the future. Of these, we estimate only 80 percent would submit an initial prior authorization request, resulting in 24,000 additional initial requests, plus the estimated CY 2026 initial requests of 232,836, for a total of 256,836 initial requests in CY 2026.

We assume that 20 percent of the estimated initial prior authorization requests received (256,836) would receive a non-affirmative decision and would resubmit their request, for a total of 51,367 level one resubmissions. We assume that subsequent resubmissions would be 10 percent of the previous level resubmission, totaling 5,137 for level 2 resubmissions, and 514 for level 3 resubmissions. In sum, we estimate the total number of submissions for Year 1 to be 256,836 initial requests plus

57,017 resubmissions for a total of 313,852 submissions. We estimate the cost of mailing medical records to be \$6,275 in Year 1. The total estimated burden for Year 1 is \$5,988,332, which includes the time associated with submitting prior authorization requests multiplied by the loaded rate of \$38.12 an hour, plus the cost of mailing records and documents.

b. Prior Authorization Process for Certain DMEPOS Items

TABLE 63: DMEPOS PRIOR AUTHORIZATION SUBMISSION BURDEN FOR YEAR 1

Activity	Estimated Responses Per Year (number of prior authorization requests submitted)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Initial Submissions	255,808	0.5	127,904	\$4,875,700
Fax and Electronic Resubmissions	56,789	0.5	28,395	\$1,082,417
Mail Initials	1,027	0.5	514	\$19,594
Mail Resubmissions	228	0.5	114	\$4,346
Mail Cost	N/A	\$5 (1,255)	N/A	\$6,275
Total	313,852	N/A	156,927	\$5,988,332

We expect an annual growth rate of 3 percent for the number of requests based on more people aging into the program and qualifying for coverage. Accordingly, in Year 2 we estimate that there would be 264,541 initial prior authorization requests from Year 1 plus and an additional 24,000 initial requests from codes that would potentially be

added to the Required Prior Authorization List in Year 2 for a total of 288,541 initial requests. Using the same rates of resubmissions described in Year 1, we estimate 64,056 resubmission requests for the total number of submissions in Year 2 of 352,597. We assume 20 percent of initial requests will be resubmitted for a level

one total of 57,708. Subsequent resubmissions would be 10 percent of the previous level resubmission, totaling 5,771 for level 2 resubmissions, and 577 for level 3 resubmissions. Accordingly, we estimate a total burden of \$6,727,543 for Year 2.

TABLE 64: TOTAL ANNUAL BURDEN

Year One	Year Two	Average Annual Burden
\$5,988,332	\$6,727,543	\$6,357,938

The annual burden for Year 1 is \$5,988,332, the annual burden for Year 2 is \$6,727,543 for an average annual burden of \$6,357,938.

The proposed provisions permit CMS to exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate of non-payable claims submitted becomes higher than 10 percent during an

assessment, we would withdraw exemption for the specific noncompliant supplier. We assessed data from previous years to determine the number of suppliers that would have met the 90 percent compliance rate.

To assess the reduction in burden for compliant suppliers, we start by looking at the total number of provider transaction access numbers (PTANs), a

unique identification number assigned by Medicare to providers and suppliers that bill Medicare for services, submitting claims for payment and mandatory prior authorization requests. That total number for 2024 was 9,298. Of the total number of PTANs, 6 percent of those PTANs met the criteria for an exemption from mandatory prior authorization requirements, or 558 total PTANs. We are unable to determine the

number of compliant suppliers in future years. However, if we average the data from previous years, the average percentage of compliant suppliers or PTANs is 4 percent.

TABLE 65: AVERAGE EXEMPT SUPPLIERS BY YEAR

CY	Total PTAN	PTAN Who Meet Criteria	Percentage of Exempt PTAN
2022	7,049	148	2%
2023	8,048	249	3%
2024	9,298	558	6%

The total burden is assessed in Table 64. By reducing the total average annual burden (\$6,357,938) by the average number of suppliers (represented by PTANs) *not* submitting prior authorization requests by 4 percent, we have an average savings of \$254,318 per year.

7. DMEPOS Competitive Bidding Program

a. ICRs for the Submission of Financial Documents (§ 414.414(d))

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/ burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements and burden.

Per § 414.414(d), each bidding entity must submit along with its bid the applicable covered documents specified in the request for bids. As discussed in section VII. of this proposed rule, based on internal review we are proposing to streamline the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. Specifically, CMS is proposing to only require bidding entities to submit a credit report with a numerical credit score or rating during the bid window. The submission of a tax return extract, income statement, balance sheet, and statement of cash flows would no longer be required, which would significantly reduce the time it takes a bidding entity’s Administrative Services Manager to assemble and upload financial documents during the

bidding process by minus 5 hours and 15 minutes (from 8 hours and 21 minutes to 3 hours and 12 minutes).

As a result of the decreased submission requirement CMS would no longer be able to utilize revenue data from the bidding entity’s tax return to determine if it meets the definition of a “small supplier” in the DMEPOS CBP (that is, a bidding entity that generates gross revenue of \$3.5 million or less in annual receipts including Medicare and non-Medicare revenue). To address this, CMS is proposing to add a question to Form A (Application for DMEPOS Competitive Bidding Program) that would allow a bidding entity to attest whether it meets the definition of a small supplier.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) due to the proposals discussed in section VIII.B.7.b. through d. of this proposed rule. As a result, we estimate there would be approximately 833.33 bidders annually (2,500 bidders/3 years) in the next round and each bidder would complete Form A.

We expect the burden associated with the new attestation requirement to be minimal since suppliers should already be aware of their current revenue levels. That said, for the purpose of scoring the PRA-related impact of this rule’s proposed changes, we estimate that it would take (on average) 6 minutes (0.1 hr) at \$104.22/hr for a bidding entity’s Administrative Services Manager to complete the attestation question. In aggregate, we estimate an additional annual burden of 83 hours (833.33 bids/ year × 0.1 hr/bid) at a cost of \$8,650 (83 hr × \$104.22/hr) for completing the attestation in Form A.

With regard to the reduction in the number of covered documents that bidding entities are required to submit

during the bid window, we estimate 500 bidders (1,500 active bids per year/3 years) since this is the revision of an existing (active) requirement. In aggregate, we estimate an annual savings of minus 2,625 hours (500 bids × – 5.25 hr/bid) and minus \$273,578 (– 4,375 hr × \$104.22/hr) for completing Form A.

Overall, we estimate an annual savings of minus 2,542 hours (83 hr – , 2,625 hr) and minus \$264,928 (\$8,650 – \$273,578).

b. ICRs for Adjustments to Single Payment Amounts (SPAs) (§ 414.408(b))

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HHS PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/ burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements/burden.

As discussed in section VII. of this proposed rule, based on internal review and industry feedback, we propose to revise § 414.408(b) which currently does not allow changes to the SPAs for the duration of a round of the DMEPOS CBP. Specifically, we propose adding an annual update factor to adjust the SPAs for the second and third year of a DMEPOS CBP contract performance period by the same annual covered item update factors applied to the fee schedule amounts for the items in non-CBAs. Therefore, when a bidding entity is formulating its bid amounts at the time of bidding and entering it on Form B (Bidding Form), a bidder would no longer need to account for inflation and/ or other potential future effects of price increases to provide certain DMEPOS.

We expect that the change would reduce the amount of time for an Administrative Services Manager to

complete Form B by approximately 24 minutes (0.4 hr) (from 3.0 hr to 2.6 hr).

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) due to the proposals discussed in section VIII.B.7.b. through d. of this proposed rule. We also expect that the average bidder would bid in 22 competitions (our active burden estimates 35 competitions) for a difference of minus 13 competitions.

In aggregate, we estimate savings of minus 14,500 hours [CURRENT (1,500 bidders $\times$ 35 bids/bidder $\times$ 3 hr/bid) – PROPOSED (2,500 bidders $\times$ 22 bids/bidder $\times$ 2.6 hr/bid)] and minus \$1,511,190 (14,500 hr $\times$ \$104.22/hr) for completing Form B. Annually, this would amount to a savings of approximately 4,833 hours (14,500 hr/3 yr) and \$503,730 (\$1,511,190/3 yr).

c. ICRs for Determining the Number of Contracts Awarded (§ 414.414(h))

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements/burden.

As discussed in section VII. of this proposed rule, based on internal review we are proposing to revise § 414.414(h) for how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS bidding entities. Specifically, we propose to use contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included in the DMEPOS CBP as well as information on current supplier utilization for new product categories. With this change, bidding entities would no longer have to

determine the capacity that they could furnish in each competition and enter the applicable capacity estimate(s) on Form B of their bid submission.

We believe it took a supplier's Administrative Services Manager approximately 90 minutes (1.5 hr) (out of 3.0 hr/bid) to determine their estimated capacity in each competition and then entering it on each Form B.

As previously mentioned, while we do not know the exact number of bidders that would bid in the next round, for purposes of scoring the PRA-related impact of this rule, we expect that the average bidder would bid in 22 competitions. While we previously estimated that the average bidder would complete 35 Form B's (5 CBAs $\times$ 7 product categories), we believe that the additional 1,000 bidders would only submit, on average, bids for approximately 2 competitions (two Form Bs) in the next round of the DMEPOS CBP, reducing the average number of Form B submissions by 13 (from 35 to 22 competitions) per bidder.

In aggregate, we estimate savings of minus 75,000 hours [CURRENT (1,500 bidders $\times$ 35 bids/bidder $\times$ 3 hr/bid) – PROPOSED (2,500 bidders $\times$ 22 bids/bidder $\times$ 1.5 hr/bid)] and minus \$7,816,500 (75,000 hr $\times$ \$104.22/hr) for completing Form B. Annually, this would amount to a savings of approximately 25,000 hours (75,000 hr/3 yr) and \$2,605,500 (\$7,816,500/3 yr).

d. ICRs for the Remote Item Delivery (RID) Competitive Bidding Program and Revising the Definition of Item Related to Medical Supplies (§ 414.402)

The following proposed changes will be submitted to OMB for review under control number 0938–1016 (CMS–10169). When ready, the finalized changes (under the CY 2026 HH PPS final rule) will be submitted to OMB for reinstatement with the changes. We let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion by soliciting comment on such outdated requirements/burden.

As discussed in section VII. of this proposed rule, based on internal review,

under § 414.402, we are proposing to create a new definition of RID competitive bidding program to mean a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.

As discussed in section VII. of this proposed rule, because we are also proposing to specify that ostomy, tracheostomy, and urological supplies are medical supplies mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act, we expect that both changes would result in an increase in burden as suppliers would potentially have additional CBAs and product categories in which they could bid.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of the aforementioned changes, we expect 2,500 bidders (an increase of 1,000 bidders) due to the proposals discussed in section VIII.B.7.b. through d. of this proposed rule. As a result, we estimate there would be approximately 833.33 bidders annually (2,500 bidders/3 years) in the next round and each bidder would complete 22 Form Bs (a decrease of 13 competitions/bidder).

Because of the new competitions being added into the DMEPS CBP, we estimate that it would take a supplier's Administrative Services Manager an additional 1 hour at \$104.22/hr to develop its bid amount for each product category that they submit a bid and an additional 6 minutes (0.1 hr) to complete Form B.

In aggregate, we estimate a burden of 20,167 hours (833.33 bidders/year $\times$ 22 bids/bidder $\times$ 1.1 hr/bid) at a cost of \$2,101,805 (20,167 hr $\times$ \$104.22/hr) for completing Form B.

e. Summary of Annual Burden Estimates for DMEPOS CBP Proposed Requirements

TABLE 66: PROPOSED DMEPOS CBP ANNUAL BURDEN ESTIMATES

Regulatory Section in Title 42 of the CFR	Form	Number of Respondents	Total Number of Responses	Time per Response (hours)	Total Time (hours)	Labor Rate (\$/hr)	Total Costs (\$)	Annualized Time (hours)	Annualized Costs (\$)
Attestation (§ 414.414(d))	Form A	833.33	833.33	0.1 hr/bid	83	104.22	8,650	83	8,650
Submission of Covered Documents (§ 414.414(d))	Form A	1,500	500	(5.25) hr/bid	(2,625)	104.22	(820,733)	(2,625)	(273,578)
Adjustments to Single Payment Amounts (§ 414.408(b))	Form B	1,000	1,000	0.4 hr/bid	(14,500)	104.22	(1,511,190)	(4,833)	(503,730)
Capacity Estimates (§ 414.414(h))	Form B	1,000	1,000	1.5 hr/bid	(75,000)	104.22	(7,816,500)	(25,000)	(2,605,500)
Develop Bid Amount (§ 414.402)	Form B	833.33	18,333	1.1 hr/bid	20,167	104.22	6,308,228	20,167	2,101,805
TOTAL	N/A	2,333 (1,500 + 833)	21,666	Varies	(71,875)	104.22	(3,831,545)	(12,208)	(1,272,353)

C. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at <https://www.cms.gov/regulations-and-guidance/legislation/paperwork-reductionactof1995/pralisting>.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1828–P, RIN 0938–AV53), the ICR's CFR citation, and the OMB control number.

IX. 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 requires the standard prospective payment amount 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, 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 affects their Medicare payments in CY 2025. In this proposed rule, we include proposed changes to the expanded HHVBP Model applicable measure set and measure weights, a new measure removal factor, and a request for information (RFI) related to potential future measure concepts.

4. Updates to the Home Health Agency CoPs to Align With the OASIS All-Payer Submission Requirements

This proposed rule updates the CoPs to further clarify that the OASIS all-payer submission requirement applies to all HHA patients receiving skilled services, not only Medicare and Medicaid patients.

5. Provider Enrollment

Consistent with section 1866(j) of the Act, we are proposing several 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, revoking, or deactivating 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 Supplier Accreditation Organizations

Section 1834(a)(20) of the Act and 42 CFR 424.57 require DMEPOS suppliers to be accredited by a CMS-approved AO to enroll in and bill the Medicare program. The main purpose of accreditation is to confirm—typically via a survey of the DMEPOS supplier's location—that the supplier meets detailed quality standards involving, for example, its administration, financial management, customer service, and DMEPOS product safety. Section 424.58 outlines some of the components and requirements of the DMEPOS accreditation program. However, this regulatory section has not been updated since its promulgation in 2006. Given the ongoing problem of fraud, waste, and abuse in the DMEPOS arena—as well as the regulatory gaps that exist in § 424.58—we believe it is necessary via this proposed rule to strengthen our oversight of DMEOS accreditation by enhancing the regulatory requirements of § 424.58.

7. DMEPOS Prior Authorization

Consistent with provisions in section 1834(a)(15) of the Act and existing authority at § 414.234 (c)(1)(ii) that permits exemption from prior authorization for certain compliant suppliers, we propose to establish guidelines for establishing an exemption and withdrawal of an exemption. Furthermore, we propose to establish notification requirements to put suppliers on notice that the exemption has either been granted or withdrawn.

8. DMEPOS Competitive Bidding Program

This proposed rule would revise the DMEPOS CBP to enhance its effectiveness in achieving the objectives of the program as mandated by section 1847(a) of the Act. This proposed rule would revise how SPAs mandated by section 1847(b)(5)(A) of the Act would be calculated and how CMS would determine the number of contracts it would award in each CBA for every product category, taking into account the ability of bidding entities (bidders) to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the CBA on a timely basis as mandated by section 1847(b)(4)(A) of the Act. This proposed rule would also apply annual inflation update factors to the SPAs. Additionally, this proposed rule would establish special payment rules for class II continuous glucose

monitors and insulin infusion pumps to pay for these items and all related supplies and accessories on a 90-day rental basis under the DMEPOS CBP. This proposed rule would classify class III continuous glucose monitors and insulin infusion pumps used in conjunction with class III continuous glucose monitors as items that require frequent and substantial servicing and make payment for the items using the same 90-day rental method and payment amounts established for class II continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP. This proposed rule would also establish the definition of “remote item delivery (RID) competitive bidding area” under the DMEPOS CBP. In addition, this proposed rule would revise the methodology used to establish bid limits and address the conditions for determining when contracts cannot be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act because the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. This proposed rule would also revise the definition of “item” to clarify that items that may be included in a CBP include medical supplies, including ostomy, tracheostomy, and urological supplies in accordance with section 1847(a)(2)(A) of the Act. Also, this proposed rule would streamline the requirements and evaluation of the DMEPOS CBP financial standards as well as the processes for evaluating and notifying a bidder of any applicable covered document(s) not submitted by the CDRD. In addition, this rule proposes to codify the DMEPOS CBP bid surety bond rider process. This proposed rule also proposes to add a Tribal exception to the DMEPOS CBP. This proposed rule would add a termination clause to the DMEPOS CBP supplier contracts that could be utilized during a public health emergency.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, “Regulatory Planning and Review”; Executive Order 13563, “Improving Regulation and Regulatory Review”; Executive Order 14192, “Unleashing Prosperity Through Deregulation”; the Regulatory Flexibility Act (RFA); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995; and Executive Order 13132, “Federalism”.

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) 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 Proposed Changes for the CY 2026 HH PPS

This rule proposes to update Medicare payments under the HH PPS for CY 2026. The net transfer impact related to the changes in payments under the HH PPS for CY 2026 is estimated to be –\$1.135 billion (–6.4 percent). The \$1.135 billion decrease in estimated payments for CY 2026 reflects the effects of the proposed CY 2026 home health payment update percentage of 2.4 percent (\$425 million increase), an estimated 3.7 percent decrease that reflects the effects of the permanent adjustment (\$655 million decrease), an estimated 4.6 percent decrease that reflects the effects of the temporary adjustment (\$815 million decrease) and an estimated 0.5 percent decrease that reflects the updated FDL (\$90 million decrease).

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, 2024. 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 67 represents how HHA revenues are likely to be affected by the proposed policy changes for CY 2026. For this analysis, we used an analytic file with linked CY 2024 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2024. The first column of table 67 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 permanent adjustment on all payments. The aggregate impact of the permanent adjustment reflected in the third column does not equal the proposed – 4.059 percent permanent adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The fourth column shows the payment effects of the recalibration of the case-mix weights offset by the case-mix weight budget neutrality factor. The fifth column shows the payment effects of updating the CY 2026 wage index (that is, the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022 (FY 2022 cost report data)) with a 5 percent cap on wage index decreases. The aggregate impact of the changes in the fifth column is zero percent, due to the wage index budget neutrality factor. The sixth column shows the payment effects of the proposed CY 2026 home health payment update percentage. The seventh column shows the payment effects of the proposed FDL. The eighth

column shows the payment effects of the temporary adjustment on all payments. The aggregate impact of the temporary adjustment reflected in the eighth column does not equal the proposed – 5 percent temporary adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The last column shows the combined effects of all the proposed provisions.

Overall, it is projected that aggregate payments in CY 2026 would decrease by 6.4 percent which reflects the 3.7 percent decrease from the permanent adjustment, the 4.6 percent decrease from the temporary adjustment, the 0.5 percent decrease from the updated FDL and the proposed 2.4 percent increase to the home health payment update percentage. As illustrated in table 67, 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 2026 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.

BILLING CODE 4120-01-P

TABLE 67: PROPOSED CY 2026 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	Permanent Adjustment	CY 2026 Case-Mix Weights Recalibration Factor	CY 2026 Updated Wage Index (with 5% cap)	CY 2026 Proposed HH Payment Update Percentage	CY 2026 Fixed-Dollar Loss (FDL) Update	Temporary Adjustment	Total
All Agencies	9,768	-3.7%	0.0%	0.0%	2.4%	-0.5%	-4.6%	-6.4%
Facility Type and Control								
Free-Standing/Other Vol/NP	718	-3.6%	0.1%	0.5%	2.4%	-0.6%	-4.5%	-5.7%
Free-Standing/Other Proprietary	8,091	-3.7%	0.0%	-0.2%	2.4%	-0.4%	-4.6%	-6.5%
Free-Standing/Other Government	101	-3.5%	0.0%	0.0%	2.4%	-0.8%	-4.3%	-6.2%
Facility-Based Vol/NP	389	-3.4%	0.1%	0.3%	2.4%	-0.8%	-4.3%	-5.7%
Facility-Based Proprietary	24	-3.6%	0.0%	-0.9%	2.4%	-0.5%	-4.5%	-7.1%
Facility-Based Government	167	-3.6%	0.2%	0.2%	2.4%	-0.6%	-4.4%	-5.8%
Subtotal: Freestanding	8,983	-3.7%	0.0%	0.0%	2.4%	-0.4%	-4.6%	-6.3%
Subtotal: Facility-based	582	-3.4%	0.1%	0.2%	2.4%	-0.7%	-4.3%	-5.7%
Subtotal: Vol/NP	1,107	-3.5%	0.1%	0.4%	2.4%	-0.6%	-4.4%	-5.6%
Subtotal: Proprietary	8,115	-3.7%	0.0%	-0.2%	2.4%	-0.4%	-4.6%	-6.5%
Subtotal: Government	268	-3.5%	0.1%	0.1%	2.4%	-0.7%	-4.4%	-6.0%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	164	-3.6%	0.1%	0.5%	2.4%	-0.6%	-4.4%	-5.6%
Free-Standing/Other Proprietary	787	-3.8%	-0.1%	0.0%	2.4%	-0.3%	-4.7%	-6.5%
Free-Standing/Other Government	62	-3.5%	-0.1%	1.1%	2.4%	-0.7%	-4.4%	-5.2%
Facility-Based Vol/NP	155	-3.5%	0.3%	1.1%	2.4%	-0.8%	-4.3%	-4.8%
Facility-Based Proprietary	8	-3.6%	0.2%	0.6%	2.4%	-0.6%	-4.6%	-5.6%
Facility-Based Government	120	-3.5%	0.2%	0.5%	2.4%	-0.8%	-4.3%	-5.5%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	554	-3.6%	0.1%	0.5%	2.4%	-0.6%	-4.5%	-5.7%
Free-Standing/Other Proprietary	7,304	-3.7%	0.0%	-0.2%	2.4%	-0.4%	-4.6%	-6.5%
Free-Standing/Other Government	39	-3.4%	0.0%	-0.5%	2.4%	-0.8%	-4.3%	-6.6%
Facility-Based Vol/NP	234	-3.4%	0.1%	0.1%	2.4%	-0.8%	-4.2%	-5.8%
Facility-Based Proprietary	16	-3.7%	0.0%	-1.6%	2.4%	-0.5%	-4.5%	-7.9%
Facility-Based Government	47	-3.6%	0.3%	-0.1%	2.4%	-0.5%	-4.5%	-6.0%
Facility Location: Urban or Rural								
Rural	1,339	-3.7%	0.0%	0.2%	2.4%	-0.4%	-4.6%	-6.1%
Urban	8,429	-3.7%	0.0%	-0.1%	2.4%	-0.5%	-4.6%	-6.5%
Facility Location: Region of the Country (Census Region)								
New England	297	-3.6%	-0.1%	1.6%	2.4%	-0.5%	-4.5%	-4.7%

Mid Atlantic	367	-3.6%	0.3%	-0.3%	2.4%	-0.5%	-4.5%	-6.2%
East North Central	1,363	-3.7%	0.0%	0.7%	2.4%	-0.4%	-4.6%	-5.6%
West North Central	548	-3.6%	0.0%	1.1%	2.4%	-0.6%	-4.5%	-5.2%
South Atlantic	1,554	-3.7%	-0.1%	0.3%	2.4%	-0.4%	-4.6%	-6.1%
East South Central	357	-3.8%	-0.1%	0.1%	2.4%	-0.3%	-4.7%	-6.4%
West South Central	1,948	-3.7%	-0.1%	-0.3%	2.4%	-0.5%	-4.6%	-6.8%
Mountain	692	-3.7%	0.0%	0.1%	2.4%	-0.5%	-4.5%	-6.2%
Pacific	2,600	-3.7%	0.0%	-1.1%	2.4%	-0.5%	-4.6%	-7.5%
Outlying	42	-3.6%	1.1%	-0.1%	2.4%	-0.4%	-4.5%	-5.1%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,285	-3.7%	-0.1%	-0.3%	2.4%	-0.6%	-4.5%	-6.8%
100 to 249	1,563	-3.6%	-0.1%	-0.4%	2.4%	-0.6%	-4.5%	-6.8%
250 to 499	1,773	-3.7%	-0.1%	-0.4%	2.4%	-0.5%	-4.5%	-6.8%
500 to 999	1,891	-3.7%	-0.1%	-0.3%	2.4%	-0.5%	-4.6%	-6.8%
1,000 or More	2,256	-3.7%	0.0%	0.1%	2.4%	-0.4%	-4.6%	-6.2%

Source: CY 2024 Medicare claims data for periods with matched OASIS records ending in CY2024 (as of March 13, 2025).

Notes: The estimated 3.7 percent decrease related to the proposed permanent adjustment includes all payments, while the -4.059 percent permanent adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. Similarly, the estimated 4.6 percent decrease related to the proposed temporary adjustment includes all payments, while the -5.000 percent temporary adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The "CY 2026 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 0.35 to 0.46. 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 9,768); totals involving facility type (only) add up to 9,565 and totals involving control type add up to 9,490.

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

BILLING CODE 4120-01-C

2. Effects of the Proposed 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.

This proposed rule proposes to remove four items as standardized patient assessment data elements beginning with the CY 2026 HH QRP.

The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities. CMS is also proposing to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure and corresponding data element. The net effect of these proposals is a decrease of four data elements at the start of care and resumption of care time points and a decrease in one data element at the transfer of care, death at home and discharge time points for a net decrease in burden.

Section VIII.B.1. of this proposed rule provides a detailed description of the net decrease in burdens associated with the proposed changes. We proposed that removal of data elements associated with the HH QRP proposals would begin with assessments as of April 1, 2026. The cost impact of these proposed changes was estimated to be a net decrease of \$17,810,282 in annualized cost to HHAs, discounted at 2 percent relative to year 2023, over a perpetual time horizon beginning in CY 2026. We described the estimated burden and cost

reductions for these measures in section VIII. of this proposed rule. In summary, the implementation of proposals outlined in this proposed rule for the HH QRP is estimated to decrease the burden on HHAs by \$1,496 per HHA annually, or \$17,810,282 for all HHAs annually.

In section III.E. of this proposed rule, we propose to amend the data non-compliance reconsideration request policy and process. For HHAs that seek to file an extension to file a request for reconsideration of a noncompliance determination, we estimate that this request will take HHAs approximately 15 minutes to complete. We believe that this data would be entered by the medical records specialists. However, HHAs determine the staffing resources necessary. For the purposes of calculating the costs we obtained median hourly wages from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates.¹⁰¹ To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 68.

TABLE 68: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Other Indirect Costs and Fringe Benefits (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical Records Specialists	29-2072	\$24.16	\$24.16	\$48.32

We estimate that the collection of this request will result in an additional 15 minutes, or 0.25 hours, per request. Based on the number of reconsiderations requests we have received in the previous 3 years, we estimate an average of 85 requests per year, for an additional 21 hours per year (0.25 hours x 85 forms per year) for all HHAs. Given an estimated \$48.32 hourly wage, we estimate an increase of \$1015 (21 hours x \$48.32) for all HHAs annually or \$11.94 per HHA that request reconsiderations.

Section VIII. of this proposed rule provides a detailed description of the net decrease associated with the proposed changes. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of \$4,326,249 or \$363 (–\$4,326,249/11,904) for each

of the 11,904 active HHAs. For the four SDOH data elements removed at start of care or resumption of care, we estimate a decrease in clinician cost of \$13,484,033 or \$1,132 (–\$13,484,033/11,904) for each of the 11,904 active HHAs. For all proposals, we estimate a decrease in clinician costs of –\$17,810,282 between 2027 and 2026 related to the implementation of the proposals outlined in this proposed rule across all HHAs or a \$1,496 decrease (–\$17,810,282/11,904). Discounted at 2 percent relative to year 2023, over a perpetual time horizon beginning in CY 2026.

3. Effects of the Expanded HH VBP 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. The changes to the applicable measure set proposed in this rule will not change those estimates because they do not change the number of HHAs in the Model or the payment methodology.

Based on policies discussed in this proposed rule, Tables 69 and 70 display the distribution of possible unweighted payment adjustments¹⁰² using CY 2023 as the performance year and CY 2022 as the baseline year for all 1-year measures. For 2-year measures (such as DTC and MSPB-PAC), payment adjustments were calculated using CYs 2022 and 2023 as the performance period and CYs 2021 and 2022 as the baseline period. Note that payment adjustments in the expanded Model are made in a budget-neutral manner.

¹⁰¹ U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm

¹⁰² Payment adjustments calculated for all HHAs with Medicare certification dates prior to January 1, 2021.

Tables 69 and 70 show the value-based incentive payment adjustments for the estimated 7,061 HHAs that would qualify to compete in the expanded Model based on CY 2023 performance data stratified by volume-based cohort, as defined in section III.F. of the CY 2022 HH PPS final rule (86 FR 62312). Using CY 2023 performance year data and the 5 percent payment adjustment, based on the 11 proposed quality measures, the 6,391 HHAs in the larger-volume cohort would have an average payment adjustment of positive 0.004 percent (+0.004 percent). Overall, smaller-volume HHAs would have an average payment adjustment of positive 0.006 percent (+0.006 percent). Eighteen states/territories do not have any HHAs in the smaller-volume cohort. The remaining states/territories have HHAs in both volume-based cohorts. Florida, for example, has 556 HHAs in the larger-volume cohort with an average payment adjustment of positive 0.289 percent (+0.289 percent) and 50 HHAs in the smaller-volume cohort with an average payment adjustment of negative 0.003 percent (– 0.003 percent).

The next columns provide the distribution of payment adjustment by percentile. For example, 10 percent of HHAs in the larger-volume cohort would receive downward payment adjustments of more than negative 2.252

percent (– 2.252 percent). The median (50th percentile) payment adjustment for the larger-volume cohort is negative 0.086 percent (– 0.086 percent). Among smaller-volume HHAs, 10 percent of HHAs would receive downward payment adjustments of more than negative 2.513 percent (– 2.513 percent). The median (50th percentile) payment adjustment for the smaller-volume cohort is negative 0.094 percent (– 0.094 percent). As an example of the range of payment adjustments in a given state, payment adjustments for larger-volume HHAs in Florida range from negative 2.284 percent (– 2.284 percent) at the 10th percentile to positive 2.945 percent (+2.945 percent) at the 90th percentile, while the median (50th percentile) payment adjustment is positive 0.211 percent (+0.211 percent).

Table 71 provides the payment adjustment distribution based on the proportion of dual-eligible beneficiaries, average case mix using Hierarchical Condition Category (HCC) scores, proportion of beneficiaries that reside in rural areas, and HHA organizational status. To define cutoffs for the “percentage of dual eligible beneficiaries,” low through high percentage dual-eligible are based on the 20th, 40th, 60th, and 80th percentiles of percent dual eligible beneficiaries, respectively, across HHAs

in CY 2021. To define case mix cutoffs, low, medium, or high acuity are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2021. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries’ core-based statistical area (CBSA) urban versus rural designation. Based on CY 2021 data, HHAs with the highest proportion of dual-eligible beneficiaries served have the highest average payment adjustment (+0.228 percent). In addition, a higher proportion of rural beneficiaries served is associated with better performance. Specifically, HHAs serving over 50 percent rural beneficiaries have an average payment adjustment of positive 0.167 percent (+0.167 percent), compared to a slightly negative average payment adjustment for HHAs serving only non-rural beneficiaries or HHAs serving up to 50 percent rural beneficiaries. Among organizational types, proprietary HHAs have a slightly negative average payment adjustment of 0.047 (– 0.047 percent), whereas HHAs in other organizational type categories have a positive average payment adjustment.

BILLING CODE 4120–01–P

**TABLE 69: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED
COHORT: LARGE-VOLUME COHORT**

Larger-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	10	(0.692)	(2.830)	(2.112)	(1.518)	(0.908)	(0.515)	(0.378)	0.252	0.793	1.152
AL	111	0.418	(1.536)	(0.798)	(0.195)	0.189	0.406	0.827	1.259	1.609	2.008
AR	88	0.265	(2.237)	(0.893)	(0.484)	(0.079)	0.327	0.648	1.063	1.473	2.495
AZ	116	(0.503)	(2.731)	(1.966)	(1.350)	(0.993)	(0.392)	(0.098)	0.309	0.721	1.863
CA	1070	0.207	(2.411)	(1.636)	(1.116)	(0.507)	0.054	0.601	1.308	2.042	3.073
CO	99	(0.219)	(2.294)	(1.669)	(1.232)	(0.810)	(0.387)	0.194	0.655	1.185	2.408
CT	62	(0.240)	(2.822)	(1.892)	(1.063)	(0.446)	0.051	0.291	0.566	1.253	2.044
DC	9	(0.759)	(2.201)	(2.067)	(1.806)	(1.315)	(1.106)	(0.800)	(0.234)	0.244	2.452
DE	12	(0.160)	(1.285)	(1.176)	(1.076)	(0.868)	(0.776)	(0.564)	0.341	0.364	1.394
FL	566	0.289	(2.284)	(1.366)	(0.898)	(0.300)	0.211	0.699	1.358	2.088	2.945
GA	95	(0.650)	(2.314)	(1.934)	(1.363)	(0.921)	(0.555)	(0.314)	(0.030)	0.354	0.998
GU	3	(2.536)	(3.294)	(3.294)	(3.294)	(2.830)	(2.830)	(2.830)	(1.485)	(1.485)	(1.485)
HI	11	(1.012)	(3.015)	(2.250)	(1.995)	(1.191)	(0.969)	(0.550)	(0.384)	0.019	0.187
IA	85	0.463	(1.554)	(1.143)	(0.672)	0.066	0.516	0.880	1.464	1.872	2.544
ID	44	0.072	(1.840)	(1.126)	(0.881)	(0.078)	0.146	0.358	0.713	1.723	1.839
IL	338	(0.010)	(2.199)	(1.601)	(1.018)	(0.519)	(0.099)	0.421	0.857	1.395	2.364
IN	116	0.071	(2.039)	(1.552)	(0.875)	(0.529)	0.007	0.525	0.900	1.400	2.435
KS	77	0.032	(2.205)	(1.524)	(0.903)	(0.438)	0.105	0.640	1.018	1.522	2.056
KY	85	0.563	(1.154)	(0.775)	(0.239)	0.090	0.605	0.930	1.244	1.727	2.411
LA	160	0.174	(1.994)	(1.319)	(0.658)	(0.127)	0.207	0.674	0.981	1.527	2.072
MA	105	0.079	(2.389)	(1.538)	(1.075)	(0.544)	(0.042)	0.381	1.058	1.506	2.705
MD	49	0.264	(1.965)	(1.442)	(0.913)	(0.074)	0.303	0.592	0.972	1.829	2.529
ME	18	0.792	(0.686)	(0.232)	(0.012)	0.374	0.771	1.050	1.536	1.592	2.568
MI	230	0.270	(1.912)	(1.273)	(0.806)	(0.384)	0.153	0.603	1.107	1.625	2.702
MN	85	(0.154)	(2.277)	(1.788)	(1.267)	(0.547)	(0.104)	0.278	0.742	1.000	2.059
MO	101	0.340	(2.003)	(1.005)	(0.592)	(0.238)	0.082	0.666	1.132	2.066	2.900
MS	42	0.245	(1.056)	(0.580)	(0.165)	0.293	0.530	0.599	0.950	1.038	1.389
MT	17	(1.066)	(2.883)	(2.610)	(2.231)	(1.929)	(1.562)	(0.684)	(0.457)	0.521	1.327
NC	146	(0.246)	(1.950)	(1.255)	(0.849)	(0.561)	(0.320)	(0.124)	0.384	0.695	1.380
ND	13	(0.186)	(2.271)	(1.868)	(1.384)	(0.467)	(0.257)	0.014	1.027	1.193	1.971

Larger-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
NE	44	0.185	(1.775)	(1.357)	(0.757)	(0.470)	(0.053)	0.879	1.221	1.712	2.152
NH	19	0.037	(1.689)	(0.986)	(0.807)	(0.383)	0.200	0.602	0.730	0.888	1.617
NJ	39	0.559	(0.674)	(0.269)	(0.206)	0.089	0.566	0.904	1.057	1.423	1.969
NM	58	(0.432)	(2.325)	(1.425)	(1.188)	(0.875)	(0.522)	(0.027)	0.331	0.510	1.577
NV	101	(0.092)	(2.513)	(1.895)	(1.400)	(1.090)	(0.445)	0.212	0.769	1.791	2.853
NY	94	0.193	(1.671)	(1.253)	(0.850)	(0.533)	0.010	0.454	0.736	1.660	2.713
OH	226	(0.170)	(2.424)	(1.838)	(1.367)	(0.765)	(0.368)	0.233	0.801	1.377	2.538
OK	175	(0.379)	(2.310)	(1.782)	(1.263)	(0.821)	(0.487)	(0.110)	0.414	0.945	1.622
OR	41	(0.540)	(2.079)	(1.839)	(1.386)	(1.041)	(0.831)	(0.243)	(0.029)	0.329	1.889
PA	179	0.041	(1.835)	(1.200)	(0.665)	(0.266)	(0.031)	0.376	0.666	1.317	1.719
PR	35	(1.647)	(3.394)	(2.891)	(2.693)	(2.425)	(2.226)	(1.937)	(1.697)	(0.392)	0.575
RI	18	0.575	(1.414)	(0.614)	(0.042)	0.198	0.413	0.761	1.321	1.973	2.648
SC	65	0.162	(1.555)	(1.064)	(0.526)	(0.109)	0.097	0.399	0.679	1.087	1.674
SD	19	1.458	(0.332)	(0.169)	0.018	0.445	0.942	1.564	2.535	3.668	4.333
TN	109	0.146	(1.941)	(1.115)	(0.537)	(0.072)	0.167	0.432	0.860	1.280	2.055
TX	778	(0.425)	(2.500)	(1.981)	(1.505)	(1.084)	(0.549)	(0.130)	0.409	1.106	1.864
UT	61	0.985	(1.701)	(1.015)	(0.219)	0.237	0.928	1.553	2.001	2.769	4.004
VA	168	(0.329)	(2.303)	(1.760)	(1.290)	(0.899)	(0.378)	(0.118)	0.377	1.075	2.034
VI	1	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182
VT	10	(1.084)	(2.084)	(1.698)	(1.569)	(1.343)	(1.182)	(1.076)	(0.807)	(0.207)	0.223
WA	58	(0.369)	(2.245)	(1.661)	(1.477)	(1.078)	(0.379)	(0.125)	0.256	1.119	2.144
WI	66	0.327	(1.450)	(1.145)	(0.649)	(0.376)	0.303	1.133	1.369	1.698	2.560
WV	45	0.025	(2.400)	(1.470)	(0.610)	(0.127)	0.246	0.502	0.819	1.080	1.660
WY	19	(0.217)	(2.396)	(1.363)	(1.155)	(0.688)	(0.404)	0.156	0.727	0.951	2.180
ALL	6,391	0.004	(2.252)	(1.570)	(1.058)	(0.539)	(0.086)	0.364	0.862	1.509	2.414

**TABLE 70: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED
COHORT: SMALL-VOLUME COHORT**

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)
AL	1	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)
AR	2	1.219	1.162	1.162	1.162	1.162	1.219	1.275	1.275	1.275	1.275
AZ	4	(0.800)	(2.776)	(2.776)	(2.345)	(2.345)	(2.158)	(1.970)	(1.970)	3.890	3.890
CA	209	0.244	(2.430)	(1.712)	(0.956)	(0.360)	0.139	0.639	1.355	2.205	2.921
CO	7	(0.565)	(4.699)	(3.813)	(0.908)	(0.908)	(0.383)	1.234	1.234	1.369	3.243
CT	0	-	-	-	-	-	-	-	-	-	-
DC	0	-	-	-	-	-	-	-	-	-	-
DE	1	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)
FL	50	(0.003)	(2.685)	(2.229)	(1.601)	(0.944)	0.029	0.468	1.141	2.231	2.836
GA	0	-	-	-	-	-	-	-	-	-	-
GU	0	-	-	-	-	-	-	-	-	-	-
HI	0	-	-	-	-	-	-	-	-	-	-
IA	11	1.412	(0.843)	(0.264)	0.565	1.200	1.766	2.082	2.176	2.771	3.237
ID	0	-	-	-	-	-	-	-	-	-	-
IL	60	0.361	(2.255)	(1.486)	(0.957)	(0.597)	(0.019)	0.788	1.287	2.089	3.443
IN	12	(0.606)	(2.826)	(2.608)	(1.733)	(1.256)	(0.579)	(0.025)	0.283	0.410	1.829
KS	3	2.566	2.257	2.257	2.257	2.456	2.456	2.456	2.984	2.984	2.984
KY	0	-	-	-	-	-	-	-	-	-	-
LA	2	(1.843)	(2.945)	(2.945)	(2.945)	(2.945)	(1.843)	(0.741)	(0.741)	(0.741)	(0.741)
MA	5	(0.883)	(3.391)	(2.247)	(1.103)	(1.059)	(1.014)	(0.613)	(0.212)	0.547	1.305
MD	0	-	-	-	-	-	-	-	-	-	-
ME	0	-	-	-	-	-	-	-	-	-	-
MI	41	0.692	(1.816)	(0.776)	(0.039)	0.208	0.696	1.088	2.103	2.371	2.934
MN	5	0.241	(2.098)	(1.511)	(0.924)	(0.847)	(0.770)	0.804	2.377	2.500	2.622
MO	4	0.695	0.132	0.132	0.467	0.467	0.663	0.858	0.858	1.323	1.323

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
MP	1	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)
MS	0	-	-	-	-	-	-	-	-	-	-
MT	2	(0.810)	(0.913)	(0.913)	(0.913)	(0.913)	(0.810)	(0.707)	(0.707)	(0.707)	(0.707)
NC	3	(0.260)	(1.583)	(1.583)	(1.583)	(0.060)	(0.060)	(0.060)	0.864	0.864	0.864
ND	0	-	-	-	-	-	-	-	-	-	-
NE	6	(1.046)	(3.063)	(2.555)	(2.555)	(1.707)	(1.569)	(1.430)	0.075	0.075	2.405
NH	2	(0.654)	(1.636)	(1.636)	(1.636)	(1.636)	(0.654)	0.328	0.328	0.328	0.328
NJ	0	-	-	-	-	-	-	-	-	-	-
NM	1	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)
NV	15	(0.214)	(1.985)	(1.959)	(1.067)	(0.510)	(0.242)	(0.075)	0.462	0.842	1.914
NY	3	0.150	(2.442)	(2.442)	(2.442)	0.309	0.309	0.309	2.582	2.582	2.582
OH	12	(0.069)	(2.573)	(1.741)	(0.555)	(0.190)	(0.064)	0.276	0.349	1.571	1.632
OK	12	(0.852)	(2.373)	(1.560)	(1.451)	(1.331)	(1.197)	(0.661)	(0.466)	(0.424)	(0.307)
OR	1	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)
PA	12	(0.380)	(2.461)	(2.016)	(1.845)	(0.706)	(0.559)	(0.349)	0.343	1.879	1.892
PR	0	-	-	-	-	-	-	-	-	-	-
RI	0	-	-	-	-	-	-	-	-	-	-
SC	0	-	-	-	-	-	-	-	-	-	-
SD	1	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442
TN	1	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)
TX	150	(0.536)	(2.795)	(2.250)	(1.827)	(1.221)	(0.741)	0.063	0.661	1.203	1.810
UT	8	0.487	(2.776)	(1.032)	(0.454)	0.047	0.355	0.662	0.775	3.169	3.503
VA	14	0.207	(2.286)	(1.428)	(0.724)	(0.670)	(0.104)	0.827	1.007	1.915	2.840
VI	0	-	-	-	-	-	-	-	-	-	-
VT	0	-	-	-	-	-	-	-	-	-	-
WA	0	-	-	-	-	-	-	-	-	-	-
WI	2	2.769	1.757	1.757	1.757	1.757	2.769	3.780	3.780	3.780	3.780
WV	3	0.353	(0.286)	(0.286)	(0.286)	0.023	0.023	0.023	1.322	1.322	1.322
WY	3	(0.229)	(1.022)	(1.022)	(1.022)	(0.734)	(0.734)	(0.734)	1.070	1.070	1.070
ALL	670	0.006	(2.513)	(1.938)	(1.177)	(0.684)	(0.094)	0.504	1.083	1.874	2.772

TABLE 71: HHVBP PAYMENT ADJUSTMENT DISTRIBUTION BY HHA CHARACTERISTICS

HHA Characteristics	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
Percentage Dual-eligible											
1st Quintile: % Dual-eligible	1,407	0.122	(2.221)	(1.523)	(1.026)	(0.431)	0.040	0.520	1.058	1.668	2.611
2nd Quintile: % Dual-eligible	1,407	0.033	(2.064)	(1.368)	(0.805)	(0.380)	0.014	0.412	0.840	1.354	2.122
3rd Quintile: % Dual-eligible	1,407	(0.060)	(2.089)	(1.442)	(0.955)	(0.519)	(0.104)	0.330	0.733	1.331	2.028
4th Quintile: % Dual-eligible	1,407	(0.317)	(2.459)	(1.932)	(1.398)	(0.938)	(0.466)	0.032	0.579	1.198	2.038
5th Quintile: % Dual-eligible	1,407	0.228	(2.525)	(1.733)	(1.101)	(0.507)	0.057	0.602	1.355	2.228	3.319
Acuity (HCC)											
1-Lowest Acuity	1,750	0.286	(2.430)	(1.675)	(1.038)	(0.415)	0.160	0.739	1.406	2.193	3.304
2-Medium Acuity	3,498	(0.062)	(2.234)	(1.555)	(1.063)	(0.554)	(0.103)	0.329	0.781	1.367	2.138
3-Highest Acuity	1,749	(0.130)	(2.232)	(1.572)	(1.076)	(0.628)	(0.237)	0.195	0.654	1.266	2.135
% Rural Beneficiaries											
1-All non-rural	3,804	(0.018)	(2.459)	(1.791)	(1.205)	(0.691)	(0.178)	0.349	0.899	1.666	2.698
2-Up to 50% rural	1,991	(0.059)	(2.151)	(1.481)	(0.979)	(0.503)	(0.102)	0.305	0.727	1.281	2.009
3-Over 50% rural	1,228	0.167	(1.920)	(1.261)	(0.755)	(0.304)	0.087	0.583	1.070	1.584	2.330
Organizational Type											
1-Vol Non-Profit-Religious	258	0.508	(1.767)	(1.034)	(0.301)	0.087	0.513	0.858	1.467	2.008	2.811
2-Vol Non-Profit-Private	521	0.089	(1.952)	(1.374)	(0.913)	(0.479)	(0.042)	0.436	0.893	1.500	2.455
3-Vol Non-Profit-Other	417	0.105	(1.929)	(1.247)	(0.768)	(0.273)	0.050	0.484	1.059	1.443	2.058
4-Proprietary	5,601	(0.047)	(2.350)	(1.700)	(1.150)	(0.632)	(0.156)	0.320	0.838	1.503	2.480
5-Govt-State/County	146	0.259	(1.674)	(1.211)	(0.688)	(0.259)	0.099	0.599	1.070	1.580	2.435
6-Govt-Govt & Voluntary	11	0.497	(0.735)	(0.357)	(0.279)	(0.055)	0.075	0.269	0.314	1.589	2.392
7-Govt-Local	91	0.270	(1.770)	(1.071)	(0.647)	(0.314)	0.491	0.669	1.038	1.748	2.308

Notes:

- Dual: low, medium, high are based on 25th and 75th percentiles of the percent of Medicare fee-for-service beneficiaries with any dual indicated across all HHAs in 2021.
- HCC Score Acuity: low, medium, high are based on 25th and 75th percentiles of the average HCC of Medicare fee-for-service beneficiaries across all HHAs in 2021.
- Percentage rural Medicare fee-for-service beneficiaries: based on CBSA of beneficiaries' ZIP code aggregated to the HHA level in 2021.

The total number of HHAs differ by category due to missing HHAs in some data sources.

across all HHAs in 2021.—*HCC Score Acuity*: low, medium, high are based on 25th and 75th percentiles of the average HCC of Medicare fee-for-service beneficiaries across all HHAs in 2021.—*Percentage rural Medicare fee-for-service beneficiaries*: based on CBSA of beneficiaries' ZIP code aggregated to the HHA level in 2021. The total number of HHAs differ by category due to missing HHAs in some data sources.

4. Updates to the Home Health Agency CoPs to Align With the OASIS All-Payer Submission Requirements

As discussed in section V. of this proposed rule, we are proposing technical revisions to the HH CoPs to further clarify that the existing requirement for reporting OASIS information applies to all HHA patients receiving skilled services. This technical change seeks to provide clarity by creating alignment between the terminology used in the CoPs and requirements for data collection and submission to OASIS for purposes of the HH QRP. It does not propose any revisions to the specific requirements for submitting data to OASIS and does not have any bearing on the change to expand the data collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). Therefore, this technical change would not result in an increase in costs for HHAs. For a review of the burden and operational costs associated with the transition to the OASIS all-payer submission requirements we refer readers to the CY 2023 HH PPS final rule "Collection of Information" section (88 FR 66877) and to the CY 2024 HH PPS final rule for the latest burden estimates (88 FR 77676).

5. Provider Enrollment

As previously noted, we are proposing several provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. This RIA addresses provisions that: (1) we believe would have a financial impact; and (2) would not, in our view, have such an impact but which require explanation.

a. Retroactive Revocations

Section 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. Under existing

§ 424.535(g)(2)(i) through (viii), 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 VI.A. of this proposed rule that we are proposing to increase significantly the number of grounds for a retroactive revocation in new § 424.535(a)(8)(iii) and (g)(2)(viii) through (xiv). These nine situations and our proposed revocation effective dates (listed in parentheses) are as follows:

- An independent diagnostic testing facility's (IDTF's) liability insurance lapsed (date the insurance lapsed).
- The provider submitted false or misleading information on its enrollment application (date the provider signed the application's certification statement).
- The provider failed to timely report a change of ownership, an adverse legal action, or addition, deletion, or change of a practice location (day after the date by which the provider was required to report the change, addition, or deletion).
- The provider's Drug Enforcement Administration (DEA) certificate of registration was surrendered in response to a show cause order (date the certificate was surrendered).
- The individual's ability to prescribe one or more drugs has been suspended or revoked by any state in which the physician or non-physician practitioner practices (date of the state's suspension or revocation).
- Under § 424.535(i), if we revoke a provider's enrollment, we can revoke all of the provider's other enrollments. The effective dates of these other revocations would be the effective date of the triggering revocation.
- A DMEPOS supplier was revoked for non-compliance with a condition or standard in § 424.57(b) or (c), such as the requirement to meet the DMEPOS quality standards (date on which the non-compliance began).
- Under § 424.535(a)(8)(i), the provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service (the earliest date of service on the claim or claims that is or are triggering the revocation).
- Under § 424.535(a)(8)(ii), CMS determines that the provider or supplier has a pattern or practice of submitting

claims that fail to meet Medicare requirements (the last date of service on the claims in question).

Table 72 contains several data categories. One is the average annual number of revocations that occur in each of the previous scenarios. Another 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 of ownership effective May 1 but fails to report it to CMS. The revocation letter is mailed to the provider on June 1, meaning the effective date is July 1. The period between the date of non-compliance and the effective date under paragraph (g)(1) is thus 60 days. However, under our proposal the provider would be ineligible for payments for services furnished during this 60-day period because its revocation would now be retroactive.

An additional category addresses the amount of savings that would accrue to the Medicare program from our proposal. Based on internal CMS data, we calculated in the fourth column in Table 72 the average amount of actual payments made to each of the providers in each of the table's nine revocation reasons in Table 72 during the estimated time period in the table's third column. We then multiplied this figure by the numbers in the second column (average annual number of revocations). The fifth and final column outlines the total annual savings that would result. To illustrate—

- There are 11 revocations per year for lapses in IDTF liability insurance.
- As shown in the fourth column of the table, each of these 11 IDTFs received an average of \$19,423 during the 3-month period identified in the third column of the chart.
- Multiplying 11 by \$19,423 results in \$213,653 in total, combined annual savings for that category of revoked providers.

We recognize that in certain prior provider enrollment regulations, we have used a standard \$50,000 average annual payment amount when calculating savings figures. However, the totals in the third column of the table reflect the actual amounts the revoked providers were paid. They are accordingly much more accurate than a base \$50,000 figure.

TABLE 72: RETROACTIVE REVOCATION GROUNDS

New Retro Revocation Basis	Number of Revocations Per Year	Estimated Length of Time Between When the Non-Compliance Occurs and 30 Days After the Revocation Letter is Sent	Based Average Payments Made to Revoked Enrollment During Estimated Non-Compliance Time Period	Estimated Total Annual Savings (Number of Revocations x Average Payments)
IDTF's liability insurance lapsed	11	3 months (0.25 years)	19,423	213,653
Provider submits false/misleading information on application	31	6 months (0.5 years)	225,824	7,000,544
Provider failed to timely report change of ownership, adverse action or practice location	461	6 months (0.5 years)	1,321,736	609,320,296
Provider's DEA certificate is suspended, revoked, or surrendered in response to show cause order OR State suspends or revokes individual's ability to prescribe	7	60 days (0.164 years)	79,227	554,589
Revocation resulting in other revocations under § 424.535(i).	3	60 days (0.164 years)	281,756	845,268
DMEPOS supplier revoked for non-compliance with condition or standard in 424.57(b) or (c).	790	3 months (0.25 years)	488,328	385,779,120
§ 424.535(a)(8)(i)	9	1 year	18,371,237	165,341,133
§ 424.535(a)(8)(ii)	130	60 days (0.164 years)	7,910,366	1,028,347,580
TOTALS & AVERAGES	1,442 Per Year	Varies	28,697,897	2,197,402,183

We accordingly project annual savings of \$2,197,402,183 stemming from our retroactive revocation proposals.

b. Expanded and Clarified Revocation Reasons

In accordance with existing § 424.535(a)(14), CMS can revoke a physician's or practitioner's enrollment if the individual has a pattern or practice of prescribing Part B or D drugs that is abusive, threatens the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. We are proposing to expand this authority to include drugs associated with services covered under Part A. We are unable to establish a savings estimate for this revision, for we cannot predict the number of instances in which we would utilize § 424.535(a)(14) for Part A prescribing patterns or practices.

We are also proposing in new § 424.535(a)(8)(i)(D) to clarify that our revocation authority under paragraph (a)(8)(i) includes situations where beneficiary attestations state that the service(s) or item(s) the provider claims were furnished to the beneficiary were,

in fact, not. As this is merely an elucidation of our existing authority to revoke in such situations, we do not anticipate additional savings therefrom.

c. Additional Deactivation Reason

We are proposing under new § 424.547 that CMS may deactivate a physician's or non-physician's practitioner's ability to order, certify, or refer the Medicare services and items identified in § 424.507(a) and (b) if the individual—

- Is enrolled in Medicare solely to order, certify, or refers beneficiaries for Medicare Part A or B services or items; *and*
- The individual has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive calendar months.

As with our proposed expansion of § 424.535(a)(14), we are unable to establish a savings or burden estimate for new § 424.547 because we cannot predict the number of instances in which we would apply this authority.

6. DMEPOS Supplier Accreditation Organizations

Section VI.B. of this proposed rule outlines our proposed revisions to §§ 424.57 and 424.58 and the reasons for them. Most of our changes would involve: (1) additional requirements an organization must meet to become and remain a CMS-approved DMEPOS AO; and (2) additional surveys that must be performed. The ICR component of these requirements was addressed in section VIII. of this proposed rule. This RIA discusses the principal non-ICR costs and potential savings associated with our proposals.

a. Costs

For purposes of our cost calculations, we will use the following median wage categories and hourly rates from the BLS May 2024 National Occupational Employment and Wage Estimates for all salary estimates. We believe these occupational classifications, some of which were used in the February 15, 2024, proposed rule referenced in section VI.B. of the subject rule, would be most applicable to our cost impact analysis:

TABLE 73: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Registered Nurses	29-1141	45.00	45.00	90.00
Medical and Health Services Managers (MHSM)	11-9111	56.71	56.71	113.42
Other Healthcare Practitioners and Technical Occupations (OHPTO)	29-9000	30.20	30.20	60.40
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28

There are generally two types of surveys that will form the bases of our calculations: (1) initial and reaccreditation surveys (which include the survey and the accreditation); and (2) “off-cycle” surveys, or ad-hoc surveys performed outside of the initial and reaccreditation process to reconfirm compliance with the quality standards. Ad-hoc surveys—which, except perhaps in cases where the supplier is adding a new product, typically does not involve the accreditation process itself but only the survey—can occur in response to, for instance, a complaint or a CMS request that a survey be performed. The hour burdens and fees associated with (1) and (2) vary widely among AOs. However, based on our information, we estimate the following, emphasizing that: (1) the hour burdens could involve multiple individuals (for example, a 6-hour burden could have two individuals contributing 3 hours each); (2) the survey costs to the AO include travel and other expenses; and (3) both the hour and cost burdens could include incidental tasks (for example, the AO contacts the supplier for additional data regarding its reaccreditation application):

• *Initial and Reaccreditation Processes and Surveys*

++ Burden to Supplier for Initial Accreditation and Survey—24 hours and \$5,000 fee the supplier pays to the AO.

++ Burden to Supplier for Reaccreditation and Survey—14 hours and \$3,000 fee.

(Note that the two preceding burdens include the supplier’s preparation and submission to the AO of its accreditation or reaccreditation materials.)

++ Burden to AO for Survey, Review/Decision, and Accreditation (Initials and Reaccreditation)—20 hours.

• *Off-Cycle Surveys.*

++ Burden to Supplier for Survey—6 hours and \$2,000 cost of the survey.

++ Burden to AO for Survey and Review/Decision—14 hours (cost addressed below).

These figures will be used as inputs for the succeeding estimates.

There is also variance among the DMEPOS AOs regarding the staff that performs the surveys and accreditation reviews. We recognize that many DMEPOS AOs hire contractors to conduct surveys and that non-medical personnel at the AO might make final accreditation decisions. Yet we also wish to remain as consistent as possible with wage categories in other CMS accreditation rulemaking efforts. For purposes of this RIA and our burden calculations only, therefore, we will assume that: (1) contractor personnel (under the OHPTO wage category) would perform the surveys; and (2) nurses and MHSMs would perform initial reviews and make final determinations regarding the supplier’s accreditation. As for the suppliers themselves, we believe that administrative personnel would work with the AO in the survey and be involved in the accreditation process (for example, preparing the application, as they do with Form CMS–855 enrollment applications).

There are five categories of surveys, reviews, and accreditations that form the bases of our accreditation cost estimates: (1) complaint investigations and surveys; (2) additional initial surveys; (3) annual reaccreditations and surveys; (4) CMS-directed ad-hoc surveys; and (5) change of ownership surveys. These will be addressed in the succeeding subsections.

(1) Complaint Investigations and Surveys

Proposed new § 424.58(e)(3)(i)(B) and (C), state, respectively, that after receiving a complaint, an AO must—

• Perform an initial review of the complaint to determine whether, based on the complaint and any other information, the supplier may be non-compliant with one or more DMEPOS quality standards; and

• Conduct a survey of the accredited facility if the AO’s initial review concludes that such non-compliance

may exist and a survey is deemed necessary.

In assessing potential ICR costs to the AO, we estimated that each year an AO would report 50 complaints to us. With 8 AOs, this would result in 400 complaints annually. We further assume the following:

• It would take an average of 4 hours for an AO to perform its initial review of potential non-compliance. The hourly rate of this task would be split between nurses and MHSMs, resulting in a wage of \$101.71 (\$90.00 + \$113.42)/2).

• Roughly 20 percent of initial reviews would result in an off-cycle survey, which would take the OHPTO 8 hours to perform; this would also result in 80 complaint surveys being performed each year (400 × 0.2).

• It would take the AO 6 hours to render a decision on the survey and whether the supplier should remain accredited (as well as to notify the supplier of the decision). We will apply the aforementioned combined \$101.71 hourly rate for this task.

• The supplier would incur a burden of 6 hours during the survey. The hourly rate would be \$44.28.

• The cost of the complaint survey would be \$2,000, which the supplier would pay to the AO.

Given these assumptions, we project the following annual figures for complaint surveys:

• Initial Review Burden to AOs—1,600 hours and \$132,426 (400 complaints × 4 hours × \$101.71).

• Survey Cost Burden to AOs—640 hours and \$35,208 (80 surveys × 8 hours × \$60.40).

• Post-Survey Decision Burden to AOs—480 hours and \$42,566 (80 × 6 hours × \$94.59).

• Burden to Suppliers During Survey—480 hours and \$18,702 (80 × 6 × \$44.28).

• Supplier Survey Fees Paid to AO—\$150,000 (80 × \$2,000).

Table 74 outlines the annual burden impact of § 424.57(e)(3)(i)(B) and (C).

TABLE 74: ANNUAL BURDEN OF COMPLAINT INVESTIGATIONS AND SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden - Initial Review of Complaint	4	1,600	101.71	162,736
AO Burden - Survey	8	640	60.40	38,656
AO Burden - Post-Survey Review/Decision	6	480	101.71	48,821
Survey Fee Collections	N/A	N/A	N/A	(150,000)
TOTAL	18	2,720	Varies	100,213
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	480	44.28	21,254
Survey Fee	N/A	N/A	N/A	150,000
TOTAL	6	480	N/A	171,254
COMBINED NET BURDEN	24	3,200	N/A	271,467

(2) Additional Surveys and Reaccreditations

Several other provisions would increase the frequency of surveys to be performed and/or reaccreditations to be undertaken:

- Proposed § 424.58(e)(8)(i)(A) states that except as otherwise directed or permitted by CMS, the AO must perform a survey of all suppliers and their locations seeking initial accreditation or reaccreditation with the AO.
- Proposed § 424.57(c)(24) states that supplier locations must be resurveyed and reaccredited every year (rather than the current 3-year period).
- Proposed § 424.58(e)(8)(ii) states that CMS may, at any time, direct the

AO to perform a survey of an accredited supplier or group thereof.

- Proposed § 424.551 states that a DMEPOS supplier must enroll as a new supplier, receive a survey, and be reaccredited if it undergoes a non-exempted change in majority ownership.

There presently are approximately 46,500 accredited and enrolled DMEPOS suppliers, and about 1,780 accredited DMEPOS suppliers enroll in Medicare each year.

We currently permit a limited amount of sampling, which allows a DMEPOS AO to forgo performing a survey for certain supplier types, such as large chain suppliers in areas without high rates of fraud, waste, and abuse. While

we do not have exact figures regarding the number of supplier locations that are not surveyed due to sampling, we estimate—solely for purposes of this RIA—the amount to be roughly 50 percent of all chain suppliers.

(a) Initial Accreditation

The only additional initial accreditation burden associated with §§ 424.58(e)(8)(i)(A) would involve surveys of 50 percent of 1,780 of the aforementioned DMEPOS suppliers (or 890) at a cost to each supplier of \$2,000 per survey. Using our previous calculations, Table 75 outlines the annual hour and cost burdens.

TABLE 75: ADDITIONAL ANNUAL BURDEN OF INITIAL SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden — Survey	8	7,120 (8 x 890)	60.40	430,048
Survey Fee Collections	N/A	N/A	N/A	(1,780,000) (or \$2,000 cost x 890 surveys)
TOTAL	8	7,120	N/A	(1,349,952)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	5,340 (6 x 890)	44.28	236,455
Survey Fee	N/A	N/A	N/A	1,780,000
TOTAL	6	5,340	N/A	2,016,455
COMBINED NET BURDEN	14	12,460	N/A	666,503

(b) Reaccreditation

The additional burden associated with reaccreditation would involve 46,500 suppliers being surveyed and reaccredited twice more than they currently are within a 3-year period. This means that approximately 93,000 new re-surveys and reaccreditations would occur within the first 3 years of this rule, or 46,500 per year. Added to this would be the 3,560 new suppliers that would become initially accredited

and enrolled during this period (1,780 × 2 years), period, thus totaling an annual average of 48,280 (46,500 + 1,780) suppliers over this period. We will use the following baselines for our estimates:

- As previously noted, we project the time burden for a survey and reaccreditation to be 14 hours for the supplier and 20 hours for the AO.
- The fee will be \$3,000.
- The survey hour and wage estimates will remain the same (for

example, 8 hours per survey for the AO).

- The following wage rates will be used:

++ Suppliers—\$44.28 (administrative personnel).

++ AO application review—\$101.71 (same as the AO post-survey wage).

++ AO surveyors—\$60.40.

- The supplier accreditation application process will take 8 hours (14 hours—6 hours for the survey), and the AO application review process will take

6 hours (20 hours—8 hours for the survey—6 hours for the final review/decision).

Table 76 accordingly outlines the burden associated with our annual resurvey and reaccreditation proposals:

TABLE 76: ESTIMATED ANNUAL NEW BURDEN OF RESURVEYS AND REACCREDITATIONS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden – Application Review	6	289,680 (6 x 48,280)	101.71	29,463,353
AO Burden – Survey	8	386,240 (8 x 48,280)	60.40	23,328,896
AO Burden – Application/Post-Survey Review/Decision	6	289,680 (6 x 48,280)	101.71	29,463,353
Accreditation Fee Collections	N/A	N/A	N/A	(144,840,000) (or \$3,000 x 48,280)
TOTAL	20	965,600	N/A	(62,584,398)
BURDEN TO SUPPLIER				
Supplier Burden – Application Process	8	386,240 (8 x 48,280)	44.28	17,102,707
Burden to Supplier During Survey	6	289,680 (6 x 48,280)	44.28	12,827,030
Accreditation Fee	N/A	N/A	N/A	144,840,000
TOTAL	14	675,920	N/A	174,769,737
COMBINED NET BURDEN	N/A	1,641,520	N/A	112,185,339

(c) CMS-Directed Off-Cycle/Ad-Hoc Surveys

We project that CMS each year would direct the performance of 100 surveys outside of the proposed annual reaccreditation surveys and the

complaint surveys. We note that per proposed § 424.58(c)(1)(xxiii)(L), the AO must have a binding written agreement with its DMEPOS suppliers regarding whether the AO, the supplier in question, or both will assume the costs

of a CMS-directed survey. Solely for purposes of this impact analysis, we will project that the supplier would pay the survey cost. Table 77 outlines our estimated net costs of ad-hoc/CMS-directed surveys:

TABLE 77: ANNUAL BURDEN OF CMS-DIRECTED OFF-CYCLE/AD-HOC SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden – Survey	8	800 (8 x 100)	60.40	48,320
AO Burden - Post-Survey Review/Decision	6	600 (6 x 100)	101.71	61,026
Survey Fee Collections	N/A	N/A	N/A	(200,000) (or 100 x \$2,000)
TOTAL	N/A	1,400	Varies	(90,654)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	600 (6 x 100)	44.28	26,568
Survey Fee	N/A	N/A	N/A	200,000
TOTAL	N/A	600	N/A	226,568
COMBINED NET BURDEN	N/A	2,000	N/A	135,914

(d) Change in Majority Ownership

Our data indicates that, on average, approximately 3,768 DMEPOS suppliers

each year undergo an ownership change involving a new owner of 50.0 percent or more of the supplier. These surveys would be conducted outside the

reaccreditation, complaint, and CMS-directed survey processes. Table 78 outlines the following annual non-ICR burden estimates.

TABLE 78: ANNUAL BURDEN OF OWNERSHIP CHANGE SURVEYS

BURDEN TO AO				
Task	Hour Burden Per Task	Total Hours	Wage (\$)	Total Cost (\$)
AO Burden – Application Review	6	22,608 (6 x 3,768)	101.71	2,299,460
AO Burden - Survey	8	30,144 (8 x 3,768)	60.40	1,820,698
AO Burden – Application/Post-Survey Review/Decision	6	22,608 (6 x 3,768)	101.71	2,299,460
Accreditation Fee Collections	N/A	N/A	N/A	(18,840,000) (or \$5,000 fee x 3,768 surveys)
TOTAL	20	75,360	Varies	(12,420,382)
BURDEN TO SUPPLIER				
Burden to Supplier – Application Process	8	30,144 (8 x 3,768)	44.28	1,334,776
Burden to Supplier During Survey	6	22,608 (6 x 3,768)	44.28	1,001,082
Accreditation Fee	N/A	N/A	N/A	18,840,000
TOTAL	14	52,752	N/A	21,175,858
COMBINED NET BURDEN	N/A	128,112	N/A	8,755,476

(3) Additional Costs**(a) Conflicts of Interest**

We are proposing in new § 424.58(n) several prohibitions against AO conflicts of interest. For instance, proposed paragraph (n)(1) would state that if a DMEPOS AO's owner, surveyor, or employee has or had an interest in or relationship with a DMEPOS supplier the AO has accredited, the AO owner, surveyor, or other employee cannot participate in the survey of that supplier. We estimated in section VIII. of this proposed rule the AO's ICR burden of explaining in its initial and reapproval applications its policies/procedures for avoiding conflicts of interest. Beyond this, though, we are unable to establish a burden estimate for this proposal. The reason is that—aside from the recent criminal case cited in section VI.B. of this proposed rule—we do not know the extent to which conflicts of interest exist among our 8 DMEPOS AOs. We request feedback from stakeholders that could help us prepare such a projection.

(b) Consulting

We are proposing in new § 424.58(m) to prohibit consulting services—as that term would be defined in that paragraph (m)—by an AO and its associated consulting divisions or companies to any DMEPOS supplier to which the AO provides accreditation services: (1) prior to an initial accreditation survey; or (2) within 6 months of the next scheduled re-accreditation survey. We do not know the degree to which such services—which, for purposes of our proposal, focus mostly on simulated surveys—are furnished by DMEPOS AOs to DMEPOS suppliers. Therefore, we are soliciting comment from AOs and suppliers for purposes of establishing an estimate regarding the financial impact of this proposal.

(c) Additional Staff

We recognize that our proposal for annual DMEPOS supplier surveys and reaccreditations would require DMEPOS AOs to hire additional personnel. Regarding surveys, we mentioned earlier that AOs often have contracted staff perform them. Although we estimated the hour and cost burden associated with the additional surveys—using a \$60.40 wage and an 8-hour burden for each contracted surveyor—we have no means of calculating any precise increase in the AO's contract costs (such as additional payments to the contractor, costs of contract revisions, or securing a new contractor); this is because we are not privy to the terms of each AO's individual contract. Accordingly, we solicit comment from stakeholders regarding potential costs beyond those relating to the surveyor hour burden. As for AO personnel that review accreditation applications, make final decisions thereon, and perform other related tasks, we will project that the eight AOs combined will hire 12 nurses and 12 MHSMs to handle this additional work. In calculating the burden, we will utilize our previously noted \$90.00 and \$113.42 wages (for nurses and MHSMs, respectively), which results in a \$101.71 average wage. We will also assume a 2,080-hour work year. This results in an hour burden of 49,920 ((12 + 12) × 2,080) and a cost of \$5,077,363, which would include training costs. We welcome comments on this projection, particularly regarding the number of individuals AOs may have to hire.

(d) AO Ownership Changes

We are proposing in new § 424.58(o) to mirror the policies and procedures in 42 CFR 488.5(f) for situations where an AO undergoes a change of ownership. We are not including a burden estimate for this proposal because we do not

anticipate a DMEPOS AO undergoing an ownership change in the coming years,

(e) Rebates

We are proposing in new § 424.58(h) and (i) that if CMS terminates or suspends a DMEPOS AO's approved status, the AO must refund to a DMEPOS supplier all payments the supplier made to the organization:

- As part of the DMEPOS supplier's request for accreditation or reaccreditation; and
- Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

We estimated in the ICR section of this proposed rule that one AO would be terminated over the next 3 years and one AO suspended over this same period. We cannot project how many suppliers' applications (and surveys) would be in process at the time of termination or suspension. However, if we assume that 46,500 suppliers would be annually reaccredited and there are eight AOs, each AO on average would have 5,813 reaccreditations each year (46,500/8), or 484 (5,813/12) per month. If we further assume that an accreditation takes 4 months to complete, approximately 1,936 accreditations (484 × 4 months) could be in process with the AO at any given time. With a \$3,000 reaccreditation fee that would be refunded and 0.66 AOs being terminated or suspended each year ((one termination + one suspension)/3 years), this results in an annual total refund amount of \$3,833,280 (\$3,000 × 1,936 × 0.66).

(f) Form CMS-855S Initial Application—Required Fee

DMEPOS suppliers that are initially enrolling in Medicare due to a change in majority ownership under proposed § 424.551 would have to pay an application fee in accordance with

§ 424.514. The application fees for each of the past 3 calendar years were or are \$730 (CY 2025), \$709 (CY 2024), and \$688 (CY 2023). Consistent with § 424.514, the differing provider application fee amounts were predicated on changes/increases in the CPI for all urban consumers (all items; United States city average, CPI-U) for the 12-month period ending on June 30 of the previous year. While we cannot predict future changes to the CPI, the application fee amounts between 2023 and 2025 increased by an average of \$14 per year. We believe this is a reasonable barometer with which to establish estimates (strictly for purposes of this proposed rule) of the provider

enrollment application fee amounts in the first 3 calendar years of the final provision (that is, 2026, 2027, and 2028). Thus, we project a fee amount of \$744 in 2026, \$758 for 2027, and \$772 for 2028.

Applying these prospective fee amounts to the annual number of projected DMEPOS suppliers impacted by our change in majority ownership proposal—specifically, 3,300 suppliers—this results in a figure of \$2,455,200 (or $3,300 \times \$744$) in the first year, \$2,501,400 in the second year, and \$2,547,600 in the third year. Averaged over this 3-year period, the amount would be \$2,501,400, though there is ambiguity about whether this effect

would be classified as a transfer rather than a cost.(4) Total Costs

Table 79 outlines the total annual net costs of our changes to §§ 424.57 and 424.58. Two things must be mentioned regarding these figures. First, and as already noted, some costs could not be calculated due to a lack of available data. We reiterate our desire for stakeholders to furnish information to assist us in preparing impact assessments for these costs. Second, accreditation fees and refunds are not included in following table because they are considered transfers rather than costs. This is reflected in the accounting statement.

TABLE 79: TOTAL ANNUAL PROJECTED NET BURDEN OF CHANGES TO §§ 424.57 AND 424.58

Task	Total Hours	Net Financial Burden (\$)
Submission of Additional Data by AO or DMEPOS Supplier (ICR Burden)	18,636	1,227,319
Complaint Surveys	3,200	271,467
Additional Initial Accreditation Surveys	12,460	666,503
Annual Reaccreditations and Resurveys	1,641,520	112,185,339
CMS-Directed Surveys	2,000	136,004
Change in Majority Ownership Surveys	128,112	8,755,476
Additional Employees	49,920	5,077,363
TOTAL	1,855,808	128,319,471

As we wish to ensure that our estimates are as thorough as possible, we solicit comment on the following matters concerning our DMEPOS accreditation cost projections:

- Whether there are any other costs that we should consider in our analysis and, if so, what those costs are. This could include costs to parties other than DMEPOS suppliers and DMEPOS AOs.
- Whether our hour estimates for each noted task (for example, initial AO review of a reaccreditation application) are reasonable and, if not, what the revised estimate(s) should be.

(b) Savings

We previously stated in this proposed rule that we anticipate considerable savings to the Trust Funds and the taxpayers resulting from our DMEPOS AO provisions. This would stem from what we believe would be dramatic reductions in improper payments to DMEPOS suppliers due to non-compliance with the DMEPOS quality standards. More frequent surveys and reaccreditations would allow us to closely monitor suppliers for non-compliance. Indeed, we noted our concern that DMEPOS suppliers fall out

of compliance with the quality standards between their initial accreditation and their reaccreditation 3 years later.

Per our internal data, we project that an average of 339 DMEPOS suppliers are revoked each year based on a termination of their accreditation under § 424.57(c)(24). We noted in Table 72 that the average supplier of the 790 that were revoked for violation of a condition or standard in § 424.57(b) or (c) received \$488,328 over a 3-month period. Although we are unable to ascertain the number of these 790 suppliers that were revoked for violating § 424.57(c)(24), we believe it is appropriate to apply the \$488,328 figure to those revoked for a loss of accreditation.

Each supplier would be reaccredited three times more frequently than it presently is. Therefore, we will use a figure of 339 revocations occurring 2 years sooner than they otherwise would have and 339 occurring 1 year sooner than they otherwise would have. This results in a 3-year total of \$497 million ($= (2 \times 339 \times \$488,328) + (339 \times \$488,328)$), or a yearly average estimate of \$166 million ($= \$497 \text{ million} \div 3$). As

this is only a 3-month total, we must multiply it by 4 to achieve an annual savings ($3 \text{ months} \times 4 = 12 \text{ months}$), which we project to be \$664 million. (It should be noted that there would be double-counting if the estimate resulting from this calculation were added to the \$386 million estimate in Table 72—because for the overlap that exists between the estimated 790 and 1,017 suppliers, either the retroactive collection brings in reimbursements equal to three months' worth of improper payments, leaving only 9 months' worth to be affected by the reaccreditation, or reaccreditation brings in 12 months' worth, leaving none to be affected by retroactive collection.)

7. DMEPOS Prior Authorization

We propose to add technical language to § 414.234 (c)(1) that provides for the exemption process in § 414.234 (c)(1)(ii). We also propose to exempt a supplier from the mandatory prior authorization process (OMB Control No. 0938–1293) in newly proposed § 414.234 (c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption

would remain in effect until CMS withdraws the exemption. In proposed § 414.234 (c)(1)(ii)(B), we would provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we propose to provide 60-day notice if an exemption is withdrawn. We would exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate of prior authorizations with non-affirmations submitted becomes higher than 10 percent during an annual assessment, we will consider withdrawing exemption for the specific noncompliant supplier, until the following periodic assessment.

a. MAC Workload Reduction

Based upon our internal data for CY 2024, looking across the 4 Durable Medical Equipment Medicare Administrative Contractor (DME MAC) jurisdictions, we assessed the number of suppliers that would have met the 90 percent threshold needed to qualify for an exemption from mandatory prior authorization each year. Based upon contractual costs to complete mandatory prior authorization, the total cost for all 4 DME MACs' workload was \$13,194,555. We assessed the reduction in workload, accounting for compliant suppliers that met the 90 percent threshold, to be an average of 17 percent reduction, or \$2,243,074 in savings in 1

year had this process been in place for CY 2024. We note that the number of compliant suppliers (for example: 6 percent in 2024) does not directly reflect the number of PARs submitted or the workload required by the MACs. In our assessment, we found that suppliers submit PARs for multiple items and multiple beneficiaries, and the most compliant suppliers submit more PARs than the noncompliant suppliers.

b. Supplier Burden Reduction

A detailed analysis of the supplier burden reduction is found in the ICR section of this rule; however, an overview of the totals is found herein.

TABLE 80: TOTAL ANNUAL BURDEN

Year One	Year Two	Average Annual Burden
\$5,988,332	\$6,727,543	\$6,357,938

We are unable to determine the number of compliant suppliers in future

years. However, if we average the data from previous years, the average

percentage of compliant suppliers or PTANs is 4 percent.

TABLE 81: AVERAGE EXEMPT SUPPLIERS BY YEAR

CY	Total PTAN	PTAN Who Meet Criteria	Percentage of Exempt PTAN
2022	7,049	148	2%
2023	8,048	249	3%
2024	9,298	543	6%

The total burden is assessed in Table 80. By reducing the total average annual burden (\$6,357,938) by the average number of suppliers (represented by PTANs) *not* submitting prior authorization requests by 4 percent, we have an average savings of \$254,318 per year.

c. Total Burden Reduction

We estimate the reduction of burden for suppliers to be \$254,318 per year. We estimate the reduction in workload for the MACs to be \$2,243,074 per year. Combined, we estimate these savings to equal a total sum of \$2,497,392 per year.

8. DMEPOS Competitive Bidding Program

We believe that the provisions of this proposed regulation related to the DMEPOS CBP and payment for CGMs have no net impact. The DMEPOS CBP is required to be implemented by the Act and impacts associated with its

implementation have already been accounted for.

a. Changes to the Calculation of SPAs and Number of Contracts To Be Awarded

From 2011 to 2018, the competitive bidding program calculated SPAs based on the median (50th percentile) of winning bids but targeted a large number of contracts to award. Current regulations set the SPA as the maximum (100th percentile) of the winning bids, but did not generate the savings required to award contracts under the Act. We expect that the combination of setting the SPA as the 75th percentile and reducing the number of contracts to be awarded will result in SPAs broadly similar to those seen in previous, successful rounds of competitive bidding, and therefore result in zero net expenditure.

b. Application of Annual Inflation Update Factors to SPA

In previous rounds of competitive bidding, bidders were expected to account for expected inflation over the contract period when making their bids and thus bid higher to account for these costs. With this change, we expect that bidders will bid lower prices, based on current year costs, with the understanding that these will be escalated by inflation in future years. Over the course of the contract, there should be no net impact from this change.

c. Revision of Payment for CGMs

The change in payment category for CGMs will have no net impact because the Medicare payment amount calculated as the bundled rental payment under the classification as items that require frequent and substantial servicing will equal the expected payments that Medicare would

have made under the current payment category.

d. Other Provisions

The other provisions of this rule are purely an administrative effort with no impact on Medicare coverage or expenditure, and, for this reason, has no cost or transfer associated with it.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach used in estimating the number of entities reviewing this proposed rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. Therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Finally, in our estimates, we have used the 973 number of timely pieces of correspondence on the CY 2025 HH PPS proposed rule as our estimate for the number of reviewers of this rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. We seek comments on this assumption. Using the median hourly wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is \$106.42 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 2.77 hours for the staff to review half of this proposed rule. For each entity that

reviews this proposed rule, the estimated cost is \$294.78 (2.77 hours × \$106.42). Therefore, we estimate that the total cost of reviewing this proposed rule is \$286,820 (\$294.78 × 973 reviewers).

E. Alternatives Considered

1. HH PPS

We described in section II.C.1.e. of this proposed rule, to achieve budget neutrality as required by law, we calculated a permanent adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, 2022, 2023, and 2024 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. One alternative to the proposed 4.059 percent permanent adjustment included proposing half the calculated permanent adjustment similar to how we finalized the permanent adjustment for CY 2025. Another alternative would be to propose a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2026 permanent adjustment over a specified period of years, rather than halving the adjustment in CY 2026. Another alternative would be to not propose an adjustment and delay the implementation of the permanent adjustment to a future year. However, we believe that a reduction, a phase-in approach, or delay in the permanent adjustment would not be appropriate, as reducing, phasing in, or delaying the permanent adjustment would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger reduction to the payment rate in future years.

Finally, we proposed to implement a temporary adjustment to begin reconciling retrospective overpayments from CYs 2020, 2021, 2022, 2023, and 2024, as discussed in section II.C.1.f. of this proposed 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 though notice and comment rulemaking.

We considered not applying a temporary adjustment, as in prior proposed rules. Another alternative would be to apply a temporary adjustment factor to the CY 2026 payment rate that would recoup the calculated temporary adjustment dollar amount, to date, of \$5.3 billion. However, due to the growing temporary adjustment amount calculated from CYs 2020 through 2024, to delay the implementation of a temporary adjustment would lead to many more

years of reductions to the payment rate to reach budget neutrality. Also, as stated previously in this proposed rule, we believe that applying both the permanent adjustment of –4.059 percent and a temporary adjustment accounting for the temporary adjustment dollar amount of \$5.3 billion to the CY 2026 payment rate may adversely affect HHAs given the magnitude of the combined adjustments to the payment rate in a single year. Although we are not establishing a timeframe to recoup the calculated temporary adjustment dollar amount of \$5.3 billion, we believe it is prudent to begin implementing some of the adjustment in order to begin to slow its continued growth. Postponing the 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 propose the implementation of the permanent adjustment decrease of 4.059 percent and a temporary adjustment decrease of 5 percent to the CY 2026 base payment rate.

2. HH QRP

Regarding our proposal to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, we considered keeping the measure, but determined the cost and burden associated with maintaining these measures outweigh the benefit of their continued collection and are proposing to remove them.

Regarding our proposal to remove four standardized patient assessment data elements we are removing these in an effort to reduce burden. We considered keeping these but believe that removing would help reduce burden.

Finally, regarding proposals to amend the reconsideration request policy and process, we considered the alternative of leaving the policy language unchanged. However, we have noted some areas in our policy where HHAs may benefit from clearly demarcated deadlines regarding requests for reconsideration.

3. Provider Enrollment

There were two principal alternatives we considered. First, we contemplated proposing more than the nine retroactive revocation grounds addressed in § 424.535(a)(8) and (g)(2)(viii) through (xiv). However, we decided to only include these nine and to address potential other grounds via future rulemaking. Second, we

considered a 6-month period (instead of our proposed 12-month timeframe) for our proposal in new § 424.547 regarding ordering, certifying, and referring physicians and non-physician practitioners. Given that this would be a new provision and that a 12-month timeframe would be consistent with that which had applied to non-billing providers and suppliers for many years, we decided that a 12-month period would be most appropriate.

4. DMEPOS Supplier Accreditation Organizations

There are several alternatives we contemplated in preparing our proposed revisions to §§ 424.57 and 424.58.

First, we considered retaining the current 3-year cycle for resurveys and reaccreditations. However, as explained in section VI. of this proposed rule, we are concerned that unqualified suppliers are becoming accredited and that existing accredited suppliers are falling out of compliance with the quality standards between their 3-year reaccreditation periods. This has potentially resulted in many millions of dollars being improperly paid to non-adherent suppliers. Only through closer vetting of suppliers via more frequent surveys can we be better assured that Medicare is only paying legitimate suppliers.

Second, existing § 424.58(b)(1) lists detailed information that DMEPOS AOs must submit with their initial approval and reapproval applications. We considered retaining this list as is and even eliminating several items therefrom so as to ease the application burden on AOs. However, as we noted in section VI.B. of this proposed rule, we have not re-approved any existing AOs since 2006. Considering this long passage of time, we believe it is critical to have as much data as possible about our AOs if and when an AO re-approval process commences after the effective date of our DMEPOS AO provisions, if finalized. Therefore, we proposed to increase the scope of information that AOs must submit with their applications. This would help ensure that: (i) we have all the data needed to make informed application decisions; and (ii) only qualified organizations perform DMEPOS accreditation activities.

Third, we contemplated duplicating the requirements that initial AO application submissions, initial AO application decisions, and AO terminations be published in the **Federal Register**. We ultimately

declined this approach and instead proposed to make these pronouncements—including those for suspensions—on our CMS website. We believe this would facilitate faster communication with interested stakeholders.

Fourth, and in a broader context, we considered the extent to which our proposed provisions should parallel those in part 488. We contemplated having practically all of provisions be distinct from part 488, meaning there would be little duplication. This was primarily because of the excessive program integrity risk that DMEPOS suppliers have traditionally posed to Medicare and the consequent need to tailor our provisions to effectively address it. While we indeed proposed a significant number of provisions that are either modifications of those in part 488 or are not included in part 488 at all, we decided to mirror part 488 to the extent possible. As explained in section VI.B. of this proposed rule, we believed this would create precedent for some of our provisions and take advantage of existing, well-established procedures regarding certified provider and supplier accreditation.

5. Prior Authorization of Certain DMEPOS Items

Regarding our proposal to clarify circumstances under which CMS would exempt a supplier from the prior authorization process in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules, we did not consider the alternative of not providing prior authorization exemptions to certain suppliers, as we believe the benefits of the exemption program provides savings to both the Trust Funds, as well as eligible suppliers.

We did not consider alternatives to the 90 percent provisional affirmation threshold. We believe that by achieving this percentage, the supplier would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a supplier to achieve 100 percent compliance to qualify for an exemption because unintentional and sporadic errors could occur that are not deliberate or systemic attempts to submit claims that are not payable. We use a 90 percent threshold for exempting hospital OPD providers from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and

payment rules. Additionally, we use a 90 percent affirmation rate threshold in our Review Choice Demonstration for Home Health Services for home health agencies demonstrating compliance with Medicare requirements. In that program, home health agencies select from different initial review choices, such as pre-claim review (which is similar to prior authorization) and postpayment review of all home health billing periods. After a 6-month review period, agencies are evaluated to determine their review approval rate. If the agency meets the 90 percent threshold, they have additional review options open to them, including relief from most reviews. This threshold represents the best balance between the need to review PARs, while reducing burden on suppliers and effectively utilizing contractor resources, creating savings to the Trust Funds.

6. DMEPOS Competitive Bidding Program

Alternative possibilities for setting the SPA were considered. However, the current method of using the maximum bid did not result in savings while the previous method of using the median, definitionally, forced half the suppliers to accept a SPA below their bid. We believe the 75th percentile represented the best balance of the need to reduce the impact of outlier bids while paying most suppliers at or above their bid amount.

Similarly, while we considered other methods to determine the number of contracts to offer in each CBA, we concluded that the chosen methodology results in the best method of balancing the need to ensure a sufficient number of bidders to meet the anticipated needs of beneficiaries, while ensuring an adequate level of business for winning bidders.

We did not consider alternatives to the other proposed changes as we believe these specific changes were needed to ensure the efficient operation of the CBP.

F. Accounting Statements and Tables

1. HH PPS

Consistent with OMB Circular A-4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table GG-82, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2026 HH PPS provisions of this proposed rule.

TABLE 82: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2025 TO CY 2026

Category	Transfers
Annualized Monetized Transfers	-\$1.135 billion
Bearers of Transfer Loss	Medicare HHAs

2. HH QRP

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 83, we have prepared an accounting statement showing the classification of

the costs associated with the ICRs for the proposed HH QRP provisions in CY 2026.

the costs associated with the ICRs for the proposed HH QRP provisions in CY 2026.

TABLE 83: HH QRP ESTIMATED COSTS FROM CY 2025 TO CY 2027

Category	Benefit
The total economic impact of these proposals including the removal of one patient COVID-19 vaccine item and proposals for the removal of one Living Situation item, two Food items, and one Utilities item proposed for implementation in CY 2026.	\$ -17,810,282

3. Expanded HHVBP Model

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 84, we have prepared an accounting statement showing the classification of

the transfers and benefits associated with the CY 2026 HHVBP provisions of this proposed rule.

the transfers and benefits associated with the CY 2026 HHVBP provisions of this proposed rule.

TABLE 84: ACCOUNTING STATEMENT: EXPANDED HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS FOR CYs 2023 – 2027

Category	Transfers	Discount Rate	Period Covered
Annualized Monetized Transfers	-\$662.4 Million	7%	CYs 2023-2027
Annualized Monetized Transfers	-\$669.7 Million	3%	CYs 2023-2027
Bearers of Transfer Loss	Hospitals and SNFs		

4. Provider Enrollment

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 85, we have prepared an accounting statement showing the classification of the costs, transfers and benefits associated with the CY 2026 DMEPOS accreditation provisions of this

proposed rule. For the costs, the DMEPOS AO figure of \$95.2 million is the total cost to the AOs out of the \$128.3 million reflected in Table 79. That is, we combined all of the net AO cost burdens from the tables and explanations in sections VIII. (ICR costs for AOs) and IX.C.6.a. of this proposed rule to arrive at the \$95.2 million figure. As noted in the “Burden to AO” portions of the tables, these costs mostly

includes the combined total from our retroactive revocation proposals (\$2.197 billion) and our change in majority ownership provisions (\$2.5 million in Form CMS–855S application fees).

TABLE 85: ACCOUNTING STATEMENT: PROVIDER ENROLLMENT - CY 2026

Category	Monetary Amount (Millions \$)
Transfers to the Federal Government	2,200

5. DMEPOS Supplier Accreditation Organizations

Consistent with OMB Circular A–4 (available at <https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf>), in table 86, we have prepared an accounting statement showing the classification of the costs, transfers and benefits associated with the CY 2026 DMEPOS accreditation provisions of this

proposed rule. For the costs, the DMEPOS AO figure of \$95.2 million is the total cost to the AOs out of the \$128.3 million reflected in Table 79. That is, we combined all of the net AO cost burdens from the tables and explanations in sections VIII. (ICR costs for AOs) and IX.C.6.a. of this proposed rule to arrive at the \$95.2 million figure. As noted in the “Burden to AO” portions of the tables, these costs mostly

arose from reaccreditation application reviews, surveys, and post-survey reviews and decision. The supplier costs, meanwhile, reflect the remainder of the the \$128.3 million total in the accounting statement. As with the AO costs, the supplier costs (excluding accreditation fee payments and Form CMS–855S application fees, which are transfers) stem mostly from surveys and the reaccreditation application process.

TABLE 86: ACCOUNTING STATEMENT: DMEPOS ACCREDITATION ANNUAL COSTS AND TRANSFERS

Category	Monetary Amount (Millions \$)
Costs	
DMEPOS AOs	95.2
DMEPOS Suppliers	33.1
Transfers	
Accreditation/Survey Fees	165.8
Bearers of Transfer Gain	DMEPOS AOs
Refunds	3.8
Bearers of Transfer Gain	DMEPOS Suppliers
To Federal Government	664

6. Proposed Exemption Process for Prior Authorization of Certain DMEPOS Items

As required by OMB Circular A–4 (available at <https://trumpwhitehouse.>

[archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf](https://www.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf)), in table 87, we have prepared an accounting statement showing the classification of

the costs, transfers and benefits associated with the Exemption Process for Prior Authorization of Certain DMEPOS Items of this proposed rule.

TABLE 87: ACCOUNTING STATEMENT: EXEMPTION PROCESS FOR PRIOR AUTHORIZATION OF CERTAIN DMEPOS ITEMS ANNUAL COSTS AND BENEFITS

Category	Monetary Amount (Millions \$)
Benefits	
To Federal Government	2.2
To DMEPOS Suppliers	0.3

7. Overall Accounting Statement

As required by OMB Circular A–4 (available at <https://trumpwhitehouse.>

[archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf](https://www.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf)), in table 88, we have prepared an accounting statement showing the classification of

the transfers, costs/savings, and benefits for certain provisions of this proposed rule for CY 2026.

BILLING CODE 4120–01–P

TABLE 88: ACCOUNTING STATEMENT - CLASSIFICATIONS OF ESTIMATED TRANSFERS, COSTS, AND BENEFITS FOR CY 2026 (in MILLIONS)

Category	Amount (\$ in millions)
TRANSFERS	
HH-Related Provisions	
HHS PPS--Annualized monetized transfers	-1135
HHVBP	-662.4 to -669.7
DMEPOS-Related Provisions	
DMEPOS AOs	165.8
From DMEPOS suppliers to DMEPOS AOs in accreditation/survey fees	
DMEPOS Suppliers	3.8
From DMEPOS AOs to DMEPOS suppliers in refunds.	
Other Provisions	
Provider Enrollment	2,200
From providers to the Federal government	
COSTS/SAVINGS	
DMEPOS-Related Provisions	
DMEPOS AOs	95.2
DMEPOS Suppliers	33.1
BENEFITS	
HH-Related Provisions	
HH QRP	-17.8
DMEPOS-Related Provisions	
DMEPOS Prior Authorization	2.5

BILLING CODE 4120-01-C*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 million¹⁰³ and approximately 96 percent of HHAs are considered small entities. Table 89 shows the number of firms, revenue, and average revenue per firm for the home health care services category (NAICS 621610).

¹⁰³ https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx.

TABLE 89: 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	\$36.62
621610	Home Health Care Services	100-499	7,099	1,869,713	\$263.38
621610	Home Health Care Services	500-999	3,866	2,829,374	\$731.86
621610	Home Health Care Services	1,000-2,499	5,218	8,370,496	\$1,604.16
621610	Home Health Care Services	2,500-4,999	2,560	8,833,076	\$3,450.42
621610	Home Health Care Services	5,000-7,499	885	5,275,636	\$5,961.17
621610	Home Health Care Services	7,500-9,999	450	3,789,016	\$8,420.04
621610	Home Health Care Services	10,000-14,999	466	5,256,982	\$11,281.08
621610	Home Health Care Services	15,000-19,999	235	3,621,448	\$15,410.42
621610	Home Health Care Services	>20,000	1,058	73,271,709	\$69,254.92
621610	Home Health Care Services	Total	28,198	113,350,417	\$4,019.80

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.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS’s practice in interpreting the RFA is to consider effects economically “significant” only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs’ visits are Medicare paid visits and therefore the majority of HHAs’ revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule will have a significant economic impact on a substantial number of small entities.

Specifically, we estimate that the net impact of the payment policies in this proposed rule will be a negative 6.4 percent impact in the aggregate for CY 2026 or approximately – \$1.135 billion. Table 67 details the total percentage payment reduction by number of 30-day periods. We estimate that smaller HHAs (those with less than 100 periods of care and thereby lower overall revenues) will receive a negative 6.8 percent payment impact in CY 2026. Also, we estimate that larger HHAs (those with more than 1,000 periods of care and thereby higher overall revenues) will receive a negative 6.2 percent payment impact in CY 2026. Furthermore, table 67 details the total percentage payment impact by facility

location. We estimate that HHAs located in the Pacific region will receive the largest impact reflecting a negative 7.5 percent payment impact. As discussed in the preamble, the net decrease in CY 2026 is mostly driven by the impact of the permanent and temporary adjustments which are reflected in the third and eighth columns of table 67. We solicit comments on this RFA analysis on small entities.

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 we find that the – 4.059 percent permanent adjustment, described in section II.C.1.g. of this proposed rule, is necessary to offset the increase in estimated aggregate expenditures for CYs 2020 through 2024 based on the impact of the differences between assumed behavior changes and actual behavior changes, 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 proposed rule, we explored alternatives to the proposed – 4.059 percent permanent adjustment including a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2026 permanent adjustment over a period of years. Another alternative would be to delay the permanent adjustment to a future year. However, we believe that a reduction to the permanent adjustment, a phase-in approach, or delay in the permanent adjustment would not be appropriate, as reducing, phasing in, or delaying the permanent adjustment would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger reduction to the payment rate in future years. In addition, we explored alternatives to the proposed – 5 percent temporary adjustment to reconcile retrospective overpayments in CYs 2020 through 2024. However, as stated previously in this proposed rule, we believe that applying both the permanent adjustment of – 4.059 percent and a temporary adjustment accounting for the temporary adjustment dollar amount of \$5.3 billion to the CY 2026 payment rate may adversely affect HHAs given the magnitude of the combined adjustments to the payment rate in a

single year. Although we are not establishing a time frame to recoup the calculated temporary adjustment dollar amount of \$5.3 billion, we believe it is prudent to begin implementing some of the adjustment in order to begin to slow its continued growth. Postponing the 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. We solicit comments on the overall HH PPS RFA analysis.

Among the over 7,000 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this proposed rule would be larger than ± 3 percent, in magnitude, for about 660 competing HHAs (9

percent) (estimated by applying the 5 percent maximum payment adjustment under the expanded Model to CY 2023 data). As a result, more than the RFA threshold of 5 percent of HHAs nationally would be significantly impacted.

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 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule is not applicable to hospitals. Therefore, the Secretary has certified that this proposed rule would

not have a significant economic impact on the operations of small rural hospitals.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$8.0 million to \$41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. This proposed rule primarily affects pharmacies and drug stores and home health equipment rental suppliers.

TABLE 90: DMEPOS SUPPLIERS SIZE STANDARDS

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/Small Entity Threshold	Total Small Businesses
446110	Pharmacies and Drug Stores	\$37.5 million	18,952
532283	Home Health Equipment Rental	\$41 million	553

Source: SUSB 2017 Country Business Patterns and Economic Census

Since we are uncertain of the DMEPOS suppliers' composition, we are asking the public for aid in

understanding the various industries that supply DMEPOS products. So far,

we have identified only the two industries in table 91.

TABLE 91: DMEPOS SUPPLIERS' CONCENTRATION RATIOS (PHARMACIES AND DRUG STORES AND HOME HEALTH EQUIPMENT RENTAL)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Total Average Revenue
SMALL FIRMS	19,505	100.0%	\$3,374,384
<100,000	706	3.6%	\$51,647
100,000-499,999	2,139	11.0%	\$290,675
500,000-999,999	2,065	10.6%	\$744,226
1,000,000-2,499,999	5,693	29.2%	\$1,745,060
2,500,000-4,999,999	5,255	26.9%	\$3,559,904
5,000,000-7,499,999	1,839	9.4%	\$6,032,844
7,500,000-9,999,999	709	3.6%	\$8,506,154
10,000,000-14,999,999	573	2.9%	\$11,926,209
15,000,000-19,999,999	226	1.2%	\$16,037,279
20,000,000-24,999,999	103	0.5%	\$18,479,010
25,000,000-29,999,999	65	0.3%	\$25,465,123
30,000,000-34,999,999	49	0.3%	\$27,426,041
35,000,000-39,999,999	37	0.2%	\$28,005,054
40,000,000-49,999,999	46	0.2%	\$31,703,478
LARGE FIRMS			
Receipts ≥50 million	318	NA	\$690,720,449.69

SOURCE: 2017 County Business Patterns and Economic Census.

Note: Home Health Equipment Rental includes firms earning up to \$49.9 million, which is greater than the \$41 million SBA size standard, and Pharmacies and Drug Stores include firms earning up to \$39.9 million, which is greater than the \$37.5 million SBA size standard.

As can be seen in table 91, almost all DMEPOS suppliers are small entities as that term is used in the RFA.¹⁰⁴ Additionally, table 91 shows the disproportionate impacts among firms, and between small and large firms. In table 91, both industries, Pharmacies and Drug Stores and Home Health Equipment Rental firm size (by receipts), firm count, percentage of small firms, and total average revenue were aggregated to determine the DMEPOS concentration ratios.

For purposes of the RFA, approximately 98.4 percent of pharmacies and drugs stores and home health equipment rental industries are considered small businesses according to the SBA's size standards with total revenues of \$49.9 million or less in any 1 year. Individuals and states are not included in the definition of a small entity.

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. Therefore, the Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of 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 2025, that threshold is approximately \$187 million. This proposed rule would 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 \$187 million in any one 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

¹⁰⁴ Note, the entire population of DMEPOS suppliers is not known at this time. However, based on our experience, the majority of DMEPOS suppliers are covered in the two industries identified.

governments, preempts State law, or otherwise has federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132 and have determined that it 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”

K. Conclusion

In conclusion, we estimate that the provisions in this proposed rule will result in an estimated net decrease in home health payments of 6.4 percent for CY 2026 (–\$1.135 billion). The \$1.135 billion decrease in estimated payments for CY 2026 reflects the effects of the proposed CY 2026 home health payment update percentage increase of 2.4 percent (\$425 million increase), an estimated 3.7 percent decrease in payments that reflects the effects of the permanent adjustment (\$655 million decrease) an estimated 4.6 percent decrease that reflects the effects of the temporary adjustment (\$815 million decrease) and an estimated 0.5 percent decrease that reflects the effects of an updated FDL (\$90 million decrease). Lastly, the implementation of the HH QRP proposed policy is estimated to increase the costs to HHAs by \$1,058.88 per HHA annually, or \$12,604,894.62 in the aggregate for HHAs annually.

X. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 24, 2025.

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 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, 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 amends 42 CFR chapter IV as follows:

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).

- 2. Section 405.800 is amended by revising paragraph (b)(2) to read as follows:

§ 405.800 Appeals of CMS or a CMS contractor.

* * * * *

(b) * * *

(2) The effective date of a revocation is as specified in § 424.535.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

- 3. The authority for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

- 4. Section 414.234 is amended by revising paragraph (c)(1) introductory text and adding paragraphs (c)(1)(ii)(A) and (B) to read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

* * * * *

(c) * * *

(1) *Items requiring prior authorization.* CMS publishes in the **Federal Register** and posts on the CMS Prior Authorization website a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment, unless otherwise exempt under paragraph (c)(1)(ii) of this section.

* * * * *

(ii) * * *

(A) An exemption is provided for a supplier that achieves a rate of payable claims submitted, based on Medicare's billing, coding or payment requirements, of at least 90 percent during an initial or periodic review and remains in effect until CMS withdraws the exemption. An exemption of a supplier is withdrawn if the rate of non-payable claims submitted, based on Medicare's billing, coding or payment requirements, becomes higher than 10 percent, based upon a periodic assessment.

(B) CMS provides a notice of an exemption or withdrawal of an exemption to the supplier at least 60 days before the effective date.

- 5. Section 414.402 is amended by—
- a. Adding the definitions of “Adjusted fee schedule amount” and “Competition”;
- b. In the definition of “Competitive bidding program” removing the phrase “Competitive bidding program” and adding in its place “Competitive bidding program (CBP)”;
- c. Adding paragraph (6) to the definition of “Item”; and
- d. Adding the definitions of “Remote item delivery competitive bidding program”, “Remote item delivery item”, and “Unadjusted fee schedule amount”.

The additions read as follows:

§ 414.402 Definitions.

* * * * *

Adjusted fee schedule amount means the payment amount established for the item under one of the following:

- (1) Subpart C of this part, with the application of § 414.105.
- (2) Subpart D of this part, with the application of § 414.210(g).
- (3) Subpart Q of this part, with the application of § 414.1690.

* * * * *

Competition means a competitive bidding area and product category combination for which a bidding entity submits a bid and for which a contract supplier enters into a DMEPOS CBP supplier contract to furnish items and

services within the product category to beneficiaries residing within the competitive bidding area.

* * * *

Item * * *

(6) Other medical equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies.

* * * *

Remote item delivery competitive bidding program means a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.

Remote item delivery item means an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person.

* * * *

Unadjusted fee schedule amount means the payment amount established for the item under one of the following:

(1) Subpart C of this part, without the application of § 414.105.

(2) Subpart D of this part, without the application of § 414.210(g).

(3) Subpart Q of this part, without the application of § 414.1690.

* * * *

- 6. Section 414.408 is amended by—
- a. Revising paragraph (b); and
- b. Adding paragraphs (e)(2)(v) and (g)(6), and (m).

The revision and additions read as follows:

§ 414.408 Payment rules.

* * * *

(b) *Changes to the single payment amount.* (1) For the second year (12-month period) of a DMEPOS CBP supplier contract period, the single payment amount for each item under each competitive bidding program is updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending 6 months prior to the start of the second year of the applicable DMEPOS CBP supplier's contract period.

(2) For the third year (12-month period) of a DMEPOS CBP supplier contract period, if applicable, the single

payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending 6 months prior to the start of the third year of the applicable DMEPOS CBP supplier contract period.

(3) In no case can the updated single payment amount for an item in the applicable CBA be greater than the unadjusted fee schedule amount for the item in such area or 110 percent of the adjusted fee schedule amount for the item in such area.

* * * *

(e) * * *

(2) * * *

(v) A Medicare enrolled provider or supplier, as the terms are defined under 42 CFR 400.202, that is operated by the Indian Health Service (IHS) or a Tribe or Tribal organization in accordance with the Indian Self Determination and Education Assistance Act (25 U.S.C. 5301 et seq).

(g) * * *

(6) Other medical equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies.

* * * *

(m) *Special temporary transition rules for payment for supplies and accessories necessary for the effective use of beneficiary owned continuous glucose monitors and insulin infusion pumps.* CMS continues, as applicable, to make separate payments under the DMEPOS competitive bidding program for supplies and accessories for class II continuous glucose monitors or insulin infusion pumps owned by the beneficiary at the time a competitive bidding program is phased in for class II continuous glucose monitors or insulin infusion pumps for the first time in a CBA where the beneficiary resides until coverage for the beneficiary-owned equipment ends, the equipment is no longer used, or at any point when the equipment has been replaced with rented equipment under the DMEPOS CBP.

- 7. Section 414.412 is amended by—

- a. Revising paragraph (b)(2);

- b. Redesignating paragraphs (b)(3) through (5) as paragraphs (b)(6) through (8);

- c. Adding new paragraphs (b)(3), (4) and (5);

- d. Adding paragraphs (b)(9) through (12);

- e. Revising paragraph (g)(3); and

- f. Adding paragraph (g)(5).

The revisions and additions read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * *

(b) * * *

(2) The bid amount for each lead item in a product category included under the DMEPOS CBP for the first time must not exceed the unadjusted fee schedule amount for the lead item.

(3) Notwithstanding paragraph (b)(4) of this section, the bid amount for each lead item in a product category included in a prior competition, must not exceed, for the same CBA, the lesser of—

(i) The most recent SPA for the item plus 10 percent; or

(ii) The unadjusted fee schedule amount for the item.

(4) If it has been more than 1 year since a SPA was paid for the item in the prior competition, the bid amount must not exceed the lesser of the—

(i) Most recent SPA made for the item, as adjusted by the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the 12-month period the most recent SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the current round of competition, plus 10 percent; or

(ii) Unadjusted fee schedule amount for the item.

(5) The bid amount for each lead item in a product category included in a prior competition but made under a bid for a new CBA, must not exceed the lesser of the—

(i) Adjusted fee schedule amount for the item plus 10 percent; or

(ii) Unadjusted fee schedule amount for the item.

* * * *

(9) The bid amount submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the remote item delivery CBP divided by 60.

(10) The bids amount submitted for rental of insulin infusion pumps included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the nonrural payment amount that would otherwise apply to the supplies and accessories for the insulin infusion

pump under subpart D of this part, with the application of § 414.210(g), for a 1-month period plus the total nonrural rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part, with the application of § 414.210(g), divided by 60.

(11) The bid amounts submitted for an OTS back brace or OTS knee brace included as a lead item in a product category in a remote item delivery CBP for the first time cannot exceed the average nonrural payment amount that would otherwise apply to the item under subpart D of this part, with the application of § 414.210(g), for the areas included in the remote item delivery CBP.

(12) The bids submitted for all other items included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the average payment amount that would otherwise apply to the item under subpart C, D, or Q of this part for the areas included in the remote item delivery CBP.

* * * * *

(g) * * *

(5) *Bid surety bond riders.* (i) Bid surety bonds submitted prior to the deadline for bid submission are reviewed to determine if they contain any deficiencies that would make the applicable bid(s) ineligible to receive a DMEPOS CBP supplier contract offer. CMS notifies the bidder of the deficiency(ies) and allow the bidder to submit a bid surety bond rider to rectify the deficiency(ies).

(ii) Bidding entities can submit a bid surety bond rider to correct the identified deficiency(s) applicable to any of the bid surety bond requirements outlined in paragraphs (g)(2)(i) and (ii) of this section. No other deficiency(ies) can be rectified by a bid surety bond rider.

(iii) Bidding entities notified of a bid surety bond deficiency have 10-business days after the date of such notice to submit a bid surety bond rider. The bidder must receive the bid surety bond rider from the authorized surety that issued the original bid surety bond.

■ 8. Section 414.414 is amended by revising paragraphs (d) introductory text (d)(1), (2)(ii)(B), (e), (f), and (h) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(d) *Financial standards.* (1) *Financial document requirements.*

(A) By the close of the bid window, the bidding entity must, in accordance

with paragraph (d)(2) of this section, submit both a business credit report with a numerical credit score or rating unless the bidding entity is unable to generate a business credit report with a numerical credit score or rating because the bidding entity has not been in operation long enough to generate a numerical score or rating.

(B) A bidding entity that is unable to generate a business credit report with a numerical credit score or rating is required to submit a business credit report showing no data or insufficient information to generate a credit score, in addition to a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS.

(C) The bidding entity must submit the documentation described in paragraphs (d)(1)(A) and (B) of this section, along with the name of the bidding entity or Authorized Official or Delegated Official, as applicable, and the date each document was prepared not earlier than 90 calendar days prior to the opening of the bid window in a form and manner specified by CMS.

(D) The bidding entity must attest in the bidding system that it is submitting one bid that includes all commonly owned or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

(2) *Financial scoring methodology.* A credit report scoring list is published before the opening of the bid window in the round specific Request for Bids Instructions or a fact sheet or both which includes all of the following:

(i) The approved credit agencies from which a bidding entity must obtain a business credit report with a numerical credit score or rating.

(ii) The approved business credit reports and associated credit scores or ratings that must be submitted.

(iii) The scoring system that will be utilized to determine if a bidding entity met the financial sustainability threshold.

* * * * *

(2) * * *

(ii) * * *

(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.

* * * * *

(e) *Evaluation of bids.* CMS evaluates composite bids submitted for a lead

item within a product category by doing all of the following:

(1) Calculating the number of suppliers selected to furnish the items and services in the competition in accordance with paragraph (h) of this section.

(2) Arraying the composite bids from the lowest composite bid price to the highest composite bid price.

(3) Selecting the number of suppliers and networks calculated under paragraph (e)(1) of this section that meet the requirements in paragraphs (b) through (d) of this section with the lowest composite bids.

(f) *Expected savings.* A DMEPOS CBP supplier's contract is not awarded for a competition under this subpart unless CMS determines that the SPA to be paid to contract suppliers for the lead item would be no greater than the lesser of—

(1) 110 percent of the adjusted fee schedule amount for the item, if applicable; or

(2) the unadjusted fee schedule amount for the item.

* * * * *

(h) *Sufficient number of contract suppliers.* (1) Notwithstanding paragraph (h)(1)(ii) of this section, for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recomputed after 2023, the number of contract suppliers selected to furnish items and services in the competition is no more than double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023, and rounded to the nearest whole number.

(i) CMS adjusts the number of contract suppliers selected in accordance with paragraph (h)(1)(i) of this section for a competition to ensure the number selected is—

(A) Not less than 50 percent of the total number of contract suppliers that furnished the lead item in 2018 or 2023 rounded up to the nearest whole number;

(B) More than 75 percent of the total number of contract suppliers that furnished the lead in 2018 or 2023 rounded down to the nearest whole number; and

(C) At least 2.

(2) For competitions included in the DMEPOS CBP in 2018 or 2023, after the first time a competition is recomputed after 2023, the number of contract suppliers selected to furnish items and

services is in the competition is equal to the number of contract suppliers CMS selected the first time the competition was recompeted after 2023, in accordance with paragraph (h)(1) of this section trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent DMEPOS CBP supplier contract period, and rounded to the nearest whole number.

(3) For competitions not included in the DMEPOS CBP in 2018 or 2023—

(i) The first time a competition is conducted after 2023, the number of contract suppliers selected to furnish items and services is at least 2, but no more than 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, and rounded to the nearest whole number.

(ii) For all subsequent recompetes for the competition, the number of suppliers selected to furnish items and services is equal to the number of contract suppliers selected in the prior competition or recompetes, as applicable, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent DMEPOS CBP supplier's contract period, and rounded to the nearest whole number.

■ 9. Section 414.416 is amended by revising paragraph (b)(1) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) *Methodology for setting payment amount.*

(1) Notwithstanding paragraphs (b)(2) through (4) of this section, a single payment amount for a lead item furnished under a competitive bidding program is equal to the 75th percentile of bid amounts submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. In cases where there is an odd number of winning contract suppliers, the SPA is determined by using the amount that is 75 percent between the two bid amounts, rounded to the nearest cent.

(2) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category (non-lead item) is equal to the single payment amount for the lead item in the same product category multiplied

by the ratio of the 2015 fee schedule amount for the non-lead item for the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands) to the 2015 fee schedule amount for the lead item for the same area.

(3) The single payment amount for an item included in a product category in a remote item delivery CBP furnished under a competitive bidding program that is not a lead item for that product category (non-lead item) is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average 2015 fee schedule amount for the non-lead item for the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands) to the average 2015 fee schedule amount for the lead item for the same area.

(i)(A) The 2015 fee schedule amounts for a continuous glucose monitor and supplies are calculated using the 2025 fee schedule amounts and removing the covered items update factors for years 2016 through 2025 specified under section 1834(a)(14) of the Act.

(B) The 2015 fee schedule amounts for the bundled monthly rental of a continuous glucose monitor are calculated by adding the 2015 fee schedule amount for the supplies to the average of the 2015 fee schedule amounts for the purchase of a new continuous glucose monitor divided by 60 for the areas included in the remote item delivery CBP.

(ii) The 2015 fee schedule amount for the monthly supplies for a continuous glucose monitor owned by a beneficiary is calculated using the 2025 fee schedule amount and removing the covered item update factors for years 2016 through 2025 specified under section 1834(a)(14) of the Act.

(iii) The 2015 fee schedule amounts for the bundled monthly rental of an insulin infusion pump are calculated using the average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 6 for the nonrural areas included in the remote item delivery CBP, and then adding the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by 9 for the nonrural areas included in the remote item delivery CBP plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the remote item delivery CBP.

(iv) The 2015 fee schedule amounts for the monthly supplies and

accessories for an insulin infusion pump owned by a beneficiary is calculated using the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by 9 for the areas included in the remote item delivery CBR plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the remote item delivery CBR.

■ 10. Section 414.422 is amended by adding paragraph (h) to read as follows:

* * * * *

(h) *Contract termination during a public health emergency (PHE) under section 319 of the Public Health Service Act.*

(1) If CMS determines in accordance with paragraph (h)(2) of this section, that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS may unilaterally terminate or modify each applicable DMEPOS CBP supplier's contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. Depending on the geographic extent of the PHE, a PHE-impacted area may refer to entire CBA(s) or only certain areas within a CBA.

(i) If the items and services in the PHE-impacted area identified in accordance with paragraph (h)(2) of this section encompass all competitions referenced a DMEPOS CBP supplier's contract, CMS unilaterally terminates the DMEPOS CBP supplier's contract.

(ii) If the items and services in the PHE-impacted area identified in accordance with paragraph (h)(2) of this section encompass only a portion of the items and services and geographic areas referenced in a DMEPOS CBP supplier's contract, CMS unilaterally modifies the DMEPOS CBP supplier's contract to remove the contract supplier's obligation to furnish specified items and services in the PHE-impacted area, as well as CMS's obligation to pay for those items and services under the DMEPOS CBP supplier's contract.

(iii) After a termination or modification of all applicable DMEPOS CBP supplier contracts, CMS reverts back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA.

(2) CMS may remove items and services furnished in a PHE-impacted

area from the DMEPOS CBP when all of the following qualifying criteria are met:

- (i) The Secretary declares a PHE.
- (ii) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA.
- (iii) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns.
- (iv) CMS determines terminating or modifying each impacted DMEPOS CBP supplier's contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 11. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 12. Section 424.22 is amended by revising paragraph (a)(1)(v)(A) and removing paragraph (a)(1)(v)(C) to read as follows:

§ 424.22 Requirements for home health services.

* * * * *

(a) * * *

(1) * * *

(v) * * *

(A) The face-to-face encounter must be performed by one of the following:

(1) A physician (as defined at § 484.2 of this chapter).

(2) A nurse practitioner (as defined at § 484.2 of this chapter).

(3) A clinical nurse specialist (as defined at § 484.2 of this chapter).

(4) A physician assistant (as defined at § 484.2 of this chapter).

(5) A certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by State law.

* * * * *

■ 13. Section 424.57 is amended by—

■ a. Revising paragraphs (c)(10), (22), (23), (24), and (e)(1); and

■ b. Adding paragraph (h).

The revisions and addition read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(c) * * *

(10) Has a comprehensive liability insurance policy in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier.

(i) In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations.

(ii) Failure to maintain required insurance at all times results in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.

(iii) An authorized official of the supplier (as that term is defined in § 424.502) must sign the liability insurance policy.

* * * * *

(22)(i) All suppliers of DMEPOS and other items and services, and all of their locations whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited to enroll in and bill Medicare.

(ii) The accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the supplier to receive payment for those specific products and services.

(iii) An accredited DMEPOS supplier may be denied enrollment, or its enrollment may be revoked, if CMS determines that it is not compliant with the DMEPOS quality standards.

(23) All DMEPOS suppliers must notify their DMEPOS accrediting organization when a new DMEPOS location is opened.

(24) All accredited DMEPOS suppliers must be surveyed and reaccredited at least once every 12 months.

* * * * *

(e) * * *

(1) *Revocation.* CMS revokes a supplier's billing privileges if it is found not to meet the conditions or standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation effective date is as specified in § 424.535.

* * * * *

(h) *Change in majority ownership.* A supplier must comply with the provisions of § 424.551 if it undergoes a change in majority ownership.

■ 14. Section 424.58 is amended by revising paragraphs (b) through (e) and adding paragraphs (f) through (o) to read as follows:

§ 424.58 Accreditation.

* * * * *

(b) *Definitions.* The following definitions apply to the provisions in this section:

Complaint means an allegation from any party and via any format that one of the DMEPOS accrediting organization's accredited DMEPOS suppliers may be non-compliant with

one or more DMEPOS quality standards or other applicable CMS requirement. The complaint need not involve actual or potential beneficiary harm.

Immediate family member means any person with whom the accrediting organization owner(s), surveyors or employees have a lineal or immediate familial or marital relationship, including all of the following:

(i) A husband or wife.

(ii) Birth or adoptive parent, child, or sibling.

(iii) Stepparent, stepchild, stepbrother, or stepsister.

(iv) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law.

(v) Grandparent or grandchild.

(vi) Spouse of a grandparent or grandchild.

Immediate jeopardy means a situation in which the DMEPOS supplier's non-compliance with one or more DMEPOS quality standards or other applicable CMS requirement has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public.

Reasonable assurance means that a DMEPOS accrediting organization has demonstrated to CMS' satisfaction all of the following:

(1) Its DMEPOS accreditation program requirements meet or exceed the Medicare program requirements.

(2) The DMEPOS suppliers that the DMEPOS accrediting organization accredits meet or exceed Medicare program requirements.

(3) The DMEPOS accrediting organization is compliant with all provisions of § 424.58.

Unannounced survey means both of the following:

(1) A survey that is conducted without any prior notice of any type (through any means of communication or forums) to the DMEPOS supplier to be surveyed such that the supplier does not expect the survey until the surveyors arrive.

(2) The DMEPOS accrediting organization schedules its surveys so that DMEPOS suppliers cannot predict when they will be performed.

(c) *Initial application procedures.* (1) *Required information.* An independent DMEPOS accrediting organization applying for initial approval of its DMEPOS accreditation program is required to furnish CMS with all the following information and materials to demonstrate that the DMEPOS accrediting organization provides reasonable assurance (as defined in paragraph (b) of this section) regarding its program.

(i) A list of the types of DMEPOS supplies, products, and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational, survey, and other accreditation processes to confirm that the DMEPOS suppliers it accredits meet or exceed the DMEPOS quality standards and Medicare program requirements. This must include all of the following:

(A) Procedures for performing unannounced surveys.

(B) Frequency of the surveys performed.

(C) Copies of the organization's survey forms.

(D) Guidelines and instructions to surveyors.

(E) Quality review processes for deficiencies identified with accreditation requirements.

(F) Dispute resolution processes and policies when there is a negative survey finding or decision.

(G) If the DMEPOS accrediting organization has the discretion to perform a survey in certain instances, how it determines whether to perform one. This must include a suggested methodology for sampling locations for surveys under a single tax identification number or organization.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another DMEPOS accrediting organization if the organization does not accredit all supplies, products, and services the DMEPOS supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the DMEPOS accrediting organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements surveyors must meet. The information must also include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the

DMEPOS accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(D) The organization's policies and procedures to avoid conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization's policies and procedures for all of the following:

(1) The separation of its consulting services from its accreditation services.

(2) Protecting the integrity of the DMEPOS accrediting organization's accreditation program (including the requirements of paragraphs (m) and (n) of this section).

(3) The prevention and handling of potential or actual conflicts of interest that could arise from situations in which a DMEPOS accrediting organization owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the accrediting organization provides accreditation services. Such interests or relationships include, but are not limited to the following:

(i) Being employed as a DMEPOS accrediting organization surveyor.

(ii) Being employed by a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(iii) Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(iv) Serving as a director or of trustee for a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(v) Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(vi) Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS accrediting organization.

(vii) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS supplier accrediting organization.

(viii) Providing consulting services to a DMEPOS supplier that the DMEPOS accrediting organization accredits.

(ix) Having any immediate family member (as defined in paragraph (b) of this section) engaged in any of the activities described in paragraphs (3)(i) through (viii) of this paragraph (D).

(x) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

(4) For notifying CMS when a conflict of interest is discovered.

(5) For the purposes of this section, a conflict of interest exists when a DMEPOS accrediting organization, the DMEPOS accrediting organization's successors, transferees, or assigns, the DMEPOS accrediting organization owner(s), surveyors, or employees, or the immediate family members of the DMEPOS accrediting organization owners(s), surveyors and other employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS accrediting organization accredits.

(E) The organization's policies and procedures for ensuring it has an adequate number of surveyors at all times.

(viii) Its processes for identifying and correcting deficiencies within its DMEPOS accreditation program.

(ix) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. This must also include a detailed description of how the organization uses its data to ensure the compliance of its DMEPOS accreditation program with Medicare program requirements.

(x) Procedures for responding to, investigating, and (as applicable) closing out complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the applicable National Provider Enrollment contractor, and CMS. This must also include a detailed outline of all of the following:

(A) The steps and research the DMEPOS accrediting organization will undertake in its initial review of the complaint as described in paragraph (e)(3) of this section.

(B) How the DMEPOS accrediting organization determines whether, in accordance with a complaint, non-compliance with a DMEPOS quality standard or other applicable CMS requirement exists, including the information it considers in its review and when and how it would take action against the DMEPOS supplier.

(xi) The organization's policies and procedures for notifying CMS of DMEPOS suppliers that fail to meet the

DMEPOS accrediting organization's requirements.

(xii) A description of all types, categories, and durations of accreditations offered by the organization.

(xiii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types, categories, and product codes of accreditation currently held by each DMEPOS supplier.

(C) The effective and expiration dates of each DMEPOS supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiv) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xvi) Information that demonstrates the DMEPOS accrediting organization's knowledge, expertise, and experience in DMEPOS.

(xvii) Information about the DMEPOS accrediting organization's ability to conduct timely reviews of accreditation applications.

(xviii) A description of the organization's accreditation decision-making process. This includes its policies and procedures for approving, denying, or terminating accreditation status for DMEPOS suppliers that fail to meet the DMEPOS accrediting organization's standards or requirements. This must include an explanation of the reasons for which it will deny or terminate a supplier's accreditation.

(xix) Policies and procedures for both of the following:

(A) Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new item type). This includes the circumstances under which the DMEPOS accrediting organization will impose a corrective action plan (CAP) in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.

(B) Ensuring that all onsite surveys are unannounced, including procedures that protect against unannounced surveys becoming known to the DMEPOS supplier before the visit.

(xx) Policies and procedures regarding when the DMEPOS accrediting organization will apply a CAP to a

DMEPOS supplier. This must include the following:

(A) The specific circumstances under which the DMEPOS accrediting organization will apply a CAP as opposed to, as applicable, denying or terminating accreditation and the rationale for why the accrediting organization believes a CAP in these situations is more appropriate.

(B) How the CAP is developed, implemented and enforced, including the following:

(1) How the DMEPOS accrediting organization determines whether a CAP is acceptable.

(2) The requirements of (and the timeframe and deadline for) the DMEPOS supplier's resumption of compliance.

(3) How the DMEPOS accrediting organization determines whether the DMEPOS supplier has resumed compliance and maintains compliance.

(4) The circumstances under which the DMEPOS accrediting organization will impose a CAP in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.

(xxi) An explanation of the following:

(A) What the DMEPOS accrediting organization considers to be a DMEPOS supplier deficiency and how it defines the term deficiency.

(B) Whether the DMEPOS accrediting organization has different levels of DMEPOS supplier deficiencies.

(xxii) In performing the functions described in this section, its processes for both of the following:

(A) Detecting and addressing potential fraud, waste, and abuse by DMEPOS suppliers (including identifying the accrediting organization's definitions of the terms fraud, waste, and abuse).

(B) Reporting this activity to CMS and, as applicable, law enforcement.

(xxiii) A statement on the DMEPOS accrediting organization's letterhead that is signed and dated by the accrediting organization's chief executive officer (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) acknowledging that, as a condition for CMS approval or continued approval of a DMEPOS accrediting organization's accreditation program, the organization agrees to all of the following:

(A) Provide CMS, within 3 business days of CMS's request, both of the following:

(1) Any of the information described in paragraph (e)(1)(i) of this section.

(2) Any other information CMS deems necessary to facilitate its oversight of the DMEPOS accrediting organization's accreditation program.

(B) Provide CMS written notification when an accreditation survey or complaint investigation identifies an immediate jeopardy situation (as that term is defined in paragraph (b) of this section). Consistent with paragraph (e)(1)(iii) of this section, this notice must be provided within 2 business days of the finding.

(C) Provide written notification to CMS of any proposed changes to the DMEPOS accrediting organization's accreditation program and that it will not implement the proposed changes without prior written notice of continued program approval from CMS consistent with paragraph (e)(2) of this section.

(D) 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 organization took such action.

(E) Notify CMS of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include the following:

(1) The reason for the decision.

(2) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.

(3) The details of the DMEPOS supplier's CAP.

(F) Submit timely, accurate, and complete data to support CMS's evaluation of the DMEPOS accrediting organization's performance.

(1) Data to be submitted includes, but is not limited to, DMEPOS supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions.

(2) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(G) In response to a written notice from CMS to the organization of a change in the CMS quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes in the organization's requirements for its DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, and requirements. This includes compliance with the following requirements:

(1) Submission of the data required in paragraph (e)(7) of this section.

(2) The proposed changes must be submitted to CMS within 30 calendar

days of the date of the written CMS notice to the organization.

(3) The organization must not implement its proposed corresponding changes without prior CMS approval.

(H) Apply and adhere to in its accreditation activities any CMS-established—

- (1) Definition(s) of deficiency; and
- (2) Deficiency levels and categories.

(I) The DMEPOS accrediting organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(J) If CMS permits the DMEPOS accrediting organization to perform surveys via a sampling process, the accrediting organization:

- (1) Will submit to CMS its planned sampling methodology in detail; and
- (2) Will not undertake sampling until CMS has approved the accrediting organization's submitted methodology.

(K) Will not include the following as patient medical records in its DMEPOS supplier surveys:

- (1) Mock files.
- (2) Fictional patient records.
- (3) Simulated documentation.
- (4) Templates.
- (5) Duplicate patient records.

(L) Have a binding written agreement with each DMEPOS supplier the DMEPOS accrediting organization accredits regarding whether the accrediting organization, the supplier in question, or both will assume the costs of a survey that CMS directs the accrediting organization to perform in accordance with paragraph (e)(8)(ii) of this section.

(M) Submit all required information to CMS both before and after approval of its DMEPOS accreditation program in a truthful, accurate, and complete manner.

(N) Adhere to the requirements of this section at all times, including the policies, procedures, practices, and agreements it outlined in paragraph (c) of this section as part of its initial or reapproval application and any CMS-approved changes thereto under paragraph (e)(2) or (e)(7) of this section.

(2) *Additional information needed.* If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application, CMS notifies the organization and afford it an opportunity to provide the additional information.

(3) *Withdrawing an application.* A DMEPOS accrediting organization may withdraw its initial application for CMS' approval of its DMEPOS accreditation program at any time before CMS posts the notice described in paragraph (c)(6) of this section.

(4) *Reasons for denial.* CMS may deny a DMEPOS accrediting organization's application for any of the following reasons:

(i) The DMEPOS accrediting organization has failed to comply with all application, data, and agreement submission requirements outlined in paragraph (c) of this section.

(ii) The DMEPOS accrediting organization has failed to provide reasonable assurance (as defined in paragraph (b) of this section).

(iii) The current number of CMS-approved DMEPOS accreditation programs is sufficient to ensure the continued administration of CMS' DMEPOS accreditation program.

(iv) The DMEPOS accrediting organization's DMEPOS accreditation program was previously terminated, suspended, or placed on probation by CMS under, respectively, paragraph (h), (i), or (j) of this section.

(v) The DMEPOS accrediting organization, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, W-2 or contracted surveyor, or W-2 or contracted health care or administrative or management services personnel thereof—

(A) Is excluded by the Office of Inspector General (OIG) from Medicare, Medicaid, and any other Federal health care program;

(B) Is debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA);

(C) Within the preceding 10 years—

- (1) Was convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;
- (2) Has had a Medicare enrollment revoked under § 424.535;
- (3) Has had a license to provide health care suspended or revoked by any State licensing authority; or

(4) Has been suspended or terminated from participating in a Federal or State health care program.

(vi) The DMEPOS accrediting organization has submitted false or misleading information on its application in order to gain CMS approval or reapproval as a DMEPOS accrediting organization.

(vii) The AO is non-compliant with any provision in this section.

(viii) CMS otherwise determines that approval of the applicant as a DMEPOS AO would not be in the best interests of the Medicare program and its beneficiaries.

(5) *Notice of approval or denial of application.* CMS sends to the DMEPOS

accrediting organization a notice of its decision to approve or deny the application within 210 calendar days from the date CMS determines the accrediting organization's application is complete. The final notice specifies the following:

(i) The basis for the decision.

(ii) If applicable, the effective date of approval.

(iii) If applicable, the term of the approval (not to exceed 6 years).

(6) *Decision announcement.* CMS announces on its website its decision to approve or deny the DMEPOS accrediting organization's application.

(i) This announcement is posted within 210 calendar days from the date that CMS determines that the DMEPOS accrediting organization's application was complete.

(ii) If the application is approved, the posting states the approval's effective date (no later than the announcement's posting date) and length (6 years or less).

(7) *Term of approval.* CMS may approve a DMEPOS accreditation organization for any period up to a maximum of 6 years.

(d) *Reapproval process.* (1)(i) *Timeline for submission.* Except as stated in paragraph (d)(1)(ii) of this section, an approved DMEPOS accrediting organization that seeks to continue as such must apply for reapproval of accreditation no later than 9 months before the expiration of its current term of approval. If the organization fails to do so, CMS, at its discretion, may provide the organization an additional 30 days to reapply.

(ii) *Discretion to request reapproval applications.* CMS may require DMEPOS accrediting organizations to submit reapproval applications under paragraph (d) of this section any time after January 1, 2026. An application must be submitted within 60 calendar days of CMS' submission request. Failure to submit the application results in the termination of the DMEPOS accrediting organization's approval.

(2) *Submission of information and statements.* As part of its reapproval application, the DMEPOS accrediting organization must submit all information and statements identified in paragraph (c)(1) of this section. CMS may also request information under paragraph (c)(2) of this section.

(3) *Withdrawing an application.* A DMEPOS accrediting organization may withdraw its reapproval application for CMS' approval of its DMEPOS accreditation program at any time before CMS posts the notice described in paragraph (d)(6) of this section.

(4) *Denial reasons.* CMS may deny a DMEPOS accrediting organization's reapproval application for any of the reasons described in paragraph (c)(4) of this section.

(5) *Notice of approval or denial of application.* CMS sends a notice of its decision to approve or deny the DMEPOS accrediting organization's reapproval application within 210 calendar days from the date CMS determines the accrediting organization's reapproval application is complete. The final notice specifies the following:

- (i) The basis for the decision.
- (ii) The effective date.
- (iii) The term of the approval (not to exceed 6 years).

(6) *Decision announcement.* CMS announces on its website its decision to reapprove or deny the DMEPOS accrediting organization's reapproval application.

(i) This announcement is posted within 210 calendar days from the date that CMS determines that the DMEPOS accrediting organization's reapproval application was complete.

(ii) If the reapproval application is approved, the posting states the reapproval's effective date (no later than the announcement's posting date) and length (6 years or less).

(7) *Term of approval.* CMS may reapprove a DMEPOS accreditation organization for any period up to a maximum of 6 years.

(e) *Ongoing responsibilities of a CMS-approved DMEPOS accrediting organization.* A DMEPOS accrediting organization approved by CMS must undertake the following activities on an ongoing basis:

(1) *Submission of information.* (i) No later than the last day of each month, provide to CMS all the following in written format (either electronic or hard copy):

(A) Copies of all accreditation survey results and reports, together with any survey related information that CMS may require. This includes both of the following:

(1) CAPs and summaries of findings with respect to unmet CMS requirements.

(2) The instances where the DMEPOS accrediting organization had the discretion to perform a survey (for example, sampling) but decided not to, including the reason(s) for the organization's decision.

(B) Notice of all accreditation decisions.

(C) Notice of all resolved deficiencies.

(D) Information about any supplier of DMEPOS and other items and services against which the CMS-approved

DMEPOS accrediting organization has taken remedial or adverse action, including termination of the supplier's accreditation.

(ii) CMS may at any time request the DMEPOS accrediting organization to submit any of the information described in paragraph (e)(1)(i) of this section or any other data CMS deems necessary to facilitate its oversight of the accrediting organization's DMEPOS accreditation program. This information must be furnished to CMS within 3 business days of the request.

(iii) Within 2 calendar days of identifying an immediate jeopardy deficiency of a DMEPOS supplier, provide CMS with written notice of the deficiency and any adverse action implemented by the DMEPOS accrediting organization.

(2) *Standard or requirement changes.* Provide written notice of any proposed changes to its accreditation standards, requirements, or survey process. This includes the addition, modification, or removal of a new DMEPOS product service category to the list of categories for which the organization accredits DMEPOS suppliers.

(i) The notice must be submitted to CMS no less than 60 calendar days before the proposal's planned effective date. It must include the following:

(A) A detailed description of the changes and the rationale for them.

(B) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(ii) CMS communicates to the DMEPOS accrediting organization in writing its approval or disapproval of the proposal within 30 calendar days of the proposed change's effective date.

(iii) CMS approval is required before the DMEPOS accrediting organization can implement the change. If the organization implements the changes before or without CMS' approval, CMS may terminate its approval of the accrediting organization.

(3) *Addressing complaints.* (i) Upon receipt of a complaint—

(A) Notify CMS in writing of the complaint no later than 5 calendar days after receipt;

(B) Using the DMEPOS accrediting organization's policies and procedures described in paragraph (c)(1)(x) of this section, perform an initial review of the complaint to determine whether, based on the complaint and any other information, the DMEPOS supplier may be non-compliant with one or more DMEPOS quality standards or other applicable CMS requirement; and

(C) Perform a survey of the DMEPOS supplier if the DMEPOS accrediting organization's initial review concludes that such non-compliance may exist. This survey must be performed no later than 21 calendar days after the accrediting organization received the initial complaint.

(ii) No later than 10 calendar days after completing the action in, as applicable, paragraph (e)(3)(i)(B) or (C) of this section, notify CMS in writing of the result of the initial review or, as applicable, the survey. The notice must include information regarding any action the DMEPOS accrediting organization took or plans to take with respect to the DMEPOS supplier, such as a termination of accreditation or a CAP.

(4) *CAPs.* Notify CMS in writing of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include all of the following:

(i) The reason for the decision.

(ii) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.

(iii) The details of the DMEPOS supplier's CAP (for example, deadline for compliance, the DMEPOS accrediting organization's plans for enforcement and ensuring compliance).

(5) *Denials and terminations.* (i) Notify CMS in writing of any decision to deny accreditation to (or terminate, revoke, withdraw, or amend the accreditation of) a DMEPOS supplier within 5 calendar days of the decision. This notification must include the reason for the denial or termination.

(ii)(A) Notwithstanding any other provision in this section, the DMEPOS accrediting organization must deny accreditation to (or terminate the accreditation of) a DMEPOS supplier if—

(1) The supplier does not meet the licensure requirements in § 424.57(c)(1)(ii);

(2) The supplier is not operational (as that term is defined in § 424.502);

(3) The supplier's location does not meet the accessibility requirements in § 424.57(c)(7)(i)(B);

(4) The supplier's Medicare enrollment is revoked due to non-compliance with one or more DMEPOS quality standards and the reenrollment bar under 424.535(c) has not expired; or

(5) Directed by CMS.

(B) If paragraph (ii)(A)(5) of this paragraph applies, the DMEPOS

accrediting organization must do the following:

(1) Deny or terminate the DMEPOS supplier's accreditation no later than 3 business days after receiving written notice from CMS to do so.

(2) Notify CMS in writing that it has taken this action within 5 business days of receiving the written notice from CMS.

(6) *Provide an annual summary of data related to accreditation.* Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(7) *Notification of change from CMS.* (i) Within 30 calendar days of receipt of a written notice from CMS to the organization of a change in the quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes to the organization's requirements for its CMS-approved DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, or other requirements. This includes all of the following:

(A) An acknowledgment of CMS's notification of the change.

(B) A revised cross walk reflecting the new requirements.

(C) An explanation of how the DMEPOS accrediting organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification it received from CMS.

(ii) The DMEPOS accrediting organization must not implement its proposed corresponding changes without prior CMS approval.

(8) *Performance of surveys.* (i) Except as otherwise directed or permitted in writing by CMS (for example, allowing sampling), the DMEPOS accrediting organization must—

(A) Perform a survey of all DMEPOS supplier locations for which the supplier seeks accreditation or reaccreditation with the DMEPOS accrediting organization. This includes, but is not limited to, accreditations for a new item type the supplier has not previously furnished or as required under § 424.551;

(B) Perform all surveys as unannounced surveys; and

(C) Not accredit the DMEPOS supplier before the survey is performed and the DMEPOS accrediting organization determines that the supplier is compliant with the quality standards.

(ii) CMS may, at any time, direct the DMEPOS accrediting organization to perform a survey of an accredited DMEPOS supplier or a group thereof.

Existence of an actual or suspected supplier deficiency is not a requirement for CMS to direct the performance of a survey of a supplier.

(iii) When performing a survey, the DMEPOS accrediting organization must also confirm that the DMEPOS supplier meets the licensure requirements in § 424.57(c).

(9) *Surveyor witnesses.* Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(10) *Data entry.* If directed by CMS, enter accreditation, survey, product code, and other data into a CMS-designated system.

(11) *Relationships.* The DMEPOS accrediting organization, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, or any W-2 or contracted surveyor, health care, administrative, or management personnel thereof, must not have any of the following:

(i) A current exclusion by the OIG from Medicare, Medicaid, and any other Federal health care program.

(ii) A current debarment, suspension, or exclusion from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(iii) Within the preceding 10 years—

(A) A conviction of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

(B) A Medicare enrollment revocation under § 424.535;

(C) A suspension or revocation of a license to provide health care by any State licensing authority; or

(D) A suspension or termination from participating in a Federal or State health care program.

(f) *Continuing federal oversight of approved DMEPOS accrediting organizations.* CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis. Means of monitoring include, but are not limited to, the reviews identified in this paragraph.

(1) *Equivalency review.* CMS may, at any time, compare the DMEPOS accrediting organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes.

(2) *Validation survey of DMEPOS supplier.*

(i). *Survey scope.* CMS may survey suppliers of DMEPOS and other items and services accredited under this section in order to validate the DMEPOS accrediting organization's survey

process. Surveys can be comprehensive or focus on certain standards or requirements.

(ii) *Discovery of a deficiency.* If CMS discovers that a DMEPOS supplier is not in compliance with the DMEPOS supplier quality standards, CMS may revoke the supplier's enrollment or require the DMEPOS accrediting organization to perform a subsequent full accreditation survey at the accrediting organization's expense.

(iii) *Authorization.* A DMEPOS supplier selected for a validation survey must—

(A) Authorize the validation survey to take place; and

(B) Permit the CMS survey team to monitor the correction of any deficiencies found during the validation survey.

(iv) *Failure to authorize.* If a DMEPOS supplier selected for a validation survey fails to comply with the requirements of paragraph (f)(2)(iii) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its enrollment revoked.

(v) *Non-compliance.* If a validation survey results in a finding that the DMEPOS supplier is not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its enrollment revoked.

(3) *Deficiencies.* (i) With respect to DMEPOS supplier compliance with the quality standards, CMS has the discretion to do all of the following:

(A) Define the term *deficiency*.

(B) Establish levels and categories of deficiencies.

(C) Revise the quality standards.

(ii) In its DMEPOS accreditation activities, the DMEPOS accrediting organization must apply and adhere to all of the following:

(A) Any CMS-established definition of deficiency.

(B) All CMS-established levels and categories of deficiencies.

(C) All CMS-established quality standards.

(4) *Review of DMEPOS accrediting organization.*

(i)(A) CMS may at any time and for any reason conduct a review of the DMEPOS accrediting organization's processes or performance to:

(1) Verify the organization's representations to CMS; or

(2) Assess the organization's compliance with its own policies and procedures, the provisions of this section, and all other CMS requirements.

(B) The scope, length, and timing of the review are within CMS' discretion. Evidence of the DMEPOS accrediting

organization's potential non-compliance with any element addressed in paragraph (f)(4)(i)(A)(2) of this section is not a prerequisite for performing a review.

(ii) Types of CMS reviews include, but are not limited, the following, and may be performed collectively or individually:

(A) Equivalency reviews under paragraph (f)(1) of this section.

(B) Conducting surveys of accredited DMEPOS suppliers under paragraph (f)(2) of this section.

(C) Examining the results of a DMEPOS accrediting organization's surveys of DMEPOS suppliers.

(D) Observing a DMEPOS accrediting organization's onsite surveys and other audits of DMEPOS suppliers.

(E) Conducting onsite inspections of the DMEPOS accrediting organization's operations and offices.

(F) Requesting and reviewing documents.

(G) Interviewing DMEPOS accrediting organization staff.

(H) Observing an accreditation organization's internal meetings concerning the accreditation process.

(g) *Voluntary termination of CMS-approved DMEPOS accreditation program.* (1) *Timing.* A DMEPOS accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. In doing so, the accrediting organization must do all of the following:

(i) Notify CMS of its decision to voluntarily terminate its approved DMEPOS accreditation program at least 120 calendar days in advance of the effective date of the termination.

(ii) Provide written notice at least 90 days in advance of the effective date of the termination to each of its accredited DMEPOS suppliers but not before notifying CMS of its decision in accordance with paragraph (g)(1)(i) of this section. The notice to each supplier must do the following:

(A) Describe the provisions in paragraph (g)(2) of this section regarding the expiration dates of the DMEPOS supplier's accreditation with the terminating DMEPOS accrediting organization.

(B) Inform the DMEPOS supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminating DMEPOS accrediting organization expires and the effective date of its accreditation with a different accrediting organization) may result in the revocation of its enrollment under § 424.535.

(2) *Supplier continuation of accreditation.* Unless the DMEPOS

supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation, the supplier's accreditation with the terminating DMEPOS accrediting organization remains in effect until the earlier of the following:

(i) The expiration of its current term of accreditation with the terminating DMEPOS accrediting organization.

(ii) The effective date of its accreditation with a different CMS-approved DMEPOS accrediting organization.

(h) *Involuntary termination.*

(1)(i) *Reasons for termination.* CMS may terminate a DMEPOS accrediting organization's approval for any of the following reasons:

(A) CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(B) CMS determines that the continued approval of a CMS-approved DMEPOS accreditation program of any DMEPOS accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a hazard to the public health.

(C) CMS determines that the DMEPOS accrediting organization is non-compliant with any provision of this section. This includes, but is not limited to, situations where the accrediting organization has failed to do either of the following:

(1) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section.

(2) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its initial application or reapproval application or a CMS-approved change thereto under paragraph (e)(2) or (e)(7) of this section.

(D) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535(a) for failing to comply with the quality standards.

(ii) CMS may terminate the DMEPOS accrediting organization's DMEPOS accreditation program effective the date of the letter described in paragraph (h)(2) of this section or any date thereafter.

(2) *Notification to DMEPOS accrediting organization.* CMS notifies the DMEPOS accrediting organization in writing of its decision to terminate the organization's accreditation approval. The notice must include all of the following:

(i) The reason for the termination.

(ii) The effective date of the termination.

(3) *Announcement.* CMS announces its termination decision (and the effective date thereof) on its website.

(4) *Notification to DMEPOS suppliers.* A DMEPOS accrediting organization whose CMS approval of its DMEPOS accreditation program has been terminated must notify, in writing, each of its accredited DMEPOS suppliers of the termination of CMS approval and its implications no later than 30 calendar days after the CMS website announcement described in paragraph (h)(3) of this section. The notice to each DMEPOS supplier must do all of the following:

(i) Describe the provisions in paragraph (h)(6) of this section regarding the expiration dates of the DMEPOS supplier's accreditation with the terminated DMEPOS accrediting organization.

(ii) Inform the DMEPOS supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminated DMEPOS accrediting organization expires and the effective date of its accreditation with a different DMEPOS accrediting organization) results in the revocation of its enrollment under § 424.535.

(5) *Collaboration.* If CMS terminates a DMEPOS accrediting organization's approved status, the DMEPOS accrediting organization must work collaboratively with CMS to direct its accredited DMEPOS suppliers to the remaining CMS-approved DMEPOS accrediting organizations within a reasonable period of time.

(6) *Continued accreditation.* (i) Unless the DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation, the supplier's accreditation with the terminated DMEPOS accrediting organization remains in effect until the earliest of one of the following:

(A) The expiration of its current term of accreditation with the terminated DMEPOS accrediting organization.

(B) The effective date of its accreditation with a different CMS-approved DMEPOS accrediting organization.

(C) A date specified by CMS based on the circumstances of the termination of the DMEPOS accrediting organization's approval.

(ii) In the event paragraph (h)(6)(i)(C) of this section is applicable, CMS notifies the affected DMEPOS supplier in writing of the deadline by which the supplier must be reaccredited.

(7) *Refunds.* If CMS terminates a DMEPOS accrediting organization's approved status, the terminated organization must refund to a DMEPOS supplier all payments the supplier made to the organization—

(i) As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

(ii) Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

(i) *Suspension.* (1) *Reasons for suspension.* CMS may suspend a DMEPOS accrediting organization's approval for any of the following reasons:

(i) CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(ii) CMS determines that the DMEPOS accrediting organization is non-compliant with any provision of this section. This can include, but is not limited to, situations where the DMEPOS accrediting organization has failed to do either of the following:

(A) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section.

(B) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its initial application or reapproval application or a CMS-approved change thereto under paragraph (e)(2) or (e)(7) of this section.

(iii) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535 for failing to comply with the DMEPOS quality standards.

(2) *Components of a suspension.* (i) Except as otherwise specified or permitted by CMS, a DMEPOS accrediting organization may not perform any Medicare DMEPOS accreditation activities while suspended.

(ii) CMS determines the length of the suspension, which lasts no longer than 1 year. Upon the expiration of the suspension period, CMS either lifts the suspension or terminates the organization's approval in accordance with paragraph (h) of this section.

(iii) CMS may suspend the DMEPOS accrediting organization's DMEPOS accreditation program effective the date of the letter described in paragraph (i)(3) of this section or any date thereafter.

(3) *Notification to DMEPOS accrediting organization.* (i) CMS notifies the DMEPOS accrediting organization in writing of its decision to suspend the organization's accreditation

approval. The notice must include the following:

(A) The reason(s) for the suspension.

(B) The effective date and length of the suspension.

(C) The terms of the suspension.

(D) The steps the DMEPOS accrediting organization must take to have the suspension lifted.

(ii) No later than 3 calendar days after the date it receives the notice of suspension, the DMEPOS accrediting organization must notify CMS in writing its acknowledgment of receipt of such notice.

(iii) No later than 3 calendar days after receipt of such acknowledgment, CMS publishes on its website a notice of the organization's DMEPOS accreditation program.

(4) *Status of DMEPOS suppliers.* (i) The accreditation status of DMEPOS suppliers currently accredited by the suspended DMEPOS accrediting organization remains in effect through the length of the suspension unless—

(A) The DMEPOS supplier's current term of accreditation with the suspended DMEPOS accrediting organization expires during the suspension;

(B) The DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation; or

(C) CMS specifies a different accreditation termination date based on the circumstances of the suspension of the DMEPOS accrediting organization's DMEPOS accreditation program.

(ii)(A) If paragraph (i)(4)(i)(A) of this section applies, the DMEPOS supplier must be reaccredited by—

(1) Its current DMEPOS accrediting organization if the suspension has been lifted; or

(2) A different CMS-approved DMEPOS accrediting organization.

(B) If paragraph (i)(4)(i)(C) of this section applies, CMS notifies the affected DMEPOS supplier in writing of the deadline by which the supplier must be reaccredited.

(iii) Any lapse in the DMEPOS supplier's accreditation (including between the date its existing accreditation with the suspended DMEPOS accrediting organization expires and the effective date of its accreditation with a different accrediting organization) may result in the revocation of its enrollment under § 424.535(a).

(5) *Lifting of suspension.* (i) CMS lifts a DMEPOS accrediting organization's suspension if it determines all of the following:

(A) The reasons for the suspension no longer exist.

(B) The DMEPOS accrediting organization demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(C) The DMEPOS accrediting organization is in compliance with all provisions of this section.

(ii) If the suspension is lifted:

(A) CMS notifies the DMEPOS accrediting organization thereof in writing.

(B) No later than 3 calendar days after the date it receives the notice described in paragraph (i)(3)(iv)(A) of this section, the DMEPOS accrediting organization must notify CMS in writing its acknowledgment of receipt of such notice.

(C) No later than 3 calendar days after receipt of such acknowledgment, CMS publishes on its website a notice of the lifting of the suspension.

(6) *Refunds.* If CMS suspends a DMEPOS accrediting organization's DMEPOS accreditation program, the accrediting organization must refund to a DMEPOS supplier all payments the supplier made to the organization—

(i) As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

(ii) Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

(7) *Multiple suspensions.* Nothing in this paragraph (i) prohibits CMS from suspending the organization's DMEPOS accreditation program more than once.

(j) *Probation.* (1) *Placement on probation.* CMS may place a DMEPOS accrediting organization's DMEPOS accreditation program on probation and require the organization's successful completion of a corrective action plan (CAP) if CMS determines any of the following:

(i) The DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(ii) The DMEPOS accrediting organization is non-compliant with any provision of this section. This can include, but is not limited to, situations where the accrediting organization has failed to—

(A) Comply with a term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or

(B) Adhere to a policy, procedure, or practice it outlined under § 424.58(c) as part of its—

(1) Initial or reapproval application; or

(2) A CMS-approved change thereto under paragraph (e)(2) or (e)(7) of this section.

(iii) There is a pattern or practice of the DMEPOS accrediting organization's

accredited DMEPOS suppliers being revoked under § 424.535(a) for failing to comply with the quality standards.

(iv) The DMEPOS organization's period of suspension under paragraph (i) of this section has expired and CMS determines that a subsequent probationary period and CAP are warranted.

(2) *Notification to accrediting organization.* (i) CMS notifies the DMEPOS accrediting organization in writing of the probation. The notice must include the following:

(A) The reason(s) for CMS' decision.

(B) The length of the probationary period, which must not exceed 1 year.

(C) The terms of the CAP.

(D) The requirements and deadline for achieving compliance.

(E) A description of how CMS will monitor the DMEPOS accrediting organization's efforts to resume compliance (for example, requests for information, surveys).

(ii) Except as otherwise prescribed in the CAP, the DMEPOS accrediting organization may continue its accreditation activities as normal.

(3) *Conclusion of period.* (i) At the conclusion of the probationary period, CMS notifies the DMEPOS accrediting organization in writing of the following:

(A) Whether the DMEPOS accrediting organization is compliant with all requirements of this section.

(B) The reason for the determination in paragraph (j)(3)(i)(A) of this section.

(C) The consequences of the determination (for example, termination or suspension of accreditation, successful completion of and cessation of the probationary period and CAP).

(ii) If CMS determines that the DMEPOS accrediting organization has resumed compliance with all requirements of this section, CMS may do all of the following:

(A) Send the notice described in paragraph (j)(3)(i) of this section.

(B) Terminate the probationary period.

(C) End the CAP before the conclusion of the assigned probationary period.

(k) *Noncompliance actions.* (1) CMS may impose a certain action in paragraph (h), (i), or (j) of this section in lieu of another such action specified in paragraph (h), (i), or (j) of this section if the same ground(s) for the action exists.

(2) CMS may terminate—

(i) A probation period (either before or in accordance with the probationary period's original expiration date) and impose a suspension or termination if grounds for either action exist.

(ii) A suspension (either before or in accordance with the suspension's original expiration date) and impose a termination if a basis for doing so exists.

(l) *Reconsiderations and rebuttals.*

(1) *Reconsiderations.* (i) A DMEPOS accrediting organization may request a reconsideration under part 498 of the following CMS initial determinations identified in § 498.3(b)(21) and (22):

(A) Denial of the DMEPOS accrediting organization's application for initial approval of its DMEPOS accreditation program under § 424.58(c)(4).

(B) Denial of the DMEPOS accrediting organization's application for reapproval of its DMEPOS accreditation program under § 424.58(d)(4).

(C) Termination of the DMEPOS accrediting organization's approval of its DMEPOS accreditation program under § 424.58(h)(1).

(2) *Rebuttals.* (i)(A) If a DMEPOS accrediting organization receives notice from CMS that its DMEPOS accreditation program has been suspended or placed on probation in accordance with paragraph (i) or (j) of this section, the DMEPOS accrediting organization has 15 calendar days from the date of the written notice of the suspension or probation to submit a rebuttal to CMS.

(B) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (l)(2)(i)(A) of this section.

(ii) A rebuttal submitted under this section must—

(A) Be in writing;

(B) Specify the facts or issues about which the DMEPOS accrediting organization disagrees with CMS' determination, as well as the reasons for disagreement;

(C) Submit all documentation the DMEPOS accrediting organization wants CMS to consider in its review of its determination; and

(D) Be submitted in the form of a letter that is signed and dated by the DMEPOS accrediting organization's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative (as defined in § 498.10 of this chapter).

(1) If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the accrediting organization; this statement would be sufficient to constitute notice of such authority.

(2) If the legal representative is not an attorney, the accrediting organization must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the accrediting organization's CEO (or similar official with authority to commit the organization to adhere to Medicare

laws and regulations) or a legal representative.

(iii) The DMEPOS accrediting organization's failure to submit a rebuttal that is both timely under paragraph (l)(2)(i) of this section and fully compliant with all of the requirements of paragraph (l)(2)(ii) of this section constitutes a waiver of all rebuttal rights under this section.

(iv) Upon receipt of a timely and compliant rebuttal, CMS reviews the rebuttal to determine whether the imposition of the suspension or probation is correct.

(v) CMS is not required to delay the imposition of the suspension or probation pending the completion of the CMS review described in paragraph (l)(2)(iv) of this section.

(vi) A determination made under paragraph (i) or (j) of this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

(m) *Restrictions on consulting.* (1) *Definition.* For purposes of this paragraph (m) only, the terms *consulting* and *consulting services* mean those services provided by a DMEPOS accrediting organization (or its consulting division or separate business entity (such as a company or corporation) that provides such services) for the review of a DMEPOS supplier's standards, processes, policies, and functions for compliance with the accrediting organization's standards, the DMEPOS quality standards, or other Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey.

(2) *Prohibitions.* Except as provided in paragraph (m)(3) of this section, an accrediting organization or its consulting division or separate business entity (such as a company or corporation that provides consulting) may not provide consulting services in the following instances:

(i) To any new DMEPOS supplier before the initial accreditation survey has been completed.

(A) For purposes of this paragraph, the term "initial survey" means the first accreditation survey performed of a supplier by a DMEPOS accrediting organization that has not previously received accreditation services from that accrediting organization.

(B) If a supplier is voluntarily or involuntarily terminated from the services of a DMEPOS accrediting organization and later retains the services of the same or a new DMEPOS

accrediting organization, the first accreditation survey performed by the same or new DMEPOS accrediting organization of that supplier would be considered an initial accreditation survey.

(ii) To a DMEPOS supplier that the DMEPOS accrediting organization accredits within 6 months prior to the next scheduled re-accreditation survey of that supplier. For purposes of this paragraph, the term “re-accreditation survey” means any subsequent accreditation survey performed by the accrediting organization following the initial survey.

(iii) To a DMEPOS supplier to which the DMEPOS accrediting organization provides accreditation services, in response to a complaint received by the accrediting organization regarding that supplier.

(3) *Circumstances permitting consulting.* A DMEPOS accrediting organization, its consulting division, or separate business entity, such as a company or corporation that provides consulting, may provide consulting to the DMEPOS suppliers it accredits only under the following circumstances:

(i) During the 6-month period after an initial or re-accreditation survey is performed.

(ii) To address complaints received and investigated by CMS or its contractor regarding a DMEPOS accrediting organization’s accredited DMEPOS supplier in which one or more immediate jeopardy deficiencies or grounds for revocation of enrollment under § 424.535 are identified. Such consulting by an accrediting organization may occur only after CMS or the CMS contractor investigation is completed and must only address those issues identified in the investigation.

(iii) Consulting services provided to DMEPOS suppliers that the DMEPOS accrediting organization does not accredit at the time the consulting services are furnished.

(iv) General education provided by the DMEPOS accrediting organization about its DMEPOS accreditation program.

(4) *Submission of report.* The DMEPOS accrediting organization must provide to CMS upon CMS’ request and with each initial and reapproval application under paragraphs (c) and (d) of this section a report containing the following information:

(i) Whether the DMEPOS accrediting organization or an associated consulting division or company established by the accrediting organization provides consulting services.

(ii) The names, National Provider Identifiers, and addresses of all

DMEPOS suppliers to which the DMEPOS accrediting organization or its associated consulting division or company has provided consulting services during the previous 6-month period.

(iii) The dates the consulting services were provided to each DMEPOS supplier.

(iv) Whether the DMEPOS accrediting organization has ever provided, or is currently providing, accreditation services to any DMEPOS supplier listed in this report.

(v) For each DMEPOS supplier listed in this report, the date—

(A) Of the most recent accreditation survey performed; and

(B) That the next re-accreditation survey is due to be performed.

(vi) A description of the consulting services provided to each DMEPOS supplier listed in this report.

(5) *Consulting firewall policies and procedures.* (i) A DMEPOS accrediting organization, its consulting division, or separate business entity (such as a company or corporation that provides consulting services to the DMEPOS suppliers the accrediting organization accredits) must have and adhere to written consulting policies and procedures, which, at a minimum, must include the following:

(A) The DMEPOS accrediting organization’s consulting services must be provided by a separate division of the accrediting organization or separate business entity, such as a company or corporation, that is separate from the accrediting organization’s accreditation division.

(B) A DMEPOS accrediting organization’s consulting division or separate business entity must maintain separate staff from that of the accrediting organization’s accreditation divisions to ensure that the consulting division staff do not perform the accrediting organization’s accreditation division functions and that the accrediting organization’s accreditation division staff do not perform consulting division functions.

(C) A DMEPOS accrediting organization’s accreditation staff and surveyors are prohibited from marketing the accrediting organization’s consulting services to the accrediting organization’s accreditation clients.

(ii) A DMEPOS accrediting organization that provides consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application submitted seeking initial CMS approval or reapproval of their DMEPOS accreditation programs.

(n) *Conflicts of interest.*

(1) *General prohibition regarding relationships.* (i) If a DMEPOS

accrediting organization owner, surveyor, or employee (currently or within the previous 2 years) has or had an interest in or relationship (as described in paragraph (c)(1)(vii)(D) of this section) with a DMEPOS supplier that is accredited by the DMEPOS accrediting organization, the accrediting organization owner, surveyor, or employee is not permitted to do any of the following:

(A) Participate in the survey of that DMEPOS supplier.

(B) Have input into the results of the survey and accreditation for that DMEPOS supplier.

(C) Have involvement with the pre- or post-survey activities for that DMEPOS supplier.

(D) Have contact with or access to the records for the survey and accreditation of that DMEPOS supplier.

(ii) For purposes of paragraph (n)(1) of this section, the term “immediate family member” has the same meaning as that term is defined in paragraph (b) of this section.

(iii) CMS may request at any time outside of the initial approval and reapproval processes that the DMEPOS accrediting organization furnish any and all information required under paragraph (c)(1)(vii)(D) of this section.

(2) An entity may not serve as a CMS-approved DMEPOS accrediting organization if it is currently a CMS contractor (or an owner or subsidiary thereof (regardless of the ownership percentage involved)) with any oversight responsibility of DMEPOS suppliers.

(o) *Change of ownership.* A DMEPOS accrediting organization that wishes to undergo a change of ownership is subject to the requirements of § 488.5(f).

* * * * *

§ 424.205 [Amended]

■ 15. Section 424.205 is amended by—

■ a. In paragraph (a) in the definition of “Coach eligibility end date”, removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”.

■ b. In paragraph (b)(4), removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”.

■ c. In paragraph (b)(6), removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;

■ d. In paragraph (c)(3),

■ i. Removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”;

■ ii. Removing the phrase “paragraph (e)(1)” and adding in its place the phrase “paragraph (d)(1)”;

■ e. In paragraph (c)(6), removing the phrase “paragraph (d)(4)” and adding in its place the phrase “paragraph (c)(4)”;

■ f. In paragraph (c)(8), removing the phrase “paragraph (d)(8)(i)” and adding in its place the phrase “paragraph (c)(8)(i)”;

■ g. In paragraph (c)(8)(ii),

■ i. Removing the phrase “paragraph (d)(8)(i)(B)” and adding in its place the phrase “paragraph (c)(8)(i)(B)”;

■ ii. Removing the phrase “paragraph (d)(8)(i)(C)” and adding in its place the phrase “paragraph (c)(8)(i)(C)”;

■ h. In paragraph (c)(10), removing the phrase “paragraph (d)(8)” and adding in its place the phrase “paragraph (c)(8)”;

■ i. In paragraph (c)(11)(iii), removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;

■ j. In paragraph (c)(12), removing the phrase “paragraph (g)” and adding in its place the phrase “paragraph (f)”;

■ k. In paragraph (c)(15), removing the phrase “paragraph (g)” and adding in its place the phrase “paragraph (f)”;

■ l. In paragraph (d)(2),

■ i. Removing the phrase “paragraph (e)(1)” and adding in its place the phrase “paragraph (d)(1)”, and

■ ii. Removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”;

■ m. In paragraph (g)(1),

■ i. Removing the phrase “§ 424.530(a)(1)” and adding in its place adding “§ 424.530(a)(1) or § 424.530(a)(18)” each time it appears;

■ ii. Removing the phrase “§ 424.535(a)(1)” and adding in its place adding “§ 424.535(a)(1) or § 424.535(a)(23)” each time it appears;

■ n. In paragraph (g)(1)(i), removing the phrase “paragraph (h)(1)(i)” and adding in its place the phrase “paragraph (g)(1)(i)” each time it appears;

■ o. In paragraph (g)(1)(ii),

■ i. Removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;

■ ii. Removing the phrase “paragraph (h)(1)(ii)” and adding in its place the phrase “paragraph (g)(1)(ii)” each time it appears;

■ p. In paragraph (g)(1)(v)(A), removing the reference “§ 424.205(d)(3)” and adding in its place the reference “§ 424.205(c)(3)”;

■ q. In paragraph (g)(1)(v)(B), removing the phrase “paragraph (h)(1)(v)” and adding in its place the phrase “paragraph (g)(1)(v)” each time it appears.

■ X. Section 424.502 is amended by revising the definition of “Deactivate” to read as follows:

■ X. Section 424.502 is amended by revising the definition of “Deactivate” to read as follows:

■ X. Section 424.502 is amended by revising the definition of “Deactivate” to read as follows:

§ 424.502 Definitions.

* * * * *

Deactivate means, except in the situations described in § 424.547, that the provider or supplier’s billing privileges were stopped, but can be restored upon the submission of updated information.

* * * * *

■ 16. Section 424.510 is amended by—

■ a. In paragraph (d)(2)(iii) introductory text removing the phrase “including—” and adding in its place the phrase “including the following:”;

■ b. In paragraph (d)(2)(iii)(A) removing the phrase “; and” and adding in its place “.”; and

■ c. Adding paragraphs (d)(2)(iii)(C) and (d)(10).

The additions read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(C) Any other documentation needed to verify and confirm the information furnished on the enrollment application. This includes, but is not limited to, documentation regarding the provider’s or supplier’s ownership or management.

* * * * *

(10) All providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application.

* * * * *

■ 17. Section 424.516 is amended by revising paragraph (e)(1) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(e) * * *

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)), an adverse legal action, or a change, addition, or deletion of a practice location.

* * * * *

■ 18. Section 424.522 is amended by revising paragraph (a) to read as follows:

§ 424.522 Additional effective dates.

(a)(1) The effective date of a reassignment of benefits under § 424.80 is the later of the dates identified in § 424.520(d)(1)(i) and (ii).

(2) Retrospective billing in accordance with a reassignment of benefits and as described in § 424.521(a)(1) is

permissible if the circumstances in § 424.521(a)(1) are applicable.

* * * * *

§ 424.530 [Amended]

■ 19. Section 424.530 is amended by—

■ a. In paragraph (a)(11)(ii), removing the word “drugs” and adding in its place the phrase “one or more drugs”;

■ b. In paragraph (a)(18)(v), removing the phrase “or (d)” and adding in its place the phrase “or (c)”.

■ 20. Section 424.535 is amended by—

■ a. In paragraph (a)(13)(ii), removing the word “drugs” and adding in its place the phrase “one or more drugs”;

■ b. In paragraph (a)(14) introductory text, removing the phrase “Part B or D drugs” and adding in its place the phrase “Medicare-covered drugs”;

■ c. In paragraph (a)(23)(v), removing the phrase “or (d)” and adding in its place the phrase “or (c)”;

■ d. Adding paragraphs (a)(8)(i)(D) and (8)(iii);

■ e. Revising paragraph (g)(1) introductory text;

■ f. Redesignating paragraph (g)(2)(viii) as paragraph (g)(2)(xv);

■ g. Adding new paragraphs (g)(2)(viii) through (xiv).

■ h. Revising newly redesignated paragraph (g)(2)(xv)(D);

The revisions and additions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

* * * * *

(a) * * *

(8) * * *

(i) * * *

(D) The beneficiary attests that the item(s) or service(s) identified on the provider’s or supplier’s claim or claims was not or were not rendered or furnished.

* * * * *

(iii) The effective date of a revocation under paragraph (a)(8) of this section is—

(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; and

(B) For revocations under paragraph (a)(8)(ii), the last date of service on the claims in question.

* * * * *

(g)(1) Except as described in paragraphs (a)(8)(iii), (g)(2), and (3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

* * * * *

(2) * * *

(viii) For revocations based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6), the date the insurance lapsed.

(ix) For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application's certification statement was signed.

(x) For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, the day after the date by which the provider or supplier was required to report the change, addition, or deletion.

(xi) For revocations based on the surrender of the provider's or supplier's provider's Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.

(xii) For revocations based on a State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs, the date of the suspension or revocation.

(xiii) For revocations of any of the provider's or supplier's other enrollments under paragraph (i) of this section, the effective date of the revocation that triggered the revocation(s) of the other enrollment(s).

(xiv) For revocations based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c), respectively, the date on which the non-compliance began.

(xv) * * *

(D) For all standard violations not addressed in paragraph (g)(2) of this section, the effective date in paragraph (g)(1) of this section applies if the effective date in paragraph (g)(3) of this section does not.

* * * * *

§ 424.540 [Amended]

■ 21. Section 424.540 is amended in paragraph (a)(8) by removing the phrase "HHA change" and adding in its place the phrase "HHA, hospice, or DMEPOS supplier change".

■ 22. Section 424.541 is amended by—

■ a. In paragraph (a)(5), removing the phrase "60-day period" and adding in its place the phrase "CMS-assigned stay period"; and

■ b. Revising paragraphs (a)(1)(i), (a)(2)(ii)(B)(2), and (3).

The revisions read as follows:

§ 424.541 Stay of enrollment.

(a) * * *

(1) * * *

(i) Is non-compliant with at least one enrollment requirement in Title 42.

(This includes situations where its change of information or revalidation application was rejected under § 424.525(a)(1) or (2).)

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(2) The stay ends (as described in paragraph (a)(5) of this section) on or before the expiration of the originally designated stay period.

* * * * *

(3)(i) The effective date of a stay of enrollment is, as applicable—

(A) The date on which the provider's or supplier's non-compliance began; or

(B) The date on which the provider's or supplier's change of information or revalidation application was rejected under § 424.525.

(ii) CMS may establish a stay of enrollment for any period up to a maximum of 60 days.

* * * * *

■ 23. Adding § 424.547 to read as follows:

§ 424.547 Deactivation based on ordering, certifying, or referring services and items.

(a)(1) CMS may deactivate a physician's or practitioner's ability to order, certify, or refer the Medicare services and items identified in § 424.507(a) and (b) if the individual:

(i) Is enrolled via the Form CMS–855O application solely to order, certify, or refer Medicare services or items; and

(ii) Has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive months.

(2) For purposes of this section only, the term "deactivate" means that the physician's or practitioner's ability to order, certify, or refer Medicare services or items has been stopped but can be restored upon the submission of updated information.

(b)(1) For a deactivated physician or practitioner to reactivate an ability to order, certify, or refer Medicare services and items, the individual must recertify that the enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

(2) Notwithstanding paragraph (b)(1) of this section, CMS may, for any reason, require a deactivated physician or practitioner to, as a prerequisite for reactivating the ability to order, certify, or refer, submit a complete Form CMS–855O application.

(c) The effective date of a reactivation of an ability to order, certify, or refer

Medicare services and items under this section is the date on which the Medicare contractor received the individual's reactivation submission that was processed to approval.

(d) A physician or practitioner may not order, certify, or refer the Medicare services or items described in § 424.507(a) and (b) while deactivated under this section.

■ 24. Adding § 424.551 to read as follows:

(a) *Definition.* For purposes of this section only, a *change in majority ownership* occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a DMEPOS supplier during the 36 months following the DMEPOS supplier's initial enrollment into the Medicare program or the 36 months following the DMEPOS supplier's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in a DMEPOS supplier through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the DMEPOS supplier's most recent change in majority ownership.

(b) *General principle.* Unless an exception in paragraph (c) of this section applies, if there is a change in majority ownership of a DMEPOS supplier by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the DMEPOS supplier's initial enrollment in Medicare or within 36 months after the DMEPOS supplier's most recent change in majority ownership, the Medicare billing privileges do not convey to the new owner. The prospective owner of the DMEPOS supplier must instead do both of the following:

(i) Enroll in the Medicare program as a new DMEPOS supplier under the provisions of § 424.510.

(ii) Undergo a survey by, and obtain a new accreditation from, a CMS-approved DMEPOS accrediting organization in accordance with §§ 424.57 and 424.58.

(c) *Exceptions.* The following situations are exceptions to the requirements of paragraph (b) of this section:

(i) A DMEPOS supplier's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(ii) The owners of the existing DMEPOS supplier are changing the

DMEPOS supplier's current business structure (for example, from a corporation to a partnership (general or limited); from a limited liability company (LLC) to a corporation; or from a general or limited to an LLC) and the owners remain the same.

(iii) An individual owner of the DMEPOS supplier dies.

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 25. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

§ 455.416 [Amended]

■ 26. Section 455.416 is amended in paragraph (c) by removing the phrase “of the *Act* and under the” and adding in its place the phrase “of the *Act* or under the”.

PART 484—HOME HEALTH SERVICES

■ 27. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C 1302 and 1395hh.

§ 484.45 [Amended]

■ 28. Section 484.45 is amended in paragraph (a) by removing the word “beneficiary” and adding in its place the word “patient”, each time it appears.

§ 484.55 [Amended]

■ 29. Section 484.55 is amended in paragraph (d)(1)(i) by removing the phrase “Beneficiary elected transfer;” and adding in its place the phrase “Elected transfer;”.

■ 30. Section 484.245 is amended by revising paragraph (d)(4) and adding paragraphs (d)(5) and (6) to read as follows:

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

* * * * *

(d) * * *

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

(A) CMS designated data submission system.

(B) The United States Postal Service.

(C) Email from the CMS Medicare Administrative Contractor (MAC).

(ii) CMS grants a timely request for reconsideration, and reverses an initial finding of non-compliance, only if CMS determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year.

(6)(i) An HHA may request, and CMS may grant, an extension to file a reconsideration request if, during the period to request a reconsideration as set forth in paragraph (d)(2) of this section, the HHA was affected by an extraordinary circumstance beyond the control of the HHA (for example, a natural or man-made disaster).

(ii) HHAs must submit the reconsideration extension request no later than 30 calendar days from the date of the written notification of noncompliance.

(iii) The reconsideration extension request must—

(A) Be submitted to CMS via email to CMS HHAPU reconsiderations at HHAPUReconsiderations@cms.hhs.gov; and

(B) Contain all the following information:

(1) The CCN for the HHA

(2) The business name of the HHA.

(3) The business address of the HHA.

(4) Contact information for the HHA's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address, which may not be a post office box.

(5) A statement of the reason for the request for the extension.

(6) Evidence of the impact of extraordinary circumstances, including, for example, photographs, newspaper articles, and other media.

(6) CMS notifies the HHA in writing of its final decision regarding the HHA's request for an extension to file a reconsideration of noncompliance request via an email from CMS.

* * * * *

■ 31. Section 484.358 is amended by adding paragraph (i) to read as follows:

§ 484.358 HHVBP Measure removal factors.

* * * * *

(i) It is not feasible to implement the measure specifications.

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

■ 32. The authority for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

■ 33. Section 498.3 is amended by adding paragraphs (b)(21) and (22) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(21) A denial of a DMEPOS accrediting organization's approval or re-approval under § 424.58(c)(4) or (d)(4) of this chapter, respectively.

(22) An involuntary termination of a DMEPOS accrediting organization's approved DMEPOS accreditation program under § 424.58(h)(1).

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025-12347 Filed 6-30-25; 4:15 pm]

BILLING CODE 4120-01-P