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

(CMS-1828-F)

Summary of Final Rule

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I. Introduction

On December 2, 2025, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register (90 FR 55342) a final rule that updates the payment rates for home health agencies (HHAs) for calendar year 2026.[1] This rule also include policies related to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP), DMEPOS supplier conditions of payment, provider and supplier enrollment requirements, and changes to DMEPOS accreditation requirement, among other issues.

CMS also finalizes, with modifications, a permanent prospective adjustment and a temporary adjustment to the 2026 home health payment rate to account for the ongoing impact of the implementation of the Patient Driven Groupings Model (PDGM). These adjustments account for any changes to the base payment rate and increases or decreases in aggregate expenditures resulting from the difference between assumed behavior changes and actual behavior changes, due to implementation of the PDGM and 30-day unit of payment. CMS modified and lowered the permanent adjustment from its proposal after commenters raised concerns that behavior change after 2022 might be attributable to factors unrelated to the implementation of the PDGM, such as the introduction of the Outcome and Assessment Information Set OASIS-E assessment; expansion of home health value-based purchasing; and increased Medicare Advantage penetration.

For the Home Health Quality Reporting Program (HH QRP), CMS finalizes its proposals, including its proposals to remove the COVID-19 Vaccine measure, remove four assessment

[1] Henceforth in this document, a year is a calendar year unless otherwise specified.

items in the standardized patient assessment, and implement a revised HHCAHPS Survey. CMS also summarizes feedback it received in response to its Requests for Information (RFI) on (i) changing the final data submission deadline from 4.5 months to 45 days, (ii) digital quality measurement (DQM) transition for HHAs, (iii) the current adoption of health information technology and standards, and (iv) future HH QRP quality measure concepts of interoperability, cognitive function, nutrition, and patient well-being.

For the Expanded Home Health Value-Based Purchasing (HHVBP) Model, CMS finalizes its proposals (i) for an additional measure removal factor, (ii) to modify the expanded HHVBP Model measure set by, beginning in 2026, removing three HHCAHPS survey-based measures and adding four measures, and (iii) to update individual measure weights and category weights. The agency also summarizes comments it received in response to RFI on future measure concepts.

For the DMEPOS CBP program, CMS is implementing certain regulatory changes to the program for preparation of a new round of competitive bidding. These changes include changing the way payment amounts are determined and the number of contracts awarded; establishing bid limits and conditions for awarding contracts if savings are not expected; revising the definition of "item" as related to medical supplies to include ostomy and urological supplies; establishing a remote item delivery (RID) CBP that could furnish remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the competitive bidding area (could be nationwide); and reclassifying all continuous glucose monitors (CGMs) and insulin infusion pumps under the frequently and substantial servicing payment category, which will allow replacement of devices more often than 5 years, among other issues.

CMS also announced as part of its DMEPOS fact sheet the timeline for the new round of competitive bidding which is expected to start no later than January 1, 2028.[2] CMS also announced the following seven product categories, all of which will be part of remote item delivery: (1) Class II CGMs and insulin pumps, (2) urological supplies, (3) ostomy supplies, (4) hydrophilic urinary catheters, (5) Off-the-Shelf (OTS) back braces, (6) OTS knee braces, and OTS upper extremity braces.

CMS estimates that the net impact of the home health final rule policies will decrease Medicare payments to home health agencies (HHAs) in 2026 by 1.3 percent (-$220 million). This decrease reflects the effects of the +2.4 percent home health payment update, an estimated -0.9 percent decrease from the permanent adjustment of -1.023 percent, an estimated -2.7 percent decrease from the temporary adjustment of 3.0 percent, and an estimated -0.1 percent decrease from the update to the fixed-dollar loss ratio (FDL) used in determining outlier payments.[3]

[2] CMS made this announcement on November 28, 2025. The fact sheet can be found at Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program – Updates and Important Information | CMS

[3] CMS finalizes a permanent adjustment of -1.023 percent and a temporary adjustment of -3.0 percent which applies only to the national, standardized 30-day period payments and does not impact payments for 30-day periods that are low-utilization payment adjustments. The estimated -0.9 percent for the permanent adjustment and the -2.7 percent for the temporary adjustment includes all payments.

II. Home Health Prospective Payment System

A. Overview

CMS reviews the statutory and regulatory history of the HH PPS from 1997. As required by the Bipartisan Budget Act of 2018 (BBA of 2018) on January 1, 2020, CMS implemented the home health Patient Driven Groupings Model (PDGM) and a 30-day unit of payment. Most recently in 2024, as required by the Consolidated Appropriations Act, 2023 (CAA, 2023), CMS established separate payment for the device used in furnishing negative pressure wound therapy (NPWT) (not for nursing and therapy services as these are already included under the HH PPS).

Medicare makes payment under the HH PPS based on a national, standardized 30-day period payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 30-day period rate includes the six home health disciplines—skilled nursing (SN), home health aide, physical therapy (PT), speech-language pathology (SLP), occupational therapy (OT), and medical social services (MSS). Payment for non-routine supplies (NRS), previously paid through a separate adjustment, are now part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service is not included in the national, standardized 30-day period payment. The 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and NPWT using a disposable device; these drugs and services must be billed by the HHA while a patient is under a home health plan of care.

The PDGM is a patient case-mix adjustment methodology that shifts the focus from volume of services to a model that relies more on patient characteristics. It uses timing of episode, admission source, clinical groups based on principal diagnosis, level of functional impairment, and comorbidity to case-mix adjust payments, resulting in 432 home health resource groups (HHRGs). Patient characteristics and other clinical information are drawn from Medicare claims and the Outcome and Assessment Information Set (OASIS). Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care.

For low-utilization episodes, HHAs are paid national per-visit rates based on the discipline(s) providing the services; this payment adjustment is referred to as a low-utilization payment adjustment (LUPA). The national, standardized 30-day episode payment rate is also adjusted for certain intervening events that trigger a partial episode payment (PEP) adjustment. In addition, an outlier adjustment may be available for certain cases that exceed a specific cost threshold.

B. Monitoring the Effects of the Implementation of PDGM

1. Routine PDGM Monitoring

Section 1895(b)(3)(D) of the Act requires CMS to annually determine the impact of assumed versus actual behavioral changes on aggregate expenditures under the HH PPS for 2020 through 2026. Analysis for routine monitoring may include analyzing overall total 30-day periods of care and average periods of care per HH user; the distribution of visits in a 30-day period of care; the percentage of periods that receive a LUPA; the percentage of 30-day periods of care by clinical

group, comorbidity adjustment, admission source, timing, and functional impairment level; and the proportion of 30-day periods of care with and without any therapy visits.

In the proposed rule, CMS examined simulated data for 2018 and 2019 and actual data for 2020, 2021, 2022, 2023, and 2024 for 30-day periods of care. CMS referred readers to the 2022 HH PPS final rule[4] for a discussion about the simulated data for 2018 and 2019. Commenters noted that a decline in utilization is not necessarily related to a reduced need for home health services. CMS states in response to comments that it will continue to monitor and analyze home health trends and vulnerabilities with the HH PPS.

C. 2026 Payment Adjustments Under the HH PPS

1. Behavior Assumption Adjustments under the HH PPS

a. Background

As directed by section 1895(b)(2)(B) of the Act, beginning in 2020, CMS adopted a 30-day period of home health service, replacing the previous 60-day period. Section 1895(b)(4)(B) of the Act further required CMS to eliminate use of therapy thresholds in assigning an episode to a case mix adjusted payment group. For 2020, section 1895(b)(3)(A)(iv) of the Act required CMS to adopt the change to a 30-day episode of care as budget neutral taking into account behavior changes from the new period of service and eliminating the use of therapy thresholds to assign a case to a payment group.

Section 1895(b)(3)(A)(iv) of the Act requires CMS to make a prospective adjustment for 2020 to maintain budget neutrality, while section 1895(b)(3)(D)(i) of the Act requires CMS to revisit the adjustment retrospectively for each year beginning with 2020 and ending with 2026. If CMS' retrospective review reveals that behavioral changes were different than assumed in the prospective adjustment, CMS is required to make both permanent and temporary adjustments to the home health rate to ensure aggregate spending neither increased nor decreased as a result of the new unit of payment and elimination of therapy thresholds. The temporary adjustment is made to either recoup past overspending or repay past underspending, while the permanent adjustment ensures that future spending neither increases nor decreases relative to continuing the prior policies.

CMS applied a prospective budget neutrality adjustment including its behavior assumption of -4.36 percent when setting the 2020 30-day payment rate of $1,864.03. CMS did not propose any changes for 2021 and 2022 relating to the behavior assumptions.

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 2020-2026, the datasets underlying the simulated 60-day episodes, and the opportunity for stakeholder input. CMS complied with these requirements by posting online the supplemental LDS and descriptive

[4] 86 FR 35881

files and the description of actual behavior changes that affected the 2023 payment rate development. CMS also conducted a webinar on these issues on March 29, 2023.[5]

b. Methodology

In the 2023 HH PPS final rule, CMS finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures. For 2020 through 2026, CMS evaluates whether the 30-day budget neutrality payment rate and resulting aggregate expenditures are equal under the PDGM to what they would have been under the 153-group case-mix system and 60-day unit of payment. In the 2024 HH PPS final rule, CMS provided an overview of the methodology and detailed instructions on each of the following steps:

- Create simulated 60-day episodes from 30-day periods;
- Price out the simulated 60-day episodes and determine aggregate expenditures;
- Price out only the 30-day periods which were used to create the simulated 60-day episodes and determine aggregate expenditures;
- Compare aggregate expenditures between the simulated 60-day episodes and actual 30-day periods; and
- Determine what the 30-day payment rate should have been to equal aggregate expenditures.

Due to an update of the OASIS instrument, in the 2025 HH PPS final rule CMS updated two methodological assumptions related to mapping and imputation of OASIS-D responses from OASIS-E. CMS refers reader to the 2024 and 2025 HH PPS final rules for further information about the methodology.

c. Calculating Permanent and Temporary Payment Adjustments

To calculate a permanent prospective adjustment, CMS determines what the 30-day base payment amount should have been in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. This is the recalculated base payment rate. The percent change between the actual 30-day base payment rate and the recalculated 30-day base payment rate would be the permanent prospective adjustment.

To calculate a temporary retrospective adjustment for each year, CMS determines the dollar amount difference between the following:

- Estimated aggregate expenditures from 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 the same year.

The temporary adjustment is applied on a prospective basis and applies only with respect to the year for which such temporary increase or decrease is made. CMS refers readers to the 2024 HH

[5] These materials can be found at https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm

PPS final rule (88 FR 77689 through 77694) for analysis for 2020 through 2022 claims and the 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of 2023 claims.

d. 2024 Final Claims Results

CMS updates its proposed rule estimates using the most recent complete home health claims data available at the time of rulemaking. Thus, this 2026 final rule uses the most current 2024 data for determining any permanent and temporary adjustments to the 2026 payment rates. CMS followed the same methodology described previously. After all exclusions and assumptions were applied, the final dataset for this final rule included 6,538,837 actual 30-day periods of care and 3,849,780 simulated 60-day episodes of care for 2024.

e. 2026 Permanent and Temporary Adjustments

In the proposed rule, CMS proposed a permanent adjustment of -4.059 percent and a temporary adjustment of -5.0 percent which applies only to the national, standardized 30-day period payments and does not impact LUPA payments The estimated -3.7 percent for the permanent adjustment and the -4.6% for the temporary adjustment includes all payments.

Based on comments received and its own analysis, CMS does not finalize the -4.059 percent permanent payment adjustment that it determined was necessary to account for behavior changes from 2024.[6] CMS will instead finalize a -1.023 percent permanent adjustment,[7] which is based only on the change in estimated aggregate expenditures CMS previously calculated for 2020 through 2022 and finalized through notice and comment in rulemaking for 2023 and 2024 (FR 87 66886 and FR 88 77869). CMS also recalculates the temporary adjustment through 2024 and estimates that this would be about $4.7 billion, or require a -5.0 percent temporary adjustment in addition to any finalized permanent adjustment. In recognition of commenters' concerns about the magnitude of the temporary adjustment, CMS is finalizing implementing a 3.0 percent reduction in 2026 to the 2026 national, 30-day payment rate.

CMS explains that several policy changes during the 2023 - 2025 period make it difficult for the agency to isolate the behaviors directly related to the PDGM implementation after 2022. These policy changes CMS cited were recalibration of case-mix weights and LUPA visit thresholds finalized in the 2023, 2024, and 2025 HH PPS final rules; reassignment of certain ICD-10-CM codes related to the PDGM clinical groups and comorbidity groups in the 2023 final rule; finalizing permanent adjustments in the 2023, 2024, and 2025 final rules; and the introduction of OASIS-E in 2023 and finalized mapping of OASIS-E to OASIS-D in the 2025 final rule for calculating functional points for functional impairment levels during repricing; and the expanded HHVBP Model.

CMS notes that as required by law, it will continue to analyze data through 2026 claims to determine if any additional permanent adjustments are needed. Any additional temporary adjustments needed to recoup the total temporary adjustment will be discussed in future

[6] CMS redid this analysis in the final rule and derived a slightly higher percentage of -4.162%.
[7] CMS provides a detailed step-by-step calculation of the total permanent adjustment needed for 2020 through 2022 and the total permanent adjustment to be applied for 2026 in the final rule (90 FR 55365-55367).

rulemaking. In response to comments, CMS states that it will also consider a schedule for the temporary adjustment in future rulemaking.

f. Comments/response

CMS received comments on its proposals for the permanent and temporary adjustment in four major areas (1) excluding data from HHAs with anomalous behavior, (2) provider margins and access, (3) methodological concerns, and (4) suggested changes in timeframe for behavior change adjustments.

Excluding data from HHAs with anomalous behavior. Several commenters expressed concerns that the data used in CMS' calculations is being distorted by potential fraudulent behavior and anomalous utilization from some home health agencies. Other suggested that CMS target the adjustments to those agencies committing billing fraud, rather than making "blanket adjustments" to the home health payment rate. In response, CMS notes that the HHA Medicare cost report is required to be certified as being true, correct, and complete, and that falsification of cost reports is subject to administrative, civil, and criminal action. CMS states that it must rely on the accuracy and completeness of cost report data when analyzing home health costs. In addition, CMS states that not all anomalous billing patterns indicate fraudulent practice, and CMS would need further evidence to determine which providers with anomalous billing patterns can be connected to fraudulent practices.

Provider margins and access. Commenters expressed concerns that CMS does not consider all-payer margins when considering application of the behavior payment adjustments. They suggested that all-payer margins were much lower than Medicare margins and thus CMS should not apply a downward adjustment as this will cause HHAs to go out of business. Some commenters stated that implementation of the adjustments would inhibit providers from investing in needed technology such as remote patient monitoring, electronic health records, and artificial intelligence that could ultimately save Medicare money. Many commenters also noted a precipitous decease in the number of HHAs, claiming that CMS data suggests that over 1,000 HHAs have closed between 2019 and 2024, and the home health users decreased by 20 percent.

In its reply, CMS disagrees with the decrease in the number of HHAs citing its analysis of the CMS market saturation data set indicating a 2.5 percent decrease from 2020-2025. MedPAC also suggests that much of the decline in the volume of home health use has been driven by a reduction in the number of beneficiaries in FFS Medicare, as a growing share of beneficiaries enrolled in MA.[8] CMS acknowledges that certain geographic areas have experienced decreases in providers including Salisbury, Maryland and Hood River, Oregon, although it's not clear whether the exits of providers in these cases can be solely attributable to payment adjustments or a result of other factors. In sum, CMS does not believe that access has been compromised greatly since the implementation of the behavior adjustments, and sees the evidence presented by commenters as anecdotal, rather than systematic.

[8] https://www.medpac.gov/wpcontent/uploads/2025/06/Jun25_ExecutiveSummary_MedPAC_Report_To_Congress_SEC.pdf

Methodological concerns. Commenters suggested that there are technical flaws in the methodology and CMS should better account for decreases in home health payments, shrinking FFS enrollment, and payment offsets occurring through lower MA benchmarks. CMS in its response notes that commenters have suggested that there are technical flaws in the methodology in previous rulemaking (87 FR 66797). Other commenters cited concerns about how primary diagnoses are assigned to the PDGM and various other technical issues. CMS reiterates that the methodology is technically accurate in that it captures actual changes in behavior that have been explained in previous rulemaking, as well as the final rule. CMS also notes that when setting home health payment rates, it looks only at Medicare FFS home health payment, and does not have a statutory requirement to account for changes in MA benchmarks.

Suggested change in timeframe for behavior change adjustments. Several commenters suggested that the behavior change observed after 2021 is no longer related to the implementation of the PDGM and change in the unit of payment, and that CMS cease the adjustments after this timeframe. Commenters mentioned additional changes that influenced HHAs' behavior change (unrelated to the implementation of the PDGM) including recalibration and LUPA updates, introduction of the OASIS-E in 2023, expansion of the HHVBP Model, and increased MA penetration, among others. Commenters stated that the exclusion of data from 2022 and beyond would result in the need for a 1 percent increase to the 30-day payment rate in 2026 and necessitate recalculating the temporary adjustments for 2020 and 2021.

CMS agrees with the commenters for many of the reasons cited and will not finalize the proposed -4.059% permanent payment adjustment. The policy changes CMS implemented from 2023 to 2025 might make it difficult to precisely isolate the behavior changes from PDGM from the other factors cited by the commenters. Instead, CMS will finalize a -1.023 percent permanent adjustment, which is based only on changes in estimated aggregate expenditures previously calculated for 2020 through 2022 and finalized through rulemaking. CMS disagrees with commenters who argued that CMS should not rely on data from 2022, but should only use 2020-2021 claims for calculating the behavior adjustments, and also disagrees that a 1 percent increase in the 30-day payment rate in 2026 is warranted. CMS also recalculating the temporary adjustments for 2023 and 2024.

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

1. 2025 PDGM LUPA Thresholds

LUPAs are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. LUPA thresholds are set at the 10th percentile value of visits, or two visits, whichever is higher for each payment group. That is, the LUPA threshold for each 30-day period of care varies based on the PDGM payment group to which it is assigned. If the LUPA threshold is met, the 30-day period of care is paid the full 30-day period payment. If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment is made using the per-visit payment amount.

CMS adopted a policy that the LUPA thresholds would be updated each year based on the most current utilization data available. For 2026, CMS updates the LUPA thresholds using 2024 home health claims utilization data (as of July 11, 2025). The LUPA thresholds for the 2026 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in Table 13 of the final rule.

2. 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. A home health period of care receives points based on responses from these functional OASIS items, which are converted to a table of points. The sum of all these points is used to group home health periods into low, medium, and high functional impairment levels, designed so that about one-third of home health periods fall within each level.

For 2026, CMS finalizes its proposal to use the 2024 claims data to update the functional points and functional impairment levels by clinical group and to use the same methodology previously finalized to update the functional impairment levels for 2026. The updated OASIS functional points table and the table of functional impairment levels by clinical group for 2026 are listed in Tables 8 and 9, respectively.

Comment/response: Several commenters opposed the proposed updates to the 2026 functional impairment points and levels and had specific concerns related to classification of high acuity patients, the use of discharge assessments, and point value changes in OASIS scoring, among other concerns. CMS states that it appreciates the comments, but notes that methodology that utilizes the OASIS elements and for calculating the functional impairment level was finalized in the 2019 HH PPS final rule (83 FR 56454). While noting commenters' concerns, CMS states that the proposed recalibration is designed to strengthen the alignment between payment and patient characteristics, not to diminish access to medically necessary services. As such, updating the functional levels would specifically capture any changes in functional impairment and any changes in resource use associated with Activities of Daily Living.

3. 2026 Comorbidity Subgroups

Thirty-day periods of care receive a comorbidity adjustment based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home health list of clinically and statistically significant secondary diagnosis subgroups with similar resource use. A comorbidity adjustment is applied to the 30-day period of care when there is the following: (1) low comorbidity adjustment – a reported secondary diagnosis on the health-specific comorbidity subgroup list that is associated with higher resource use; or (2) a high comorbidity adjustment – two or more secondary diagnoses on the home health-specific comorbidity subgroup list.

For 2026, CMS continues to use the same methodology used to establish the comorbidity subgroups updated based on 2024 home health data with linked OASIS data (as of July 11, 2025). Using updated data, CMS finalizes its proposal to update the comorbidity subgroups to

include 20 low comorbidity adjustment subgroups and 98 high comorbidity adjustment interaction subgroups as identified in Tables 10 and 11 in the final rule.

Comment/response: Commenters were broadly supportive of CMS' proposal to implement the proposed low and high comorbidity adjustments using 2024 claims data. They believed these adjustments would result in more accurate payments. Other commenters had specific concerns about the removal of certain diabetic subgroups, coding logic for conditions such as rheumatic mitral and aortic valve disease, and inconsistencies with certain high comorbidity pairings. CMS appreciate the review of comorbidity subgroup refinements and reminds commenters that many of the specific concerns do not meet the statistical and utilization thresholds to qualify for inclusion in the payment adjustment. CMS states that this ensures that payment adjustments are based on demonstrated cost patterns rather than clinical potential alone.

4. 2026 PDGM Case-Mix Weights

The PDGM case-mix methodology (as finalized in the 2019 HH PPS final rule) results in 432 unique case-mix groups called home health resource groups (HHRGs). CMS annually recalibrates the PDGM case-mix weights using a fixed effects regression model with the most recent and complete utilization data available at the time of annual rulemaking. For 2026, CMS generates the recalibrated case-mix weights using 2024 home health claims data with linked OASIS assessment data (as of July 11, 2025), updated from the proposed rule. CMS believes that recalibrating the case-mix weights using data from 2024 would be reflective of PDGM utilization and patient resource use for 2026.

Table 12 in the final rule shows the coefficients of the payment regression used to generate the weights and the coefficients divided by average resource use for PDGM payment groups. The final 2026 case-mix weights are provided in Table 13 in the final rule and will also be posted on its HHA Center webpage.

To determine the case-mix budget neutrality factor for 2026, CMS continues its practice of using the most recent complete home health claims data at the time of rulemaking, which is 2024 data. CMS calculates a case-mix budget neutrality factor for 2026 of 1.0052.

Comment/response: Commenters expressed concerns about data integrity behavior assumptions and the impact on high acuity patients. Commenters also requested that CMS increase transparency by publishing multiyear comparative tables impact simulations, and clearer explanations of OASIS mapping assumptions. In reply, CMS states that annual recalibration is essential to ensure that weights reflect current utilization patterns and patient characteristics. CMS acknowledges that annual recalibration may contribute to year-to-year variability, but the agency's overarching intent is to align payments as closely as possible with actual resource use as reported by HHAs.

E. Home Health Payment Rate Updates

1. 2026 Home Health Market Basket Update

The update will equal the projected increase in the market basket adjusted for changes in economy-wide productivity. Based on IHS Global Insight Inc.'s third quarter forecast for 2025 with historical data through second-quarter 2025, the HH PPS market basket update for 2026 is as follows:

Market Basket Update	Change (in %)
Market basket forecast	3.2
Total factor productivity	-0.8
Net update for HHAs reporting quality data	**2.4**
Net update for HHAs NOT reporting quality data	**0.4**

As noted below, the final update factor also includes budget neutrality adjustments for the wage index and case-mix recalibration.

2. 2026 Home Health Wage Index

CMS continues to use the pre-floor, pre-reclassified hospital wage index as the wage index to adjust the labor portion of HH PPS rates for 2026, using FY 2022 hospital cost report data as its source for the updated wage data. The 2026 HH PPS wage index would not take into account any geographic reclassification of hospitals, but it would include the 5 percent cap on wage index decreases. In the 2023 HH PPS final rule (87 FR 66851 through 66853), CMS finalized for 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. In addition, if a geographic area's prior calendar year wage index is calculated based on the 5 percent cap, then the following year's wage index would not be less than 95 percent of the geographic area's capped wage index. In the 2025 HH PPS final rule (89 FR 88354) CMS finalized adoption of the revised OMB delineations from OMB Bulletin 23-01 with a 5 percent cap on wage index decreases at the core-based statistical area (CBSA) level as well as at the county level.

CMS makes special provisions for 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. For urban areas without inpatient hospitals, CMS uses the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For 2026, the only urban area without an inpatient hospital wage data is Hinesville, GA (CBSA 25980), and CMS calculates a proxy 2026 wage index value for this area of 0.8779. For rural areas that do not have inpatient hospitals, CMS uses the average wage index from all contiguous CBSAs as a reasonable proxy. As a result of the revised OMB delineations, rural North Dakota is a rural area without a hospital from which hospital wage data can be derived. Based on the use of hospital wage data from contiguous areas, CMS calculates a 2026 HH PPS wage index of 0.8329 for rural North Dakota. For Puerto Rico, CMS finalizes a wage index value of 0.3653 (5 percent cap-adjusted). In addition, based on the adoption of the revised OMB delineations, Delaware now has one rural

area with a hospital from which hospital wage data can be derived, and CMS finalizes a 2026 wage index of 1.0095 for this area. CMS also calculates a wage index value for American Samoa and Northern Mariana Islands of 0.9611, using Guam as a reasonable proxy.

The final HH 2026 wage index is available on the CMS website at: https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.

Comment/response: Commenters continue to express concern with the updates to the home health wage index, with particular opposition related to wage index updates in rural areas. Commenters stated that utilizing hospital wage data does not adequately reflect HHAs' costs of recruiting and retaining employees in rural areas, or the increased travel costs and lost productivity in serving rural areas. As discussed in the 2022 HH PPS final rule (86 FR 62285), CMS states that it does not believe a population density adjustment is appropriate at this time and while rural areas cite the additional cost of traveling from one patient to another, urban areas cite the added costs associated with needed security measures and traffic congestion. Thus, in the absence of home health specific data, CMS continues to assert that the pre-floor, pre-reclassified hospital wage index is appropriate for the geographic adjustment of home health claims.

4. 2026 Annual Payment Update

a. Background

CMS discusses the methodology it uses to compute the case-mix and wage-adjusted 30-day period rates as set forth in §484.220. It first multiplies the national, standardized 30-day period rate by the patient's applicable case-mix weight. It then divides the case-mix adjusted amount into labor (74.9 percent) and non-labor (25.1 percent) portions.[9] The labor portion is multiplied by the appropriate wage index based on the site of service and summed to the non-labor portion. In the 2024 HHS PPS final rule (88 FR 77726), CMS finalized a rebasing of the home health market basket to reflect 2021 cost report data.

Next, CMS may adjust the resulting 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect:

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

Implementation of the PDGM and the 30-day unit of payment began in 2020, and CMS is required to annually analyze data (for 2020 through 2026) to assess the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. As discussed above, CMS is implementing a permanent behavior adjustment of -1.023 percent in 2026 to help ensure that payments under the PDGM do not exceed what payments would have been under the 153-group payment system, as required by law.

[9] A detailed description of how CMS rebased the HHA market basket and labor-related share is available in the 2024 HH PPS final rule (88 FR 77726 through 77742).

CMS is also implementing a temporary 3.0 percent reduction to the 2026 base payment rate with a temporary adjustment factor of 0.9700. This temporary adjustment will not be included in the starting base rate for 2027.

b. 2026 National, Standardized 30-Day Period Payment Amount

To determine the 2026 national, standardized 30-day period payment rate, CMS applies a permanent behavioral adjustment factor, case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, the home health payment update percentage and the temporary adjustment factor. The permanent and temporary adjustment factors have the largest effect on the calculation of the standardized amount. The 2026 30-day payment amount is about -1.0 percent less than the 2025 30-day payment amount.

The following table shows the standardized amounts, as displayed in Tables 14 and 15. CMS shows the rates without temporary adjustment for illustrative purposes. The actual 2026 national standardized 30-day period payment rate includes the final temporary adjustment as shown below.

2026 National, Standardized 30-Day Episode Payment Amount, for HHAs Submitting and Not Submitting Quality Data		
	HHAs submitting quality data	HHAs not submitting quality data
2025 30-day budget neutral standardized amount	$2,057.35	
Permanent adjustment factor	x 0.98977	
Case-mix weights recalibration neutrality factor	x 1.0052	
Wage index budget neutrality factor	x 1.0025	
HH payment update percentage	x 1.024	x 1.004
2026 30-day payment amount (without temporary adjustment)	**$2,101.26**	**$2,060.22**
Temporary adjustment factor	0.9700	
2026 30-day payment amount (with temporary adjustment)	**$2,038.22**	**$1,998.41**

c. 2026 National Per-Visit Rates for 30-Day Periods of Care

Computations are presented for the 2026 per-visit amounts for each type of service. These amounts are used for LUPAs and in outlier calculations. The per-visit amounts for those HHAs submitting the required quality data (Table 16 in the final rule, reproduced below) are as follows:

HH Discipline	2025 Per-Visit Rates	2026 Wage Index Budget Neutrality Factor	2026 HH Payment Update Factor	2026 Per-Visit Payment Amount
Home Health Aide	$78.20	1.0005	1.0240	$80.12
Medical Social Services	$276.85	1.0005	1.0240	$283.64
Occupational Therapy	$190.08	1.0005	1.0240	$194.74
Physical Therapy	$188.79	1.0005	1.0240	$193.42

HH Discipline	2025 Per-Visit Rates	2026 Wage Index Budget Neutrality Factor	2026 HH Payment Update Factor	2026 Per-Visit Payment Amount
Skilled Nursing	$172.73	1.0005	1.0240	$176.96
Speech-Language Pathology	$205.22	1.0005	1.0240	$210.25

HHAs that do not submit required quality data will have the payment update for per-visit services reduced from 2.4 percent to 0.4 percent, resulting in the following payment rates (Table 17 in the final rule, reproduced below):

HH Discipline	2025 Per-Visit Rates	2026 Wage Index Budget Neutrality Factor	2026 HH Payment Update Factor	2026 Per-Visit Payment Amount
Home Health Aide	$78.20	1.0005	1.004	$78.55
Medical Social Services	$276.85	1.0005	1.004	$278.10
Occupational Therapy	$190.08	1.0005	1.004	$190.94
Physical Therapy	$188.79	1.0005	1.004	$189.64
Skilled Nursing	$172.73	1.0005	1.004	$173.51
Speech-Language Pathology	$205.22	1.0005	1.004	$206.14

d. LUPA Add-on Factors

Under previously adopted policy, to determine the LUPA add-on payment for a 30-day period of care, CMS multiplies the per-visit payment amount for the first skilled nursing, PT, or SLP visit in a LUPA period that is the first 30-day period of care or the initial 30-day period of care in a sequence of adjacent periods.

In an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, CMS updated the LUPA add-on factors for PT, SN, and SLP in the 2025 HH PPS final rule (89 FR 55378) using 2023 data. These factors had not been revised since the 2014 HH PPS final rule, during which 2012 data was used. Also, in the 2025 HH PPS final rule, CMS finalized its proposal to discontinue the use of the PT LUPA add-on factors as a proxy and established a definitive LUPA add-on factor for occupational therapy (OT). The LUPA add-on factors are 1.7200 for SN; 1.6225 for PT; 1.6696 for SLP; and 1.7238 for OT.

e. Payments for High-Cost Outliers Under the HH PPS

Under the HH PPS, outlier payments are made for episodes whose estimated costs exceed a threshold amount. The outlier threshold amount is the sum of the wage- and case-mix adjusted PPS episode amount and a wage-adjusted fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost for the episode that surpasses the wage-adjusted threshold; this proportion is referred to as the loss-sharing ratio.

CMS notes that the FDL amount and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed 2.5 percent of estimated total HH PPS payments, as required by statute. CMS has historically used a value of 0.80 for the loss-sharing ratio, meaning

that Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount. No changes were proposed to the loss-sharing ratio for 2026.

For 2025 payment, CMS finalizes an FDL ratio of 0.37 (0.46 in the proposed rule) for 2026 based on analysis of 2024 claims data (as of July 11, 2025).

F. Regulation Change to Face-to-Face Encounter

CMS reviews the regulatory and statutory background regarding the requirement that prior to certifying a patient's eligibility for the home health benefit, the physician ordering such home health care must document that the physician himself or herself or a non-physician practitioner (NPP) has had a face-to-face encounter with the patient. CMS believes this type of physician involvement is critical from both a quality of care and a program integrity perspective. In the 2011 HH PPS final rule CMS stablished additional restrictions that limited the practitioners who could perform the face-to-face encounter 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 in §422.22(a)(1)(v)(C)). CMS has received requests to change the current face-to-face encounter policy to allow any practitioner to perform the face-to-face encounter. Commenters have stated that Section 3708 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) permitted this additional flexibility and CMS agrees.

As such, CMS finalizes its proposal 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, 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. CMS also removes §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.

CMS believes the additional flexibility will 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. In addition, CMS believes that these revisions will also address concerns that the current regulations do not align with the CARES Act language.

Comment/response: All commenters expressed strong support for the proposed changes that would expand who can conduct face-to-face encounters. They stated that the proposed changes would improve access to care and administrative efficiency due to operational flexibility, streamline processes, reduce administrative complexity, encourage team-based care, among other improvements. A few commenters requested that CMS provide additional clarification and guidance related to implementation details and documentation requirements. CMS replies that

CMS will provide additional information through subregulatory guidance with clarifying information and examples, if needed. CMS reminds readers that these changes only add flexibility to the face-to-face encounter and do not otherwise change the intent documentation requirements, or acceptable formats of the face-to-face encounter.

III. Home Health Quality Reporting Program (HH QRP)

A. Statutory Authority and Background

The HH QRP[10] is a pay-for-reporting program authorized under section 1895(b)(3)(B)(v) of the Act. Under the program the annual HH market basket percentage increase is reduced by 2 percentage points for HHAs that do not report required quality data.[11] The program was modified by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act), which added requirements for HHAs to begin entering standardized patient assessment data elements (SPADEs) into the HH assessment tool, the Outcome and Assessment Information Set (OASIS).

For the 2023 program year, 820 of the 11,549 HHAs (approximately 7.1 percent) did not receive the full annual percentage increase for failing to meet assessment submission requirements.

B. Overview of Provisions

CMS is finalizing its proposals to (i) 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, (ii) remove four assessment items (two food items, one living situation item, and one utilities item), (iii) make clarifications regarding its policy that allows providers that fail to provide complete and timely data to submit a request for reconsideration if they can demonstrate full compliance, (iv) implement a revised HHCAHPS Survey beginning with the April 2026 sample month, and (v) update regulatory text to account for all-payer data submission of OASIS data.

In addition CMS summarizes feedback it received in response to its RFIs on (i) changing the final data submission deadline from 4.5 months to 45 days after the end of the period, (ii) digital quality measurement (DQM) transition for HHAs, (iii) the current adoption of health information technology and standards, and (iv) future HH QRP quality measure concepts of interoperability, cognitive function, nutrition, and patient well-being.

CMS estimates that the implementation of the policies finalized in the rule for the HH QRP will reduce the burden on HHAs by $17,810,282 annually across all HHAs.

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[10] More information on the HH QRP can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits. The HH QRP regulations are under 42 CFR 484.245 and 484.250.

[11] Depending on the HH market basket percentage increase applicable for a particular year, as further reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, the 2 percentage-point reduction may result in the 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.

C. Measures Currently Adopted for the 2026 HH QRP

The HH QRP for 2026 (before the finalized policies in the rule) includes 19 measures, as shown in Table C-19 of the rule. The table below is based on Table C-19 but reflects the finalized removal of the Patient/Resident COVID-19 Vaccine measure.

Measures Adopted for 2026 HH QRP

Short Name	Measure Full Name & Data Source
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)
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program
DC Function	Discharge Function Score
Dyspnea	Improvement in Dyspnea
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medication (CBE #0176)
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation of Care (CBE #0526)
ToH-Patient*	Transfer of Health Information to the Patient-PAC Measure
ToH-Provider*	Transfer of Health Information to the Provider-PAC Measure
Patient/Resident COVID-19 Vaccine ##	*COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date*
## Removal of the measure is finalized beginning with the 2026 HH QRP. **Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider*	
Claims-based	
PPH	Home Health Within-Stay Potentially Preventable Hospitalization
DTC	Discharge to Community-Post Acute Care (PAC) HH QRP (CBE #3477)
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB) –PAC HH QRP
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP
HHCAHPS-based (CAHPS Home Health Care Survey CBE #0517)* **	
• Communication - How well did the home health team communicate with patients • Overall Rating - How do patients rate the overall care from the HHA • Professional Care - How often the home health team gave care in a professional way • Team Discussion - Did the home health team discuss medicines, pain, and home safety with patients • Willing to Recommend - Will patients recommend the HHA to friends and family	
****The HHCAHPS has 5 components (all listed) that together are used to represent one measure.*	

D. Removal of COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine Measure) Beginning with 2026 HH QRP

CMS is finalizing its proposal, beginning with the 2026 HH QRP, to remove the Patient/Resident COVID-19 Vaccine measure under removal factor 8 – the costs associated with a measure outweigh the benefit of its continued use in the program. The measure was adopted into the HH QRP in the 2024 HH PPS final rule.[12] CMS describes that since adoption of the measure, the number of COVID-19 cases and deaths have declined and the agency now believes the costs and

[12] 88 FR 77762-77764.

burden to providers of reporting the measure outweigh the benefit of continued information collection regarding COVID-19 vaccination among patients in HHAs.

Beginning with patients discharged on or after April 1, 2026, HHAs will not be required to collect and submit the Patient/Resident COVID-19 Vaccine measure data. The data from the Patient/Resident COVID-19 Vaccination is Up to Date OASIS[13] item (O0350) will no longer be used in the calculation of the measure. Effective April 1, 2026, the item will be removed from the OASIS. Until the item is removed, HHAs would be able to submit any valid response on a Transfer, Death at home, or Discharge OASIS assessment without any quality measure implications. CMS states that the item would need to be completed with a valid response (0-No, 1-Yes, or dash) in order for the submission to not be rejected by the iQIES.

E. Removal of Four SPADEs Beginning with 2026 HH QRP

HHAs are statutorily required, as a post-acute care (PAC) provider,[14] to submit standardized patient assessment data under the HH QRP with respect to the admission and discharge of an individual (or more frequently as specified by the Secretary) using a standardized patient assessment instrument, which for HHAs is OASIS. Standardized patient assessment data is data required with respect to the following categories: (1) functional status, such as mobility and self-care at admission to and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow; and (6) other categories deemed necessary and appropriate by the Secretary.[15] Under the "other categories deemed necessary and appropriate" authority, CMS created the social determinants of health (SDOH) category.

CMS is finalizing its proposal to remove four standardized patient assessment data elements (SPADES) under the SDOH category (one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330)). These items had been adopted in the 2025 HH PPS final rule.

As finalized, HHAs will no longer need to collect and submit these items beginning with patients discharged on or after April 1, 2026, and the items will not be required for purposes of meeting HH QRP requirements beginning with the 2026 HH QRP.[16]

CMS states that its determination to remove the four SPADES is based on the burden associated with reporting these items. The agency believes that the burden to collect and share clinical data

[13] OASIS refers to the Outcome and Assessment Information Set.
[14] Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit standardized patient assessment data required under section 1899B(b)(1) of the Act, which requires PAC providers to submit such data under applicable reporting provisions.
[15] These six categories are specified under section 1899B(b)(1)(B) of the Act.
[16] Note that, as finalized in the 2025 HH PPS final rule, HHAs are required to report these items beginning for the 2027 HH QRP.

will become less burdensome as health information technology (HIT) advances and data interoperability becomes standardized. CMS expresses that the agency would like to work towards the workflow for these items being part of a low burden interoperable electronic system.

Selected Comments/Responses. A slight majority of commenters supported the removal of the four SPADES, noting that there may be less burdensome ways to obtain SDOH data. Many commenters opposed the proposal and described the value of collecting the SPADES, including for helping HHAs to identify barriers to access to care and deficits particularly in rural patients' living situations. CMS, however, believes that the four items should be removed from OASIS before the start of data collections and submission. The agency states it does not have a specific use for the items in the HH QRP and they are not clinical items related to direct patient care. Therefore, CMS believes the burden of collecting these data outweighs their value.

F. Amending Data Non-Compliance Reconsideration Request Policy and Process

1. Background.

At the end of the data reporting and submission period, CMS reviews data received from HHAs to determine if the HH QRP reporting requirements were met. An HHA may request (and CMS may grant) exceptions and extensions for the reporting requirements when there are certain extraordinary circumstances out of the control of the HHA. If such an exception or extension is granted, the HHA's PPS payment is not reduced for failure to comply with the requirements of the HH QRP.

In the 2018 HH PPS final rule,[17] CMS codified at §484.245(d) a reconsideration policy and process for HHAs, which specifies (i) that written notification of non-compliance is to be sent to an HHA determined to be in non-compliance, (ii) the process to request reconsideration, (iii) the information an HHA would need to include in such request, and (iv) how CMS notifies the HHA of the final decision. In that same rule, CMS finalized (but did not include in its codification of the regulation) its policy that in very limited circumstances (that is, extenuating circumstances that prevented the HHA from filing a reconsideration request) the agency can grant a request of an HHA to extend the deadline to submit a reconsideration request.

CMS describes that it has become aware of inconsistences between the preamble text and regulatory text regarding HHA requests for reconsideration and is therefore proposing changes to the regulations to resolve the inconsistencies. Specifically, the agency notes its current policy does not specify a deadline from when the extenuating circumstances occurred by which the HHA would need to submit a request for an extension.

2. Amending and Codifying Requirements Related to Requests for Extension to File Reconsideration Request.

CMS is finalizing its proposals to make modifications to and codify requirements related to requests for an extension to file reconsideration requests beginning with the 2027 HH QRP. CMS is specifying at §484.245(d) that an HHA may request, and CMS may grant, an extension

[17] 82 FR 51752.

to file a request for reconsideration of a non-compliance determination if, during the period to request a reconsideration, the HHA was affected by an extraordinary circumstance beyond the control of the HHA. The HHA will need to submit its request for an extension to CMS via email not later than 30 calendar days after the date of the written notification of non-compliance. The request will be required to contain the CCN as well as business name and address of the HHA, contact information of the CEO or designated personnel, the reason for requesting the extension, and evidence of the impact of the extraordinary circumstances. CMS will notify the HHA by email of its final decision regarding the extension request.

3. Codifying the Bases on Which CMS Can Grant a Reconsideration Request.

Under its current policy, CMS may reverse an initial finding of non-compliance if (i) the HHA provides proof of compliance with all requirements during the reporting period or (ii) 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. The agency upholds an initial finding of non-compliance if the HHA does not show any justification for non-compliance, but these bases for granting a reconsideration request are not currently in regulation.

CMS is finalizing its proposal to modify its reconsideration policy, and codify the policy at §484.245(d) to provide that the agency will grant a timely request or reconsideration and reverse an initial finding of non-compliance only if the agency determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year. The agency states it will consider full compliance to include when an exception or extension is granted under the extraordinary circumstance exception and extension policy (ECE) under §484.245(c) for HHAs that comply with the ECE policy requirements.

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

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 temporarily suspended OASIS requirements for collection of data on non-Medicare and non-Medicaid patients. CMS finalized in the 2023 HH PPS final rule that, beginning with the 2027 program year, the agency will end the temporary suspension of OASIS data collection on non-Medicare/non-Medicaid HHA patients and on the requirement for HHAs to submit all-payer OASIS data for purposes of the HH QRP.[18] There is a two-quarter voluntary phase-in during which HHAs will be able to start submitting this data for patients who begin receiving home health care services with an OASIS start of care (SOC) M0090 date from January 1, 2025, through June 30, 2025, but the data will not be used for purposes of CMS making a compliance determination. Beginning with the 2027 program year, the new all-payer OASIS data reporting will be required, with HHAs needing to report OASIS data on all patients (excluding those who are exempt from OASIS data collection), regardless of payor, who begin receiving home health care services with an OASIS SOC M0090 date between July 1, 2025, and June 30, 2026.

CMS finalizes its proposed technical changes to update terminology to clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services, and aligns the language in the CoPs with the OASIS all-payer submission requirements.

[18] 2023 HH PPS final rule (87 FR 66862-66865).

The HHA CoPs at §484.45(a) require 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 not later than 30 days after completing the assessment of the beneficiary. The OASIS all-payer submission requirements refer to a "patient" instead of "beneficiary." CMS is aligning the terminology and therefore changing the reference in the HHA CoPs from "beneficiary" to "patient." In addition, CMS is removing the term "beneficiary" from the language at §484.55(d)(1)(i) that references a "beneficiary elected transfer" in order to support the transition to OASIS all-payer submission requirements. The agency clarifies that this policy will not change current patient exemptions for OASIS, which are (i) patients under the age of 18, (ii) patients receiving maternity services, and (iii) patients receiving only personal care, housekeeping, or chore services.

H. Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey Updates

CMS describes its efforts to shorten and update the HHCAHPS survey, including a revised survey tested in a mode experiment conducted by CMS in 2022. The revised survey includes the following changes:

- Addition of three new questions to assess new topics of importance to patients: (i) Whether the care provided helped the patient take care of their health; (ii) Whether the patient's family/friends were given sufficient information and instructions; and (iii) Whether the patient felt the staff cared about them "as a person."
- Six questions about medications were reduced to two questions.
- Removal of four questions: (i) Whether someone asked to see the prescription and over-the counter medicines the patient was taking; (ii) Whether the patient is taking any new prescription medicines or whether the patient's medicines have changed; (iii) Whether home health providers talked to the patient about the purpose for taking new or changed prescription medicines; and (iv) Whether home health providers talked to the patient about when to take the medicines.
- Removal of 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 a revised composite measure - Whether the patient got information about what care and services they would get when they first started getting home health care.

The above changes result in a revised Care of Patients composite measure, revised Communications between Providers and Patients composite measure, and three new stand-alone measures that remain from the current Specific Care Issues composite measure. The three stand-alone measures include one relating to talking about home safety, one reviewing prescribed and over-the-counter medicines, and one talking about medicine side effects. The Overall Rating measure in the revised survey included a minor wording change only. No changes were made to the Willingness to Recommend the Agency measure.

CMS is finalizing its proposal to update the HHCAHPS measures beginning with the April 2026 sample month. Table C-20 in the rule compares the current and revised or new HHCAHPS Survey measures, including a comparison of the questions included for each.

The Summary Star Rating is currently based on the Overall Rating of Care and three composite measures that are equally weighted. CMS is finalizing its proposal to instead calculate the Summary Star Rating based on the Overall Rating of Care, the two modified Care of Patients and Communications between Providers and Patients composite measures, and the three new stand-alone measures. The Overall Rating of Care and each of the composite measures will each have a weight of one, and each of the three new stand-alone measures would have a weight of one-third. Since the three stand-alone measures are new measures for the survey (since they would be reported individually instead of as part of the previous composite measure), CMS describes it will need to wait until it has four quarters of data before it could begin public reporting. Similarly, the agency believes the modifications to the two composite measures are substantive and therefore each revised composite measure should also be treated as new for purposes of public reporting and Star Ratings. Therefore, CMS will wait to publicly report the revised composite measures until it has four quarters of data.

CMS anticipates the first Care Compare refresh in which publicly reported measure scores will be updated to include the new measures will be October 2027, with scores calculated using data from Q2 2026 through Q1 2027. During the transition period between the current and new surveys, CMS will continue to publicly report the Overall Rating measure (which had only non-substantive changes made) and the unchanged Willingness to Recommend the Agency measure. Also, during the transition period, scores and Star Ratings for the Overall Rating and Willingness to Recommend measures will be calculated by combining scores from quarters using the current and new survey and continue to be reported.

HHA's HHCAHPS survey scores are adjusted for the effects of case mix before public reporting. The following variables are included in the current case-mix adjustment model: 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. After testing the revised survey, CMS is finalizing its proposal to remove the adjustment for diagnoses of schizophrenia or dementia because the agency believes that adjustment is no longer significant.

In addition, CMS is finalizing its proposal to add mode adjustment (in addition to case-mix adjustment) with the revised survey to take into account impacts in how someone responds to the survey based on the mode of survey administration. CMS will use the mail-only mode as the reference mode for making such adjustments.

I. RFI: HH QRP Quality Measure Concepts Under Consideration for Future Years

In the 2026 HH PPS proposed rule CMS issued an RFI that sought comment on four concepts for future measure for the HH QRP – interoperability, cognitive function, well-being, and nutrition. In the final rule, CMS summarizes comments received; the agency does not respond to the comments, but indicates it will take the feedback into consideration in future measure development efforts. Some of the comments reviewed include the following:

Interoperability. CMS sought feedback on approaches to assess interoperability in the HH setting, such as measures that evaluate the level of readiness of interoperable data exchange or that evaluate data systems' ability to securely share information.

Many commenters supported the value and importance of interoperability and believed that national standards would be critical for an interoperability measure concept. Most commenters also expressed that federal funding would be needed to support home health agencies in building and maintaining an interoperable infrastructure. Several commenters who stressed the importance of interoperability also did not support an interoperability measure concept for HH because of financial and operational barriers.

Cognitive function. CMS describes that the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM©) are two sources of information on cognitive function currently collected in HHAs, both of which have been incorporated in OASIS. Additional testing, though, is needed to transform concepts in the BIMS and CAM into measures for the HH QRP. CMS sought feedback on 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, CMS sought feedback on the feasibility of measuring improvement in cognitive functioning during a HH stay, the cognitive skills that are most likely to improve during a HH stay, conditions for which maintenance would be more practical, and types of intervention that have been demonstrated to assist in improving or maintaining cognitive functioning.

Commenters believed that addressing cognitive function in home health care is critical. Many commenters noted that the OAISIS tool already has tools that evaluate cognitive function. Other commenters noted the complexities of cognitive function and difficulties of any tool sufficiently addressing the range of cognitive function challenges. Many commenters suggested that CMS focus on a cognitive function measure that involves maintenance or limiting decline in cognitive function rather than improvement.

Well-being. CMS sought feedback 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.

Commenters provided various suggestions on well-being measure concepts. Many commenters suggested that CMS should consider a process rather than outcome measure since an HHA would have limited ability to affect the broad concept of well-being. Others believed the measure concept would not be appropriate for the HH QRP because HHAs could not address such a broad issue within the timeframe of HH care.

Nutrition. CMS sought feedback on tools and frameworks that promote healthy eating, exercise, nutrition, or physical activity.

Many commenters supported the importance of nutrition in home health and some suggested a range of different nutrition tools. The most commonly referenced tool was the Malnutrition Care Score (MCS), which is an electronic clinical quality measure (eCQM) adopted into the Hospital Inpatient Quality Reporting program. Several commenters did not support a nutrition measure

concept for various reasons, including lack of reimbursement for services that support nutrition interventions.

J. RFI: Potential Revision of Final Data Submission Deadline Period from 4.5 Months to 45 Days

CMS is required by statute to publicly report the performance of post-acute care (PAC) providers, including HHAs, on the quality, resource, and other measures applicable to the PAC provider, to provide confidential feedback reports to PAC providers on their performance before it is made public, and to ensure that each PAC provider has the opportunity to review and submit corrections to the information that is to be made public prior to the data being made public.[19] The timeframe for HHAs to submit data required for the HH QRP is not specified in statute.

Currently, HHAs have approximately 4.5 months after the reporting quarter to make any needed corrections to the assessment-based data. During the time of data submission for a quarterly reporting period and up until the quarterly submission deadline, HHAs are able to review and correct errors in the assessment data used to calculate the measures. There is about a 9-month lag between the end of data collection and when measures are publicly reported, and the agency states that the biggest contributor to this lag is the 4.5-month timeframe for data submission. CMS describes that a goal of public reporting of data collected under the HH QRP and other quality reporting programs is to provide consumers with the most current information in order to facilitate informed decision-making. CMS believes that the time between when data on measures is submitted and when the data are made publicly available may be too long for those purposes.

CMS believes that if the data submission timeframe were reduced from its current 4.5-month timeframe to 45 days, the lag between the end of the data collection period and public reporting could be reduced by up to three months. According to an analysis conducted by CMS on the potential impact of shortening the data submission timeframe, only 1.3 percent of all OASIS assessments were submitted after 60 days.

In the 2026 HH PPS proposed rule, CMS issued an RFI that sought feedback on the potential future reduction of the submission deadline from 4.5 months to 45 days. In the final rule, CMS summarizes comments received, does not respond to any comments, but indicates it will take the feedback into consideration in the future.

Most commenters supported a reduction in the final data submission deadline. Some commenters suggested any reduction have a phased-in implementation and many commenters suggested CMS pilot the reduced timeframe before national implementation. Other commenters cautioned that the reduced timeframe could harm HHAs with additional administrative burden. Some suggested 60 or 90 days instead of 45 days.

K. RFI: Advancing Digital Quality Measurement in the HH QRP

As part of its effort to advance digital quality measurement (dQM), CMS is considering ways to advance Fast Healthcare Interoperability Resources® (FHIR)-based reporting of patient

[19] See section 1899B(g) of the Act.

assessment data for the submission of the OASIS. In the 2026 HH PPS proposed rule, the agency sought information on how HHAs integrate technologies into existing systems and how the integration affects workflow, particularly to identify the challenges during the integration and to determine support that is needed. The agency provided many specific questions on which it sought feedback regarding the state of health IT use in HHAs.

In the final rule, the agency summarizes comments received, does not respond to any comments, and indicates it intends to use the feedback to inform future dQM transition work and potential future rulemaking.

Many commenters supported transitioning to dQMs in the HH QRP because they believed using FHIR as a standard could reduce administrative burden and improve data quality. Some commenters suggested a phased implementation and some recommended funding opportunities be provided. Several commenters expressed concerns about IT readiness across HHAs.

L. Form, Manner, and Timing of Data Submission

CMS did not have any proposals in the 2026 HH PPS proposed rule regarding the form, manner, or timing of data submissions under the HH QRP.

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

As discussed in section III.C.2, CMS is finalizing its proposal to remove the Patient/Resident COVID-19 measure beginning with the 2026 HH QRP. The data from O0350 Patient's COVID-19 Vaccination is Up to Date may be submitted using any of the three valid responses without any quality measure implications. Therefore, CMS is also finalizing its proposal that the measure rates will be publicly reported for the last time with the January 2026 Care Compare refresh on Medicare.gov, based on data from Q1 of 2025.

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

A. Background and Overview

The CMS Center for Medicare and Medicaid Innovation (CMMI) tested under section 1115A of the Act the "original" Home Health Value-Based Purchasing Model (HHVBP-O) in nine states from 2016 through 2021. Payments were adjusted based on HHAs' performance on the model's measures as summed into a Total Performance Score (TPS). The model produced average annual savings to Medicare of $141 million, as well as an average TPS increase of 4.6 percent, without evidence of adverse risks. The model's results met statutory criteria to be certified for expansion, as announced by CMS on January 8, 2021. Final payment adjustments under the HHVBP-O model were made during 2021.

The expanded HHVBP Model[20] began nationwide testing January 1, 2022, starting with a "pre-implementation year" of 2022 during which agencies could familiarize themselves with the expanded model, but during which time their performance would not trigger future payment

[20] The expanded HHVBP Model regulations are under 42 CFR part 484, subpart F.

adjustments. Beginning with the 2023 performance year, measures are scored and TPSs are calculated annually and will trigger payment adjustments two years after each performance year. The first payment year was 2025 based on 2023 (the first performance year). Payment adjustments range from -5% to +5% for all model test years. The model requires all Medicare-certified HHAs to participate and they are termed "competing HHAs."

In this rule, CMS finalizes its proposals (i) for an additional measure removal factor, (ii) to modify the expanded HHVBP Model measure set by, beginning in 2026, removing three HHCAHPS survey-based measures and adding four measures, and (iii) to update individual measure weights and category weights. The agency also summarizes comments it received in response to its RFI seeking comment on future measure concepts.

In the 2022 HH PPS final rule, CMS estimated that the expanded HHVBP model would generate a total projected 5-year gross FFS savings of $3,376,000,000. CMS states that the changes finalized in this rule will not change that estimate, since the changes do not change the number of HHAs in the model or the payment methodology. Tables 52 and 53 of the rule show the value-based payment adjustment for the estimated 7,061 HHAs that would qualify to compete in the model based on 2023 performance data stratified by volume-based cohort. Based on the 11 quality measures, the 6,391 HHAs in the larger-volume cohort would have an average payment adjustment of +0.004 percent. Overall, smaller-volume HHAs would have an average payment adjustment of +0.006 percent.

B Changes to HHVBP Measure Removal Factors

There are currently eight measure removal factors that CMS considers when determining whether to remove measures from the expanded HHVBP Model measure set.[21]

To address situations when it is no longer feasible to implement a quality measure, CMS is finalizing its proposal to add a removal factor 9: "It is not feasible to implement the measure specifications."

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

The expanded HHVBP Model currently includes five HHCAHPS survey-based measures:

- The following three measures, which are each currently based on multiple items/questions from the HHCAHPS survey: (i) Care of Patients, (ii) Communications between Providers and Patients, and (iii) Specific Care Issues; and
- The following two measures, which are each single-item/question measures: (i) Overall Rating of Home Health Care and (ii) Willingness to Recommend the Agency.

CMS is finalizing (described in further detail below) a number of changes to the survey questions, which are used to calculate the measures that are used in the expanded HHVBP Model, as well as changes to the related measures for the HH QRP in section III.H, which will become effective beginning with the April 2026 sample month.

[21] Measure removal factors are codified at §484.358.

1. Removal of Three HHCAHPS Survey-Based Measures

Given the finalized changes to the HHCAHPS survey-based measures described in section III.H, CMS is also finalizing its proposal to remove, beginning with 2026, the following three HHACAHPS survey-based measures from the HHVBP measure set using the removal factor 9 being finalized in section IV.B:

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

Since the changes to the HHCAHPS survey instrument are being finalized, several of the survey questions used to calculate the first two measures described above will no longer match the measure specifications and the third listed measure will be impossible to calculate as currently specified. The agency believes that removing the three measures under this rulemaking cycle will give CMS time to collect the required data to potentially develop updated benchmarks and achievement thresholds for revised or new measures. However, CMS states that if it decides to propose to include in the expanded HHVBP Model the new versions of the Care of Patients and Communications between Providers and Patients measures being finalized for the HH QRP and the individual item measures being finalized to replace the Specific Care Issues measure for the HH QRP, it would do so through future rulemaking.

2. Addition of Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC)

Policy. CMS finalizes its proposal to add the claims-based MSPB-PAC measure to the HHVBP measure set beginning in 2026. The measure was added to the HH QRP on January 1, 2017, as required by the IMPACT Act. CMS believes that including the measure in the HHVBP measure set will provide incentives for improved care coordination and for providers to find more efficient resource utilization because the measure would ensure HHVBP payment adjustments to reflect HH patient outcomes and how well HHAs can produce those outcomes at lower costs.

Measure description. The measure evaluates Medicare payments for parts A and B services (excluding services that are clinically unrelated to PAC treatment over which HHAs may have limited influence), relative to Medicare spending for other HHAs, for an episode of care that includes the period during which a patient is under HHA care plus a defined period after the end of HHA care. Specifically, the episode of care would be measured from admission for the home health services up to 30 days after the end of the home health treatment period. The measure is payment standardized and risk-adjusted.[22]

The measure will use two years of data, with 2022 and 2023 as baseline data. The 2026 performance would be calculated based on 2025 and 2026 performance data. CMS anticipates it will report preliminary benchmarks, achievement thresholds, and improvements thresholds for the measure in the October 2025 Interim Performance Reports (IPR).

[22] Measure specifications can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/2016_07_20_mspb_pac_ltch_irf_snf_measure_specs.pdf.

3. Addition of OASIS-Based Function Measures

CMS is finalizing its proposal to add three OASIS-based function measures to the HHVBP measure set beginning with 2026: (i) Improvement in Bathing; (ii) Improvement in Upper Body Dressing; and (iii) Improvement in Lower Body Dressing. CMS states that these measures are already used for other purposes in CMS models and programs and that adding the measures to the HHVBP would not create additional burden for HHAs because the data is already collected on OASIS assessments. The baseline data will cover 2023 to calculate benchmarks and achievement thresholds for the measures. CMS anticipates it will provide HHAs with the benchmarks, achievement thresholds, and improvement thresholds for the measures in the October 2025 IPRs.

The additional measures are intended to complement the Discharge (DC) Function Score measure that was added to the HHVBP beginning with 2025. The expanded HHVBP Model's Technical Expert Panel (TEP) raised concerns that the DC Function Score measure does not consider bathing or dressing abilities, which are metrics that have been identified as critically important for HH patients.

4. Updates to Individual Measure Weights and Category Weights

To take into account the changes being finalized to the measure set, CMS also finalizes its proposed revisions to the weights of the individual measures and the measure category weights beginning with the 2026 performance year.

Based on the data shown in Table D-22 of the rule, below is a comparison of the current and finalized individual measure weights and category weights.

2025 and Finalized Individual Measure Weights and Category Weights for the Expanded HHVBP Model

Measure	2025 Measure Weights		Finalized 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%	13.00%
Discharge Function Score	20.00%	28.57%	15.00%	18.75%
Improvement in Bathing	-----	-----	3.5%	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	26.00%	37.14%	15.00%	18.75%
Discharge to Community-PAC	9.00%	12.86%	15.00%	18.75%
Medicare Spending Per Beneficiary-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%	-----	-----

Measure	2025 Measure Weights		Finalized Measure Weights	
	Larger-Volume Cohort	Smaller-Volume Cohort	Larger-Volume Cohort	Smaller-Volume Cohort
Communication Between Providers and Patients	6.00%	0.00%	-----	-----
Specific Care Issues	6.00%	0.00%	-----	-----
Overall Rating of HH Care	6.00%	0.00%	10.00%	0.00%
Willingness to Recommend 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%**

D. RFI: HHVBP Quality Measure Concepts Under Consideration for Future Years

1. Falls with Major Injury (FMI) Measure

The FMI measure is a claims measure that is based on OASIS data. Since 2022 CMS has reported rates for the measure on Care Compare. However, an OIG study[23] found that more than half of falls with a major injury were not reported on OASIS assessments and OIG concluded that a low fall rate reported on Care Compare could be because of a low rate of providers reporting, not a low rate of falls. CMS is working on a respecified version of the FMI measure that uses more data sources (FFS claims, encounter data, and OASIS data) and includes additional injuries not currently covered by the measure to produce a more complete data set.

In the 2026 HH PPS proposed rule, CMS requested comments on the potential future addition of the respecified FMI measure to the HHVBP measure set. CMS also requested general feedback on any other potential future model concepts. In the final rule, CMS summarized comments received.

Several commenters agreed that CMS should include the FMI measure in the HHVBP applicable measure set in the future because it would improve the completeness of the data set and falls are a concern relevant to home health that should be tracked. Other commenters expressed concerns about the accuracy of reporting, holding providers accountable for factors outside of their concern, and the potential that providers may be discouraged from admitting high-risk patients. CMS says it will consider the feedback in its future efforts.

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

CMS anticipates proposing through future rulemaking new HHCAHPS Survey-based measures to replace the Care of Patients, Communication Between Providers and Patients, and Specific Care Issues measures finalized in this section for removal, which would be based on data collected from the revised HHCAHPS Survey instrument. CMS describes how it would need one year of data to establish benchmarks and achievement thresholds while it would require two years of data to measure improvement and establish improvement thresholds.

[23] https://oig.hhs.gov/reports/all/2023/home-health-agencies-failed-to-report-over-half-of-falls-with-major-injuryand-hospitalization-among-their-medicare-patients/

In the 2026 HH PPS proposed rule, CMS sought feedback about *initially* measuring HHA performance on these potential measures based only on achievement to potentially allow it to begin using the revised measures (if proposed) beginning with the 2028 performance year. After sufficient data are available, 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

CMS also refers to the finalized HHCAHPS survey instrument modifications under section III.H, which include removing several items from the Specific Care Issues measure. In the 2026 HH PPS proposed rule, CMS sought feedback on the future possibility of adding each of the three remaining HHCAHPS survey items under that measure as a single-item measure under the HHVBP. The agency sought comment on the possibility of giving each of those single-item measures a weight of one-third the weight of other HHCAHPS items, which would collectively equal the same relative weight of the current specific Care Issues measure. The three items are the following:

- 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 two months of care, did home health staff from this agency talk with you about any side effects of your medicines?

In the final rule, CMS summarizes the comments it received. Several commenters disagreed with the agency's potential future uses for HHCAHPS Survey-based measures. Several other commenters did not support using only achievement points and believed incorporating achievement and improvement points at the same time would better recognize agencies that are improving and avoid additional disruptions. All commenters stated that agencies should be given the two-year period before these measures are reintroduced. CMS states it will consider the feedback in its efforts to refine the expanded HHVBP model in the future.

V. Updates to HHA Conditions of Participation (CoPs) to Align with OASIS All-Payer Submission Requirements

HHAs are required to submit data collected by the OASIS assessment as an HHA CoP. As described in section III.G, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 temporarily suspended OASIS requirements for collection of data on non-Medicare and non-Medicaid patients. CMS finalized in the 2023 HH PPS final rule that, beginning with the 2027 program year, the agency will end the temporary suspension of OASIS data collection on non-Medicare/non-Medicaid HHA patients and on the requirement for HHAs to submit all-payer OASIS data for purposes of the HH QRP.[24]

[24] 2023 HH PPS final rule (87 FR 66862-66865).

CMS is finalizing its proposed technical changes to update terminology to 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 OASIS all-payer submission requirements. The HHA CoPs at §484.45(a) require 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 not later than 30 days after completing the assessment of the beneficiary. The OASIS all-payer submission requirements refer to a "patient" instead of "beneficiary". CMS is aligning the terminology and therefore changing the reference in the HHA CoPs from "beneficiary" to "patient." In addition, CMS is removing the term "beneficiary" from the language at §484.55(d)(1)(i) that references a "beneficiary elected transfer" in order to support the transition to OASIS all-payer submission requirements. The agency clarifies that the proposal will not change current patient exemptions for OASIS, which are (i) patients under the age of 18, (ii) patients receiving maternity services, and (iii) patients receiving only personal care, housekeeping, or chore services.

VI. Provider Enrollment, Certain DMEPOS Accreditation Policies and DMEPOS Prior Authorization

A. Provider Enrollment

CMS is finalizing several changes to the existing Medicare provider enrollment regulations as well as a change to one of the Medicaid provider enrollment provisions.

1. Medicare Enrollment

The statute[25] requires the Secretary to establish a process for the enrollment of providers[26] into the Medicare program. The central purpose of the enrollment process is to verify that providers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable federal and state requirements. CMS summarizes the provider enrollment procedures and enrollment requirements which are generally codified in 42 CFR §§424.500 through 424.575.

CMS offers two principal categories of legal authorities for the proposed Medicare provider enrollment provisions, including section 1866(j) of the Act (which furnishes specific authority regarding the enrollment process for providers and suppliers) and sections 1102 and 1871 of the Act (which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program).

CMS notes that a number of comments received addressed multiple proposals and topics simultaneously, particularly with respect to revocations and stays of enrollment. Thus, in the final rule, CMS consolidated its summary of comments and responses and its final action into a single section labeled "Comments Received".

[25] Section 1866(j)(1)(A) of the Social Security Act
[26] Applies to "providers and suppliers" unless otherwise noted

a. Medicare Provider Enrollment Revocation and Denial Reasons, Revisions to Other Revocation Policies, Retroactive Revocations, and Stays of Enrollment

(1) Revocations and Denials

Under §424.535(a) and §424.530(a), CMS may revoke or deny (respectively) a Medicare provider's enrollment for several reasons including exclusion by the HHS Office of the Inspector General, felony conviction, a pattern of improper or abusive billing, or termination by another Federal health care program. If a provider's enrollment is revoked, that provider generally is barred from reenrolling in Medicare for up to 10 years, depending on the severity of the basis for revocation.

CMS proposed several additions and revisions to its revocation and denial policies:

- Under §§424.535(a)(13)(ii) and 424.530(a)(11)(ii)), CMS may revoke or deny a Medicare provider's enrollment for any state where the individual practices when the state suspends or revokes the person's ability to prescribe drugs. CMS proposed to revise §§424.535(a)(13)(ii) and 424.530(a)(11)(ii) to change "prescribe drugs" to "prescribe one or more drugs." This change would clarify that the state's prohibition need only apply to one drug as sufficient to warrant revocation or denial by CMS.
- Under §424.535(a)(14), CMS may revoke a Medicare provider'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. CMS proposed 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.
- Under §424.535(a)(8)(i)(A) to (C), the regulations enumerate certain example situations in which CMS may revoke enrollment if a 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. CMS proposed to include the situation in which the provider or supplier has submitted claims for payment involving service or items that the beneficiary states were never furnished.

Comments and responses are summarized below in (4). **CMS is finalizing its revocation and denial revisions as proposed.**

(2) Retroactive Revocations Bases

Section 424.535(g) addresses revocation effective dates. Paragraphs (g)(2)(i) through (viii) list eight situations where the revocation effective date is retroactive, generally meaning that the revocation becomes effective back to the date on which the provider's non-adherence to Medicare requirements commenced.[27] Due to continued serious concerns about improper payments to non-adherent providers and its responsibility to protect the Trust Funds, CMS proposed to further expand the bases for which the agency can apply a retroactive revocation effective date.

[27] In §424.535(g)(2), for example, the date of a felony conviction or the date of a state license suspension.

First, CMS proposed to add 7 new retroactive bases to §424.535(g)(2)[28] as follows:

- For revocations based on a lapse in the independent diagnostic testing facility's (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.

Second, CMS proposed to apply retroactive effective dates when CMS revokes a provider's enrollment for abusing billing privileges (described at §424.535(a)(8)(i) and (ii)).[29] Specifically, 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. The revocation effective date under paragraph (a)(8)(ii), meanwhile, would be the last date of service on the claims in question.

Finally, CMS proposed to make several technical changes involving retroactive revocations that it believed would be necessary as a result of the previous proposals. The technical changes are not reproduced in this summary for sake of brevity.

Comments and responses are summarized below in (4). **CMS is finalizing its retroactive revocation bases revisions as proposed.**

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

Under §424.541(a)(1) and (2), CMS can impose a stay of enrollment against a provider if the provider is non-compliant with at least one enrollment requirement in Title 42 and can remedy

[28] As proposed, the new bases would be designated as paragraphs (g)(2)(viii) through (xiv). Note that CMS proposes to remove the current basis at paragraph (g)(2)(viii), as explained in more detail below.

[29] Abusive billing practices include the following: Under paragraph (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, and under paragraph (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 non-compliance by submitting a CMS form, as applicable to the situation. In the proposed rule, CMS explains that a 'stay' 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.

In the proposed rule, CMS explains its belief that a provider submitting incomplete information should not be penalized as harshly as the provider that submits no information, but should be offered a stay of enrollment rather than deactivation. CMS therefore proposed to expand §424.541(a)(1)(i) to allow for a stay of enrollment (rather than deactivation) in instances where the provider's change of information or revalidation application is rejected under §424.525(a)(1) or (2).

In addition, CMS proposed several revisions related to the effective date of the stay, including:

- Instead of the stay period commencing upon the notification letter's postmark date, CMS proposed that the effective date of the stay would be, 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.
- CMS proposed several revisions clarifying that the stay period need not be 60 days but can be any timeframe up to that point.

Comments and responses are summarized below in (4). **CMS is finalizing its revisions to stay of enrollment authority as proposed.**

(4) Comments Received

The summary below includes selected comments and responses. A full review of the comments and responses can be found in the preamble of the final rule at section VI.A.1.c.(1).(d).

In general, numerous commenters believed CMS's proposals were overly punitive towards legitimate providers. They believe that the provisions lacked due process and failed to allow providers and suppliers to correct honest mistakes before CMS takes action. Commenters stated that revocations, in general, unfairly occur based on minor transgressions and financially devastate providers, even if the revocation is overturned on appeal. Commenters recommended that CMS consider the unintended consequences of the proposal. In response, CMS recognizes the concerns raised but reiterates its need for prompt action to prevent payments to non-compliant providers. CMS states that the agency's practice is to revoke providers only when truly warranted and after careful investigation. CMS reminds readers that enforcement is not limited to fraud but also applies to any non-compliance. While the agency understands the harm that can occur for providers who experience a revocation, it is ultimately the provider's responsibility to ensure constant adherence to Medicare enrollment requirements.

Commenters expressed concern about CMS' expanded revocation reasons, particularly beneficiary attestation as a ground for revocation, stating that there is a high potential for unintentional and innocuous misunderstandings and errors to be construed as fraud. Others suggested that a 'stay' of enrollment would be more appropriate than a revocation, or that a

revocation should only be imposed when there is a pattern. Others stated that CMS should require a 'stay' instead of giving MACs discretion to impose deactivation or revocation. In response, CMS notes that revocation based on beneficiary attestation is not a new revocation ground, and that the agency's proposal simply reiterates its authority in this regard. CMS states it would only revoke a provider's enrollment on the basis of a beneficiary attestation (1) after a thorough investigation of the facts of the case; and (2) when it is truly warranted. CMS declines commenter suggestions to develop an informal appeals process or 'stay' before a revocation would occur because a delay would leave the Medicare program at risk. Additionally, CMS notes that the MACs impose deactivations and revocations only at CMS' direction. CMS notes that revocation scenarios have never required a pattern of conduct. CMS assures stakeholders that the agency has no intention whatsoever of revoking the enrollment of legitimate providers under §424.535(a)(8)(i)(D) on spurious and unfair bases.

A commenter supported CMS' proposal to change the term "Part B or D drugs" in §424.535(a)(14) to "Medicare-covered drugs". A commenter supported CMS' proposal to change the term "prescribe drugs" in §§424.535(a)(13)(ii) and 424.530(a)(11)(ii) to "one or more drugs" while another opposed these changes, stating that a provider on this basis could be revoked for isolated or unrelated state licensing issues without any educational opportunity or appeal. In response, CMS reiterates that the agency always carefully examines the facts of the case before undertaking revocation action, and that providers can appeal a §424.535(a)(13) revocation per 42 CFR part 498.

A few commenters raised operational considerations and concerns with the provider enrollment process. While CMS views these comments as largely out of scope, CMS states it will take the information into consideration as it continues to take steps to enhance its provider enrollment process.

Numerous commenters opposed the concept of retroactive revocations in general. Some commenters questioned CMS' ability to determine a date of non-compliance for purposes of establishing the effective date. Several commenters specifically opposed retroactive revocation for administrative errors or for failure to submit certain changes of information citing reasons, such as IRS delays, that may be outside the control of the enrolled provider and delay reporting to CMS. Commenters expressed concern that these revisions would result in the punishment of otherwise compliant providers and create fear and instability in the marketplace. In response, CMS notes that retroactive revocations are designed to recoup payments to which the provider was not entitled due to its non-compliance. The agency's allowance of prospective revocation dates for the grounds in proposed §424.535(g)(viii) through (xiv) has resulted in hundreds of millions of dollars in payments to non-compliant providers; the agency accordingly believes it has an obligation to the American taxpayers to stop this. Additionally, as a result of careful case review, CMS is confident it will be able to ascertain the point at which non-compliance commenced. CMS further notes that retroactive revocation has been in effect for numerous years during which time the agency has not seen widespread fear or instability in the provider community. CMS states it remains the provider's responsibility to timely report enrollment information, however, the agency reiterates that it does not take action unless deemed truly necessary and only after a thorough examination of the circumstances of the case.

Regarding CMS' proposal to apply retroactive revocation to all other provider or supplier enrollments (under section 424.535(i)), commenters expressed concerns related to fairness and sought clarity as to whether retroactive revocations would be applied to other supplier locations under the same TIN or to all supplier locations under a common ownership. In response, CMS notes that §424.535(i) has been effective since 2019 and that the agency generally only invoked this provision in exceptional circumstances, not for minor matters, and that its application is not automatic. CMS can apply §424.535(i) to any and all of a provider's enrollments—including those under different names, numerical identifiers, or business identities.

b. 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.[30]

The deactivation concept has only applied to Medicare billing privileges rather than the ordering, certifying, and referring (OCR) of Medicare services and items described in §424.507(a) and (b). However, CMS states that this does not mean improper OCR poses a significantly less risk to the Medicare program and its beneficiaries than billing for Medicare services. Accordingly, CMS proposed to add new §424.547(a)(1)(i) and (ii) to state 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.[31]

Additional related and conforming changes were proposed by CMS. They included:

- 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.
- Adding the following language to the beginning of the definition of deactivate at §424.502: "Except in the situations described in § 424.547".
- Adding some of the deactivation and reactivation procedures and impacts found in §424.540 within new §424.547.

[30] CMS most recently addressed this issue in the CY 2024 HH PPS final rule that appeared in the November 13, 2023, Federal Register (88 FR 77676) in which CMS reduced the previous 12-month period to 6 months.
[31] CMS noted that starting with a 12-month period would be consistent with the 12-month timeframe it originally established in 2006 for provider billing, but that the agency may consider a shorter timeframe in future rulemaking after implementation, if warranted.

Comment/response: Several commenters expressed concern about the impact that application of CMS' deactivation provision would have on HHAs and hospices and made a variety of requests to CMS related to its processes and application of authority. In response, CMS states it will ensure databases are updated and maintain deactivation process efficiency. CMS notes that, similar to §424.540(a)(1), CMS will exercise its new §424.547 authority only after careful consideration and when deemed necessary. CMS further notes that this provision's purview is limited to Medicare fee-for-service individuals, and that it is unable to carve out regulatory exceptions when applying the authority.

A commenter stated that CMS' deactivation provision is contrary to the agency's regulations because there is no requirement that hospice physicians or physician members of the interdisciplinary group ("IDG") must order, certify, or refer for hospice services. Another stated their belief that the proposal could harm practitioners with low Medicare billing volumes but who otherwise deliver quality care. In response, CMS states that the agency's proposal involves the separate issue of a lack of ordering, certifying, and referring over a 12-month period by those enrolled via the Form CMS-855O and the consequent program integrity risk due to dormant provider numbers. As such, CMS declines to delay the requirement or to exempt certain practitioners. CMS clarifies that §424.547 applies to all the services and items referenced in §424.507. It is not limited to, for example, home health services.

Final action: After reviewing these comments, **CMS is finalizing this proposal without modification.**

c. Liability for Furnished Information

Under existing §§424.535(a)(4) and 424.530(a)(4), CMS may revoke or deny a provider's enrollment, if the provider or supplier certified as "true" misleading or false information on the enrollment application. CMS explains it has a longstanding policy that the enrolling provider bears ultimate legal responsibility for the accuracy and thoroughness of all data on the enrollment application to be enrolled or maintain enrollment in Medicare, even if a third party fills out the application on the provider's behalf. Attestations and certifications included on enrollment applications reinforce this policy. To emphasize this point, CMS proposed to add new paragraph (d)(10) to §424.510. Paragraph (d)(10) would state 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.

Comment/response: Several commenters supported CMS' proposed revision to §424.510, however, several commenters opposed it, stating their belief that it is unfair to shift legal liability to providers for all application information since providers often rely upon third parties for this information and the policy would increase risk of revocation for clerical errors and errors of data outside the provider's control. In response, CMS reasserts that the ultimate responsibility for submitting truthful and accurate information must rest with the provider, and that reliance on a third party is an independent business decision under which the provider may choose to assume some risk.

Final action: After reviewing these comments, **CMS is finalizing its proposal without modification**.

(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 because the potential exists for improper payments based on inaccurate enrollment information. 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 certain information and proof related to, for example, the provider's business and licensure.

Even so, in the proposed rule, CMS expressed concern about the MACs' ability to verify all information on the applications they receive. Therefore, CMS proposed in new §424.510(d)(2)(iii)(C) that the agency may require the submission of any other documentation needed to verify and confirm the information furnished on the enrollment application, including documentation regarding the provider's or supplier's ownership or management which poses a particular concern.

Comment/response: Several commenters supported the proposed change to §424.510 however, another commenter requested clear guidance on what documentation is required to better ensure consistency among the MACs. In response, CMS states it will instruct MACs on what documentation to request and when.

Final action: After reviewing the comments, **CMS is finalizing its proposal without modification**.

(e) Reassignment Effective Dates

In the provider enrollment context, 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.[32] Existing §424.522(a) states that a reassignment is effective beginning 30 days before the Form CMS-855R is submitted if all applicable requirements during that period were otherwise met. However, Form CMS-855R is now obsolete and the collection of reassignment information is currently facilitated via the Form CMS-855I and Form CMS-855B applications. CMS therefore proposed a revision to §424.522(a) to reflect the elimination of the Form CMS-855R.

Additionally, CMS believes that because reassignments are often initiated at the same time a physician or practitioner enrolls in Medicare via the Form CMS-855I, and reassignments are now captured on it, the effective dates of the two (that is, the initial enrollment and the reassignment) should be determined in the same manner. CMS therefore proposed to revise §424.522(a) to establish an effective date for the reassignment of benefits that mirrors the provisions in

[32] Consistent with 42 CFR 424.80

§424.520(d)(1)(i) and (ii)[33] related to the effective date of billing privileges for physicians and non-physician practitioners. Finally, CMS proposed to revise §424.522(a) to permit retrospective billing pursuant to a reassignment as described in §424.521(a)(1) if the circumstances in §424.521(a)(1) apply.[34]

Comment/response: A commenter requested that CMS increase the retroactive billing date to 60 days before their effective date instead of 30 days to ensure that providers have sufficient time to balance administrative requirements for multiple enrollments and multiple providers and to align with the maximum 60-day stay of enrollment period. In response, CMS declines the suggestion out of concern that the agency may be unable to determine whether the provider was compliant with enrollment requirements between the 31st and 60th days, which would be well before the provider submitted their enrollment application.

Final action: After reviewing this comment, **CMS is finalizing its proposal without modification**.

(f) DMEPOS Liability Insurance

Section 424.57(c) outlines a number of standards that DMEPOS suppliers must meet to become or remain 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. Considering the importance of the liability insurance requirement, CMS states it must ensure that the supplier, through its signature on the policy, is bound by its terms. Accordingly, CMS proposed to modify §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.

Comment/response: Several commenters opposed CMS' proposal to require an authorized official to sign the comprehensive liability insurance policy, stating that the authorized official's signature on the enrollment application is sufficient. Others objected for operational or practical reasons stating that in large organizations, the authorized official might not be the same person responsible for maintaining the company's liability insurance. In response, CMS clarifies its goal is to ensure that the individual(s) signing both documents have the authority to do so. An 'authorized official' is not required to have the title of chief executive officer or president, but must have the authority described in the definition. Moreover, the signing authorized official need not be the same person for both Form CMS-855 and the liability insurance policy.

[33] 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 (1) the date of filing of a Medicare enrollment application that a MAC subsequently approved; or (2) the date the individual first began furnishing services at a new practice location.

[34] 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 (1) 30 days before their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or (2) 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.

Final action: After reviewing these comments, **CMS is finalizing its proposal without modification**.

(g) Adverse Legal Actions

Consistent with §424.516(b) through (d), certain Medicare provider and supplier types, such as DMEPOS suppliers, must report any adverse actions (for example, felony convictions) imposed against them, their owners, managing employees or organizations, or corporate directors or officers within 30 calendar days of the action. However, other provider and supplier types have 90 days to report this information. To make these timeframes consistent and to ensure that CMS is alerted much sooner of the concerning actions, CMS proposed to require (within §424.516(e)(1)) that all providers and suppliers, regardless of type, would have 30 days, rather than 90 in some instances, to disclose any adverse legal action.

Comment/response: Several commenters opposed CMS' proposal for all providers and suppliers to report adverse action changes within 30 days, with one commenter stating that it may create compliance burdens without clear evidence of improved oversight outcomes. In response, CMS notes that certain other provider and supplier types have long been subject to a 30-day adverse action reporting requirement, yet the agency is unaware of any undue burden that has resulted therefrom.

Final action: After reviewing these comments, **CMS is finalizing its proposal without modification**.

(h) 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). Under §424.205(b) or (d), CMS may revoke or deny enrollment of an MDPP if the MDPP violates an enrollment condition or standard, respectively. These sections were established at different times and §424.205 has undergone revisions to its organizational structure, resulting in a number of mismatches and errors across the regulations which CMS proposed to correct. The details of these mismatches and errors, along with the proposed corrections, are summarized by CMS in the preamble of the final rule.

Additionally, when an MDPP supplier fails to meet certain conditions and standards, CMS has authority under both §§424.530(a)(1) and (a)(18) to deny an MDPP supplier's enrollment. CMS also has authority under both §§424.535(a)(1) and (a)(23) to deny an MDPP supplier's enrollment. Thus, CMS proposed to reference both authorities by adding "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).

CMS did not receive any comments on these proposed changes and is therefore **finalizing them without modification.**

(i) Deactivation Reason Clarification

Section 424.550(b) addresses "change(s) in majority ownership" (CIMO)[35] 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. CMS notes that in such situations, §424.540(a)(8) permits CMS to deactivate the seller's billing privileges, because the seller is leaving Medicare. However, §424.540(a)(8) currently only references sellers in an HHA CIMO and not those in a hospice CIMO. As a technical clarification, CMS proposed to include a hospice CIMO seller within the scope of §424.540(a)(8).

CMS did not receive any comments on this proposal. Therefore, **CMS is finalizing its proposal without modification**.

2. Medicaid and CHIP Enrollment and Termination

The Medicaid program and the Children's Health Insurance Program (CHIP)[36] are joint federal and state health care programs. In operating Medicaid and CHIP, 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. States may also establish their own provider enrollment requirements which must be met in addition to the applicable federal provider enrollment requirements.

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.[37] One such requirement, outlined in section 1902(a)(39) of the Act, 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.[38]

This provision of section 1902(a)(39) of the Act is 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 other state. That is, the word "and" is between the references to Medicare and 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, CMS proposed to change the aforementioned "and" reference to "or".

[35] As CIMO is defined in §424.502
[36] Medicaid is under title XIX of the Social Security Act and CHIP is under title XXI of the Social Security Act.
[37] All of subpart E, and 42 CFR 455.107 in Subpart B, are applicable to CHIP in accordance with §457.990.
[38] Under §455.417. CMS has developed and currently operates the required 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.

CMS received no comments on this proposal and is therefore **finalizing it without modification.**

B. DMEPOS Supplier Accreditation Process

In this section of the final rule, CMS addresses the changes it is finalizing related to the DMEPOS supplier accreditation process at §424.58. These proposals are finalized as proposed with three minor modifications (addressed below). In the final rule, CMS repeats the proposals it made, which are expansive and detailed, and summarizes and responds to comments in a separate section. As a result, HPA has elected to summarize the proposals at a very high level in order to focus on comment section and CMS' final policies. Additionally, HPA has developed the following table which summarizes the effect of CMS' final policies on the regulation.

New structure of paragraphs and headings at §424.58	Previous §424.58 paragraphs related to finalized policies	Effect of final policies on previous §424.58 paragraphs
§424.58(a) Scope and Purpose	§424.58(a)	Unchanged
§424.58(b) Definitions	None	New
§424.58(c) Initial application procedures	§424.58(b)(1)	Modified and expanded
§424.58(d) Reapproval process	§424.58(b)(1)	Modified and expanded
§424.58(e) Ongoing responsibilities of a CMS-approved AO	§424.58(c)	Modified and expanded
§424.58(f) Continuing federal oversight of AOs	§424.58(d)(1) to (2) §424.58(b)(2) to (6)	Modified and expanded
§424.58(g) Voluntary termination of CMS-approved accreditation program	None	New
§424.58(h) Involuntary termination	§424.58(d)(3) to (4)	Modified and expanded
§424.58(i) Suspension	None	New
§424.58(j) Probation	None	New
§424.58(k) Noncompliance actions	None	New
§424.58(l) Reconsiderations and rebuttals	§424.58(e)	Modified and expanded
§424.58(m) Restrictions on consulting	None	New
§424.58(n) Conflicts of interest	None	New
§424.58(o) Changes of ownership	None	New

1. Overview of DMEPOS Accreditation and Legal Authorities for Proposed Provisions

a. DMEPOS Suppliers Background and Program Integrity Concerns

Among the types of providers and suppliers that must enroll in Medicare to bill the Medicare program are DMEPOS suppliers. Examples of such suppliers include: Medical supply companies; 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. In general, such suppliers enroll in Medicare via the Form CMS-855S application[39] which is devoted to this single provider type.

[39] Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); OMB Control No. 0938-1056.

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.

In the proposed rule, CMS explained that 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. However, serious concerns remain.

b. Quality Standards for DMEPOS Suppliers

By statute[40], the Secretary is required to establish and implement DMEPOS quality standards for suppliers of certain items, including covered items, prosthetic devices, and others.[41] CMS explains that the standards are both extensive and detailed because the agency must confirm that the supplier is bona fide and legitimate. All DMEPOS supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards to enroll in and bill Medicare.[42]

c. Accreditation of DMEPOS Suppliers by a CMS-approved Accrediting Organization (AO)

DMEPOS suppliers must be accredited by a CMS-approved accrediting organization (AO) to enroll in and bill Medicare.[43] All DMEPOS supplier locations must be separately accredited, however, the statute exempts certain individuals unless the Secretary determines the quality standards specifically apply to them. There are presently 8 DMEPOS AOs. To become an AO or be retained or reapproved as one, the AO must meet certain regulatory requirements which include, for example, submitting certain information during an applications process, undergoing various CMS reviews, and furnishing ongoing information to CMS about its activities.

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. In accordance with CMS' subregulatory guidance, DMEPOS suppliers currently must be surveyed once every 3 years following initial accreditation.

[40] Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added section 1834(a)(20) of the Act
[41] As described in sections 1834(a)(13), 1834(h)(4), and 1842(s)(2) of the Act (respectively).
[42] 42 CFR §424.57(c)(24)
[43] Consistent with section 1834(a)(20)(F)(i) of the Act (and with certain exceptions)

d. Concerns About the Existing DMEPOS Accreditation Process, Linkage and Conclusion

The proposed rule contained a substantial number of proposed additions and revisions to CMS' current DMEPOS accreditation process. Aside from the overarching need to improve and strengthen its process, CMS outlines several other reasons behind its proposals including those related to:

- Efficacy of some AO accreditation surveys and reviews;
- Accreditation process differences between the AOs and potential inconsistencies in how quality standard compliance determinations are made;
- Vulnerabilities introduced when some suppliers don't receive surveys;
- The scope of the DMEPOS accreditation process components, as outlined at 42 CFR §424.58 which, in CMS' view, does not address other important topics that should be included;
- The fact that, since 2006, CMS has neither approved any AOs nor undertaken a full reassessment of the performance and suitability of existing AOs; and
- The unique program integrity risk that DMEPOS suppliers pose.

CMS noted that the agency recently proposed updated and supplemental provisions to enhance CMS' oversight of certified provider and supplier AOs (under 42 CFR part 488)[44] and that the agency desired to promulgate similar proposals for DMEPOS accreditation under §424.58.

e. Legal Authorities for Proposed Provisions

For its proposals, CMS relies on its authorities granted by sections 1834(a)(20)(A) and (B) of the Act which requires the Secretary to establish and implement quality standards for the suppliers of DMEPOS items and services by recognized independent AOs, and to designate and approve one or more independent AOs for purposes of applying the quality standards. Section 1834(a)(20)(F)(i) of the Act (and with certain exceptions) requires DMEPOS suppliers to submit to the Secretary evidence of accreditation by an AO. CMS also relies on its authorities. Finally, CMS references sections 1102 and 1871 of the Act which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

2. <u>DMEPOS Accreditation Proposed Provisions</u>

Section 424.58, which governs DMEPOS accreditation, contains several principal paragraphs designated (a) – (e). CMS proposed to entirely reorganize the regulation's paragraph structure and designations in §424.58 related to DMEPOS accreditation.

a. Definitions (New §424.58(b))

CMS proposed to establish several new definitions new §424.58(b), including definitions for "complaint", "immediate jeopardy", "reasonable assurance", "unannounced survey", and "immediate family member".

[44] In the February 15, 2024, Federal Register (89 FR 11996), CMS published a proposed rule titled "Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions."

b. Initial Application for Approval of AO's Accreditation Program (New §424.58(c))

CMS proposed to outline the process by which an entity may apply or reapply to become an AO in new paragraphs (c) and (d), respectively. CMS noted it had not revisited the data elements that AOs must submit as part of the application process since 2006. The agency now believes much more detailed and comprehensive data should be submitted so that it can fully ascertain a current or prospective AO's qualifications. Accordingly, CMS proposed changes and additions to the initial application procedures as follows:

(1) Reasonable Assurance Opening Statement (New §424.58(c)(1)). An AO applying for approval or reapproval of its DMEPOS accreditation program must furnish certain information to CMS. CMS proposed language to 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)). CMS' proposed revision would require an AO to furnish, as part of its initial application, 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. CMS proposed to retain and redesignate the currently required six elements for describing the AO's operational process. In addition, CMS proposed to require the AO to submit, as part of its initial application, a 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.

(3) Redesignation of Existing Data Submission Provisions (New §424.58(c)(1)(i), (ii), (iv), (v), (vi), and (vii)(A), (B), and (C)). CMS proposed to retain and redesignate the additional information that an AO must currently furnish, strictly for organizational purposes.

(4) Conflicts of Interest, Consulting Services, and Number of Surveyors (New §424.58(c)(1)(vii)(D) and (E)). CMS proposed that the AO would be required, in its initial application, 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. Additionally, CMS proposed to include that 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.[45] CMS also proposed to require the AO to outline its policies and procedures for ensuring it always has an adequate number of surveyors.[46]

[45] CMS notes that this requirement duplicates the requirement proposed for national AOs seeking to accredit certified providers and certified suppliers under Part 488 (see 89 FR 11996)

[46] CMS notes that this requirement would be somewhat similar to the current requirement for national AOs applying to CMS under §488.5(a)(6).

(5) AO Program Deficiencies (New §424.58(c)(1)(viii)). CMS proposed to require the AO to describe, in its initial application, its processes for identifying and correcting deficiencies within its accreditation program.

(6) Use of Data to Ensure Program Compliance (New §424.58(c)(1)(ix)). CMS proposed to retain and redesignate the existing requirement that an AO, as part of the application process, must submit a description of 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. CMS proposed that the AO must also submit a detailed description explaining how the AO uses its data to ensure the compliance of its accreditation program adheres to Medicare program requirements.

(7) Complaint Process (New §424.58(c)(1)(x)). Currently the AO must furnish to CMS, as part of the application process, 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. CMS proposed to specify additional information that the AO must include for how it responds to complaints. Additionally, CMS proposed that the AO must submit its procedures for closing out complaints. Finally, CMS proposed to change the NSC reference to "the applicable National Provider Enrollment contractor" because they have replaced the NSC as CMS' DMEPOS enrollment contractors.

(8) Redesignation of Additional Data Submission Provisions (New §424.58(c)(1)(xi) through (xv)). CMS proposed to retain and redesignate several other types of information an AO must submit as part of the application process. CMS proposed that the AO must additionally submit each supplier's accreditation product codes and effective date.

(9) Knowledge and Experience (New §424.58(c)(1)(xvi)). CMS proposed to require an AO to submit, in its initial application, information that demonstrates the AO's knowledge, expertise, and experience in DMEPOS at new §424.58(c)(1)(xvi).[47]

(10) Review Timeliness (New §424.58(c)[1](xvii)).[48] CMS proposed that the DMEPOS AO, as part of its initial application, furnish information about its ability to conduct timely reviews of supplier accreditation applications.[49]

(11) Decision-Making Process (New §424.58(c)(1)(xviii)). CMS proposed to require the AO, as part of its initial application, to describe its accreditation decision-making process, including its policies and procedures for approving, denying, or terminating a DMEPOS supplier's accreditation status. This would also include an explanation of the reasons for which the AO will deny or terminate a supplier's accreditation.

[47] CMS notes that this provision mirrors existing §488.1010(a)(4), which pertains to home infusion therapy supplier accreditation.
[48] In this section, CMS appears to have inadvertently dropped the (1) from the regulatory citation in the preamble. HPA has added it in brackets to this summary in order to match the finalized reg text.
[49] CMS explains that this requirement mirrors an existing requirement for provider and supplier AOs found at §488.1010(a)(6)(vii).

(12) Surveys (New §424.58(c)(1)(xix)). CMS proposed that the AO, as part of its initial application, furnish its policies and procedures related to performance of surveys, including how the AO determines whether and when a survey is performed, and ensuring that all onsite surveys are unannounced.

(13) Corrective Action Plans (CAPs) (New §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. CMS proposed several provisions to enable the agency to gain a clearer understanding (and, more importantly, to exercise greater oversight) of the AOs' CAP processes as part of the AO's initial application submission. Information to be submitted would include 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.

(14) Describing and Defining DMEPOS Supplier Deficiencies (New §424.58(c)(1)(xxi)). CMS proposed that the AO, in its initial application, must furnish to CMS an explanation of what it considers to be a supplier deficiency, how it defines the term deficiency, and whether the AO has different levels of DMEPOS supplier deficiencies.

(15) Potentially Fraudulent Activity (New §424.58(c)(1)(xxii)). While the AO's principal function is to perform accreditation activities, CMS states that the AO must not disregard possible fraud, waste, or abuse by suppliers and believes that the AO should have procedures in place for handling these and other situations and referring them to CMS and, as applicable, law enforcement. Therefore, CMS proposed that the AO, in its initial application, must describe its processes for detecting, addressing, and reporting potential fraud, waste, and abuse by suppliers. The description would identify the AO's definitions of the terms "fraud", "waste", and "abuse".

(16) Agreement of Compliance (New §424.58(c)(1)(xxiii)).[50] CMS believes that DMEPOS AOs should have to explicitly agree to certain conditions as part of the application process. CMS therefore proposed that the AO's chief executive officer (CEO) (or similar official with authority) must 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). Additionally, the AO must agree to:

- Provide CMS within 3 business days of CMS' request: (1) any of the data described in §424.58(e)(1)(i), and (2) any other information CMS deems necessary to facilitate its oversight of the AO's accreditation program.
- 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.
- Furnish notification of any changes to its accreditation standard, requirements, or survey process to CMS in writing and that the AO will not implement such changes absent prior written notice of continued program approval from CMS.

[50] CMS notes that some of the requirements proposed in new §424.58(c)(1)(xxiii) would refer to proposed new paragraphs in §424.58 (addressed later in the preamble).

- Provide notification in writing to CMS within 3 business days of the AO's action to terminate or make another change in a supplier's accreditation status.[51]
- Inform CMS of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. The notification 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.
- Submit timely, accurate, and complete data to support CMS' evaluation of the DMEPOS accrediting organization's performance. The data to be submitted would include, but not be limited to, DMEPOS supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions; and the organization must submit necessary data according to the instructions and timeframes CMS specifies.
- 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, within 30 calendar days, 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.
- Accept and adhere to any CMS-established deficiency definitions and levels and categories thereof.
- Submit all required information to CMS both before and after approval of its accreditation program in a truthful, accurate, and complete manner.
- Comply with all of the requirements in §424.58 at all times.

Additionally, CMS proposed that the AO must agree that:

- Its surveyors can serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation finding.
- 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.
- The AO will not use mock files, fictional patients, simulated documentation, duplicate patient records, or templates in its surveys.
- The AO will 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.

(17) Additional Information Needed and Withdrawal of Application (New §424.58(c)(2) and (c)(3)). CMS believes it may need additional information to fully assess the AO's credentials. Thus, CMS proposed that if the agency determines that further data is necessary to make a determination on the AO's request for approval, CMS would notify the organization and afford it an opportunity to provide this data. Additionally, CMS proposed that an AO may withdraw its initial application for approval of its accreditation program at any time before CMS posts the approval notice.[52]

[51] CMS notes a similar existing requirement for home infusion therapy suppliers at 488.1010(a)(17)(iv).
[52] CMS has a similar existing requirement with respect to AO applications for HIT supplier accreditation at §488.1010(c).

(18) Reasons for Denial of an AO's Application (new §424.58(c)(4)). Section 424.530(a) lists 18 reasons for which CMS can deny provider or supplier enrollment applications, including those from DMEPOS suppliers. While DMEPOS AOs, unlike DMEPOS suppliers, neither enroll in Medicare nor receive Medicare payments, an AO's qualifications and performance can impact the payment of hundreds of millions of Medicare dollars. CMS therefore believes it is especially important to have clear reasons in §424.58 for which the agency can deny an AO's application for approval of its accreditation program. CMS proposed denial grounds in new paragraphs (c)(4)(i) through (viii), several of which duplicate those in existing §424.530(a).

(19) Notice of Approval/Denial, Public Notice, and Length of Approval (New §424.58(c)(5) through (7)). CMS noted that the existing regulation did 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 address this issue, CMS proposed to incorporate several notice of denial procedures including the timing, contents, and posting of the notification.[53] CMS also proposed that CMS may approve an accreditation program for any period up to a maximum of 6 years.

c. AO Reapproval Process (New §424.58(d)).

In new §424.58(d), CMS proposed the application procedures for reapproval of an AO's DMEPOS accreditation program. Many of these procedures generally duplicate those for initial applications in terms of content and rationale (established at new §424.58(c)(1)-(7)). CMS proposed that 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. CMS further proposed to retain discretion to grant the AO an additional 30 days to reapply. Additionally, CMS may require AOs to submit reapproval applications any time after January 1, 2026 (the updated regulation effective date). Such an application would have to be submitted within 60 calendar days of CMS' request; if it is not, CMS would terminate the AO's DMEPOS accreditation approval.

d. Ongoing Responsibilities of a CMS-Approved AO (New §424.58(e)).

CMS proposed to expand on the existing ongoing AO requirements at §424.58(c)(1) through (6).

(1) Submission of Information, Requested Information, and Immediate Jeopardy Deficiencies (New §424.58(e)(1) to (3)). Currently, under §424.58(c)(1), AOs are required to provide CMS, in a written format (either electronic or hard copy) and on a monthly basis, five categories of data (at existing subparagraphs (i) through (v)). CMS proposed to retain the AO's monthly data submission requirements and expand on them. Select proposals included:

- In the opening paragraph of (c)(1) (which CMS is redesignating as new paragraph (e)(1)(i)), CMS proposed to change the reference "on a monthly basis" to "no later than the last day of each month." As noted below, CMS is not finalizing this proposal.
- The data submission 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.

[53] These requirements mirror existing provider and supplier accreditation regulations (§§488.1010(d) and 488.1020).

- The AO must submit monthly notice of resolved deficiencies.
- CMS proposed to retain requirements related to monthly reporting of accreditation decisions and adverse actions.

Additionally, CMS proposed that, at any time, CMS may request the AO to submit any of the information described in paragraph (e)(1)(i) or any other data CMS deems necessary to facilitate its oversight of the AO's accreditation program. The AO must furnish this data to CMS within 3 business days. Finally, CMS proposed to retain the requirement that AOs provide CMS notice of immediate jeopardy deficiencies and any adverse action implemented by the AO in response within 2 calendar days of its identification (new paragraph (e)(1)(iii)).

(2) AO Standard or Requirement Changes (New §424.58(e)(2))

Currently, on a monthly basis, AOs are required to provide notice to CMS of any proposed changes to its accreditation standards, requirements, or survey process; the AO cannot implement the change without prior CMS approval. If the organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the AO. CMS proposed several changes related to this notification requirement and processes which would become codified at new §424.58(e)(2), including:

- Requiring the AO's notice of proposed changes to be written, which is the current practice, and that the notice must include "the addition, modification, or removal of a new DMEPOS product service category to the list of categories for which the organization accredits DMEPOS suppliers."
- Instead of submitting this information monthly, CMS would require the AO to submit the notice at least 60 calendar days before the proposed change's intended effective date. The notice must 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.
- CMS would furnish the AO written approval or disapproval of the proposed change within 30 calendar days of the revision's effective date.
- Restating for emphasis that CMS may terminate or suspend its approval of the AO if the latter implements the change before or without CMS approval.

(3) Complaints (New §424.58(e)(3))

Currently, AOs are required to provide monthly notice to CMS of all complaints involving suppliers. To address a lag in notice of complaints and ensure they are thoroughly considered, CMS proposed to revise complaint submission requirements which would be codified in new §424.58(e)(3). Specifically, CMS proposed that, upon receipt of a complaint, the AO must:

- 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.

In addition, CMS proposed that, no later than 10 calendar days after completion, the AO would give CMS written notice of the result of the initial review or, as applicable, the survey performed by the AO. Further, this 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.

(4) CAPs (New §424.58(e)(4))

CMS proposed that AOs would be required to notify CMS in writing of any decision to apply a CAP to a specific supplier within 10 days of the decision. The AO would be required to include in the notification: the AO's 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.

(5) Accreditation Denials and Terminations (New §424.58(e)(5))

CMS proposed to establish additional notification requirements related to denials and terminations of DMEPOS suppliers. Specifically, CMS proposed the following:

- The AO would be required to 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.
- Notwithstanding any other provision in §424.58, an AO must deny or terminate a supplier's accreditation under certain conditions (such as when directed by CMS or when the supplier is not operational).
- If directed by CMS to deny or terminate the supplier's accreditation, the AO must do so 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.

(6) Annual Summary of Data and CMS Changes (New §424.58(e)(6) and (7))

Currently, AOs must provide to CMS, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. CMS proposed to retain this requirement without change and redesignate it as new §424.58(e)(6).

Currently, AOs must, within 30 calendar days of a change in CMS requirements, submit to CMS: (1) an acknowledgement of CMS's notification of the change; (2) a revised cross walk reflecting the new requirements; (3) an explanation of how the AO plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification of change it receives from CMS. CMS proposed to retain this requirement with revisions and one addition at new §424.58(e)(7)(i) and (ii), respectively, for more specificity as outlined in the final rule preamble. CMS proposed that the AO must not implement its proposed corresponding changes without prior CMS approval.

(7) Performance of Surveys (New §424.58(e)(8))

Requirements related to accreditation surveys for DMEPOS suppliers are not currently codified in regulation, and not every DMEPOS supplier receives an accreditation survey. Therefore, CMS proposed stricter and more expansive requirements regarding the performance of surveys that would be codified in new §424.58(e)(8). They included the following**:**

- The AO would be required to perform a survey of all supplier locations for which the supplier seeks accreditation or reaccreditation, except as otherwise directed or permitted in writing by CMS (for example, allowing sampling).
    - This requirement would include accreditations for a new item type the supplier has not previously furnished or as required under §424.551.[54]
    - An AO would be required to perform all surveys as unannounced surveys.
    - An AO would be prohibited from accrediting the DMEPOS supplier before the survey is performed and determines the supplier is compliant with the quality standards.
- CMS may, at any time, direct the AO to perform a survey of a supplier or group thereof; the existence of an actual or suspected supplier deficiency would not be a requirement for CMS to direct the performance of such a survey.
- When performing a survey, the AO would be required to confirm that the supplier meets the licensure requirements in §424.57(c).

(8) Surveyor Witnesses (New §424.58(e)(9))

Currently, AO are required to allow its surveyors to serve as witnesses if CMS undertakes an adverse action against a supplier in response to an accreditation finding.[55] CMS did not propose to make changes to this requirement, however, consistent with its reorganization of §424.58, this requirement would become new paragraph §424.58(e)(9).

(9) Entrance of Data into System (New §424.58(e)(10))

CMS proposed that, if directed by CMS, the AO must enter accreditation, survey, product code, and other data into a CMS-designated system to which CMS and National Provider Enrollment (NPE) contractors would have access.

(10) Adverse Actions (New §424.58(e)(11))

As discussed earlier in the preamble, CMS proposed to 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). In new §424.58(e)(11), CMS proposed 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.

[54] Section §424.551 was newly proposed and addressed elsewhere in this final rule.
[55] Currently required at §424.58(c)(3)

e. Continuing Federal Oversight of AOs (New §424.58(f))

Existing §424.58(d) outlines specific criteria and procedures for CMS' ongoing review of AOs (which includes equivalency reviews and validation surveys) and for withdrawing approval of AOs. CMS proposed to retain some of the provisions of existing §424.58(d), which would become new §424.58(f), along with changes to parts of its contents and structure that CMS believes is necessary to improve clarity and strengthen oversight. CMS also proposed to address the current §424.58(d) provisions regarding terminations of AOs in new paragraph (h) as discussed below. As a result, CMS proposed to revise the opening paragraph of new §424.58(f) to state that CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis. Additionally, CMS proposed that the means of monitoring would include, but not be limited to, the reviews identified in new paragraphs (f)(1) to (4) as discussed in more detail below.

(1) Equivalency Reviews (New §424.58(f)(1))

Currently, under §424.58(d)(1), an equivalency review involves CMS' comparison of the AO's standards (and the AO's application and enforcement thereof) to CMS requirements and processes under certain specified circumstances.[56] CMS proposed, at new paragraph (f)(1), 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 Suppliers (New §424.58(f)(2))

CMS proposed several modifications related to validation survey policies which were intended to both consolidate and streamline current requirements and to enhance that agency's ability to perform such surveys. Specifically, at new §424.58(f)(2), CMS proposed to retain authority to perform validation surveys of DMEPOS and other items and services accredited in order to validate the AO's survey process on an ongoing basis. Additionally, CMS proposed to:

- Incorporate all validation survey provisions within new paragraph (f)(2), rather than having them separated as they currently are between existing (b)(2) and (d)(2).
- Remove the references to specific circumstances under which: (1) such surveys may be conducted or (2) CMS may reach conclusions that indicate problems with the AO's accreditation program.
- Retain and redesignate all existing requirements at §424.58(b)(3) through (6) as new §424.58(f)(2)(ii) to (v), with one technical revision to change "supplier billing number" to "enrollment" because the latter is the more accurate term.

(3) Deficiencies (§424.58(f)(3))

As previously discussed, CMS proposed that an AO would submit, as part of its application, a statement to CMS under which, among other things, the AO would agree to accept and adhere to

[56] Currently specified circumstances at paragraph (d)(1)(i) to (iii) include when: (i) CMS imposes new requirements of changes its survey process; (ii) an AO proposes to adopt new standards or changes its survey process; or (iii) the term of an AO's approval expires.

any CMS-established deficiency definition as well as levels and categories of deficiencies.[57] 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, CMS proposed the following, at new paragraph (f)(3):

- CMS would have discretion to: (1) define the term 'deficiency'; (2) establish levels and categories of deficiencies; and (3) revise the quality standards.
- 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.

(4) Additional Reviews (§424.58(f)(4))

CMS proposed to expand upon the reviews of DMEPOS AOs it already conducts**.** These new review requirements would be codified at new paragraph (f)(4) in which CMS proposed:

- That CMS may, at any time and for any reason, conduct a review of the AO's processes or performance to (1) validate the AO's representations to CMS; or (2) assess the AO's adherence to its own policies and procedures, the provisions of §424.58, and all other CMS requirements.
- That the scope, length, and timing of a review would lie within CMS' discretion. Furthermore, evidence of the AO's potential noncompliance with any of the policies and requirements would not be required for CMS to perform a review.
- To codify types of reviews that CMS may perform collectively or individually. CMS explained that some types of reviews are already reflected in existing provisions at (d)(2) while the others are newly proposed types that are similar to reviews proposed in the February 15, 2024 proposed rule for certified providers and suppliers in 42 CFR 488.8(h). They include such activities as equivalency reviews, examining results of surveys, and conducting onsite inspections of the AO's operations and offices.

f. Terminations of CMS-Approved AO Accreditation Programs (New §424.58(g) and (h))

(1) Voluntary Terminations (New §424.58(g))

To ensure that DMEPOS AOs seeking voluntarily termination follow a specific, uniform process for doing so and, more importantly, that CMS and accredited suppliers are given adequate notice thereof, CMS proposed to establish voluntary termination procedures in new §424.58(g).[58] CMS proposed that an AO may voluntarily terminate its CMS-approved DMEPOS accreditation program at any time. In doing so, the AO would be required to do the following:

- 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:

[57] As proposed, the provision would be codified at new §424.58(c)(1)(xxiii).
[58] These provisions mirror existing sections 488.5(c)(2), 488.8(g)(2), and 488.1045(a) which outline procedures for an AO to voluntarily terminate its CMS-approved certified provider/supplier or HIT supplier accreditation program.

- Describe the provisions concerning the expiration dates of the supplier's accreditation with the terminating AO (as discussed below); 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) would result in the revocation of its enrollment under §424.535.

CMS proposed 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 would remain effective until the earliest of the expiration of its current term of accreditation with the terminating AO or the effective date of its accreditation with a different CMS-approved AO.

(2) Involuntary Terminations (New §424.58(h))

Currently, there are two reasons for which CMS can terminate its approval of an AO's DMEPOS accreditation program, including: (1) a failure of the AO to adequately ensure that its suppliers comply with the quality standards or (2) that the AO has not met its obligations regarding initial application or reapproval application procedures. CMS proposed to expand the reasons it may terminate a DMEPOS AO, including if CMS determines that:

- The AO no longer demonstrates reasonable assurance;
- 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.
- 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.

Additionally, CMS proposed that it may terminate the AO's accreditation program effective the date of the termination letter or any date thereafter.

CMS proposed to establish new operational procedures for terminating an AO's approval and to address the consequent impact on suppliers:[59]

- CMS would give written notice to the AO of its termination decision. The notice would include the reason for and effective date of the termination.
- As with AO initial application submissions, CMS would announce its decision (and the effective date thereof) on its website.
- 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: (1) explain the provisions concerning the expiration dates of the supplier's accreditation with the terminated AO, and (2) inform the supplier that any lapse in its accreditation results in its enrollment being revoked under §424.535.

[59] The new policies in §§424.58(h)(2) through (4) would be akin to various provisions in §§488.1030(f), 488.8(e), and 488.1045(b).

- If CMS terminates an AO's approved status, the AO 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.

Further, CMS proposed that, 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 would remain 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. Should CMS specify such a date, CMS would notify the affected supplier about it in writing and identify the deadline by which the supplier must be reaccredited by a different AO.

Finally, CMS proposed that the terminated AO would have to refund all payments made by a supplier 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.

g. AO Suspensions and Probations (New §424.58(i) and (j))

Currently, termination is the only remedy available to CMS under §424.58 to address AO performance issues. CMS does not believe AO non-compliance should only be addressable by a termination-or-no-termination approach. Having multiple available remedies would allow the agency to correspond its action to the relative severity of each case. Therefore, CMS proposed to establish the ability to suspend an AO's accreditation program or put the AO on probation if necessary.

(1) Suspension (New §424.58(i))

CMS proposed to establish the ability to suspend an AO's accreditation and to specify (1) reasons for suspension, (2) the components of a suspension, including a prohibition on conducting any DMEPOS accreditation activities while suspended which would be a maximum of a year, (3) notification procedures, (4) the status of DMEPOS suppliers currently accredited by the AO, (5) conditions under which the suspension would be lifted, (6) refunds of DMEPOS supplier payments.

Further, CMS proposed that nothing in §424.58(i) would prohibit CMS from suspending an AO's accreditation program more than once.

(2) Probation (New §424.58(j))

To further enhance its ability to address DMEPOS AO non-compliance in a manner proportional to the degree of its non-compliance, CMS proposed to establish a process for placing a DMEPOS AO's accreditation program on probation in lieu of a termination or suspension.[60] Under this

[60] Existing regulatory provisions at Part 488 contain a probation process for AOs that accredit certified providers and suppliers, and for HIT suppliers.

new probation process, CMS proposed to specify (1) reasons for placing the AO's accreditation program on probation and requiring successful completion of a CAP, (2) contents of the notification to the AO, and (3) contents of the notification of the conclusion of the probationary period.

CMS proposed that, except as otherwise prescribed in the CAP, the AO could continue its accreditation activities as normal. If the agency determines that the AO has resumed compliance, CMS may send notice to the AO, terminate the probationary period, and end the CAP before the conclusion of the assigned probationary period. Because AOs, under these actions, would typically be able to continue their activities without interruption, CMS did not propose to post notice of the probation and CAP on the CMS website.

h. CMS Discretion, Change in Non-Compliance Actions (New §424.58(k))

CMS stressed its belief in the importance of having several types of administrative actions to address AO non-compliance. CMS therefore proposed that the agency would have discretion to impose a certain action (specifically, those proposed in new paragraphs (h), (i), or (j)) in lieu of another such action specified in those paragraphs if the same ground(s) for the action exists. CMS explains this means that, for example, if the AO is non-compliant with the requirements at §424.58, CMS could choose to terminate the AO's approval rather than suspend the accreditation program or place it on probation.

Additionally, CMS proposed that it would be able to terminate 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. CMS proposed it would be able to terminate 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.

i. Reconsiderations and Rebuttals (New §424.58(l))

(1) Denials and Involuntary Terminations (New §424.58(l)(1))

CMS proposed to remove the existing reconsideration provisions from §424.58(e) and replace them with the reconsideration processes at 42 CFR part 498 instead. This new reconsideration provision would be codified at new §424.58(l)(1). It would apply following CMS's initial determinations of a denial of the AO's application for initial approval or reapproval under new paragraphs (c)(4) and (d)(4) or a termination of the AO's approval under new paragraph (h)(1).

CMS provides two reasons for this proposal. First, the Part 498 procedures are available to providers and suppliers when their enrollments are denied or revoked, and CMS views the denial of an AO's application and the involuntary termination of the AO's approval to be akin to such situations. Second, Part 498, unlike existing §424.58(e), contains procedures for appeals beyond the initial reconsideration level, and CMS believes these rights should be available to denied or involuntarily terminated AOs.

(2) Suspensions and Probationary Periods (New §424.58(l)(2))

With respect to suspensions and probationary periods, CMS explains that neither of these would involve the elimination of the AO's DMEPOS accreditation program approval altogether (as would a termination) and they could be very brief. For these reasons, CMS believes a rebuttal process would be more appropriate than a reconsideration process for AOs whose accreditation programs have been suspended or placed on probation. CMS proposed to establish a new rebuttal process for DMEPOS AOs that would duplicate the rebuttal process in §424.546 for a deactivation of Medicare billing privileges. This new rebuttal process would be codified at new §424.58(l)(2)) and would apply to DME AOs that have received notice from CMS that its accreditation program has been suspended or placed on probation. Details of the proposed rebuttal timeline, requirements, and processes are outlined in the preamble of the final rule.

As proposed, CMS would not be required to delay the imposition of the suspension or probation pending the completion of CMS' review of the rebuttal. Finally, a determination based on the rebuttal would not be an initial determination under §498.3(b) and therefore, would not be appealable. CMS states that this would clarify for AOs that a rebuttal is the only administrative remedy available for suspension or probation.

j. Consulting (New §424.58(m))

CMS proposed to establish new regulations to restrict DMEPOS AO consulting. The proposals would include:

- Definitions for the terms "consulting" and "consulting services, which would not be restricted to fee-based consulting.
- Circumstances under which an AO, its consulting division, or separate business entity would be prohibited from providing consulting services.
- Circumstances under which an AO, its consulting division, or separate business entity would be permitted to provide consulting services to the suppliers it accredits.
- The contents of a report that the AO must furnish to CMS upon CMS' request, and with each initial and reapproval application, including 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 written consulting firewall policies and procedures with which the DMEPOS AO, its consulting division, or separate business entity have and comply. These written procedures must be submitted to CMS by a date specified by CMS and with each application submitted seeking initial CMS approval or reapproval of their DMEPOS accreditation programs.

k. Other Relationships Involving Potential Conflicts of Interest (New §424.58(n))

Existing §424.58 contains no provisions related to conflicts of interest. CMS expressed concerns that relationships between the DMEPOS AO officials and the suppliers accredited by the AO could unduly influence the AO's survey performance and result and, consequently, the AO's

accreditation decision.[61] Therefore, CMS proposed to include new conflict of interest policies in regulation at §424.58(n).

First, CMS proposed that if an AO owner, surveyor, or employee (currently or within the previous 2 years) has or had an interest in or relationship with a supplier that is accredited by the AO, the accrediting organization owner, surveyor, or employee is not permitted to do certain specified activities such as participating in the survey of that DMEPOS supplier.

Second, CMS proposed that an entity would be prohibited from serving as a CMS-approved 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. CMS specifically expressed concerns for conflicts of interest that may arise with National Provider Enrollment contractors (NPECs) and DME Medicare Administrative Contractors (MACs). CMS solicited comment on whether this prohibition should extend to situations where there are familial relationships between owners and employees of DMEPOS AOs and the CMS contractor.

l. AO Changes of Ownership (New §424.58(o))

Existing 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)). These procedures address requirements for the AO to submit a written notice and request CMS approval for the change, various acknowledgements and notifications to affected providers and suppliers, and other related matters. Currently, §424.58 contains no process for DMEPOS AO ownership changes. CMS proposed to require that a DMEPOS AO that wishes to undergo a change in ownership would be subject to the requirements at §488.5(f). CMS proposed to establish and incorporate this new requirement at new §424.58(o). CMS notes that this same cross-referencing approach is used for HIT supplier accreditation at §488.1030.

m. Requirement for Suppliers to be Accredited (Revisions to §424.57)

Existing §424.57(c)(22) states that DMEPOS suppliers and all of their locations must be accredited by a CMS-approved AO to receive and retain a supplier billing number. Given CMS' proposed strengthening of the DMEPOS accreditation program requirements in §424.58, the agency proposed corresponding changes to §424.57.

(1) Temporary Accreditation and 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. To conform to the policies CMS proposes for new §424.58(e)(8)(i)(A) and (C), CMS proposed that §424.57(c)(23) would be revised to remove references to AO accreditation and would be limited to stating that all suppliers must notify their AO when a new DMEPOS location is opened. CMS explained that

[61] CMS notes it expressed similar concerns and made similar proposals related to conflict of interest in the February 15, 2024 proposed rule for organizations that accredit Medicare-certified providers and suppliers (Part 488). CMS provides Table 24 in the final rule preamble comparing the proposals.

allowing a supplier to become accredited for three months without the important vetting survey presents a serious risk of beneficiary harm and improper Medicare payments.

(2) Accreditation Frequency (§424.57(c)(22) and (24))

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. CMS proposed to move this language to §424.57(c)(22).

CMS noted that neither §424.57 nor §424.58 address the frequency with which surveys must be performed or how often a supplier must be reaccredited, although according to sub-regulatory guidance, DMEPOS suppliers must undergo an unannounced survey once every 3 years following initial accreditation. Therefore, to address what CMS views as a very serious vulnerability, CMS proposed to require, at revised §424.57(c)(24), that DMEPOS suppliers be surveyed and reaccredited at least once every 12 months.

(3) Changes in Majority Ownership (CIMO) and the "36-Month Rule"

CMS recognizes the importance of survey and accreditation processes under its provider enrollment provisions (at §424.550(b)(1)) which articulates certain rules that apply in the event of a CIMO. CMS proposed that that a DMEPOS supplier undergoing a CIMO would be required to enroll as a new DMEPOS supplier and be newly accredited and surveyed under §424.58. These requirements would be codified in new §424.551 and would mirror the provisions that currently exist for HHAs and hospices under §424.550(b)(1) and (b)(2), and the existing definition of "change of majority ownership" at existing 42 CFR 424.502, with some tailoring to apply to DMEPOS suppliers.

First, CMS proposed that a change in majority ownership would occur 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 would include 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.

Second, CMS proposed that, unless an exception applies, if there is a change in majority ownership of a DMEPOS supplier by sale 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 enroll as a new DMEPOS supplier (under §424.510) and undergo a survey by, and obtain a new accreditation from, a CMS-approved DMEPOS accrediting organization in accordance with §§424.57 and 424.58.

Third, CMS proposed certain specific situations which would be exceptions to re-enrollment and survey requirements, such as internal corporate restructuring or death of an individual owner.

Finally, CMS proposed to:

- 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.
- 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.

3. Solicitation of Comments

In light of the volume of changes that CMS proposed to the DMEPOS accreditation program, the agency solicited comment on specific topics it addressed in the proposed rule. The questions are repeated in this section of the preamble of the final rule without any additional commentary, acknowledgement, or comment summary.

4. Costs and Savings

As outlined in greater detail in the regulatory impacts section of the final rule, CMS projects that the cost of its final policies will be approximately $128 million annually. While CMS states that it understands the financial impact this could have on the DMEPOS community, the agency continues to believe that this amount 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.

CMS continues to 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 which, in turn, could reduce risks to patients' health safety. CMS thus concludes that the saving of potentially billions of taxpayer dollars and the preservation of beneficiary safety justifies the burden associated with these requirements.

5. Selected Comments and CMS Responses

a. Annual Surveys and Reaccreditations (Revised § 424.57(c)(24))

As noted above, CMS proposed to require, at revised §424.57(c)(24), that DMEPOS suppliers be surveyed and reaccredited at least once every 12 months. Additionally, CMS proposed stricter and more expansive requirements regarding performance of surveys (at new §424.58(e)(8)) within which the AO would be required to perform a survey of all supplier locations for which the supplier seeks accreditation or reaccreditation, except as otherwise directed or permitted in writing by CMS (for example, allowing sampling). CMS explained it did not anticipate allowing exceptions, however, the proposed caveat would permit the agency flexibility to address particular circumstances that may arise. Additionally, an AO would be prohibited from accrediting the DMEPOS supplier before the survey is performed and a determination is made regarding supplier compliance with the quality standards.

Many commenters opposed CMS' annual survey and reaccreditation proposal believing it would impose significant operational, administrative, and financial burdens on DMEPOS suppliers. Commenters noted that more paperwork does not correlate to increased quality of care. Several commenters believed that annual surveys are unnecessary because DMEPOS suppliers already undergo extensive screening and review. Others stated that since hospitals and HHAs have a 3-year cycle, DMEPOS suppliers should, too. In response, CMS states that all provider and supplier types are different, including with respect to the program integrity risks they pose. CMS believes the proposed (and now finalized) policy for an annual cycle is warranted, without exceptions, as a result of the very serious and longstanding payment safeguard issues involving DMEPOS suppliers. Additionally, CMS recognizes the burden, but believes that suppliers will accrue indirect benefits via: (1) savings to the Trust Funds; and (2) the Medicare revocation of suppliers that are not as committed to adhering to the quality standards as compliant suppliers are. CMS also believes that, based on past experience, smaller suppliers will generally be able to afford and perform annual reaccreditations with no material decrease in their overall participation in Medicare or in beneficiary access to care. Moreover, this burden is only annual, not tri-annual.

Many commenters raised concerns related to unintended or negative consequences of these additional requirements. Commenters cited various supplier types that could be at risk, such as smaller and community-based DMEPOS suppliers, pharmacies, orthotic and prosthetic suppliers, or others, and requested exemptions. Some worried that, to avoid CMS' proposed requirement, some multi-location DMEPOS suppliers might transition to sites that do not require accreditation or exit the program. Others raised concerns for beneficiary access and impact on quality. In response, CMS does not anticipate any negative consequences. The agency believes it must do everything in its power to fulfill its obligation to protect the Medicare program, and cannot allow the prospect of negative consequences to deter it from undertaking critical program integrity and quality of care measures such as annual surveys and reaccreditations. Still, CMS recognizes the importance of these issues and will carefully monitor its enhanced requirements to ensure that patient access to care remains sufficient.

A commenter stated that CMS should adopt the position that DMEPOS suppliers will not be penalized if their AO is unable to conduct an annual survey and reaccreditation through no fault of the supplier. In response, CMS states it is unable to establish such a broad, blanket, and absolute exemption, because each situation is different, however, CMS will closely monitor the implementation of its policies.

A number of commenters offered alternatives to an annual survey. For example, a number of commenters requested that CMS permit sampling as a standard practice, that CMS should base the frequency of surveys on the general and historical performance of suppliers and the risk the supplier poses, or on the fact that some suppliers are already heavily regulated by the states (such as large pharmacies). Commenters recommended that in lieu of revised §424.57(c)(24), CMS should establish a short form or checklist whereby a supplier can report any material changes to its business or perform ad-hoc surveys. In response, CMS reiterates its rationale from the proposed rule that the agency cannot commit to permitting sampling due to the need to ensure that all DMEPOS suppliers are compliant with the quality standard. However, CMS also

recognizes that there could be isolated instances where it might be warranted, hence its proposal in §424.58(c)(1)(iii)(G) to have AOs discuss their suggested sampling methodology. Whether CMS will allow sampling at a later time will depend on circumstances, but CMS states it will attempt to ensure consistency. CMS reemphasizes that passage of a survey – or even multiple consecutive surveys – does not guarantee that a supplier is or will remain compliant for the entirety of each of their 3-year cycles. In CMS' view, only via more frequent surveys can CMS better confirm that there are no lapses in the supplier's compliance and that DMEPOS beneficiaries are protected. CMS believes that a thorough, comprehensive review by an independent organization (rather than relying solely upon the supplier's checklist assertions or ad-hoc surveys) is the best means of ensuring compliance.

Commenters noted that many of the concerns raised by CMS related to fraud and abuse seem limited to only large or new suppliers, or that they are an overreaction to certain recent high-profile cases. Commenters contended that there are more effective means for CMS to combat DMEPOS supplier fraud, waste, and abuse than revised §424.57(c)(24), and provided various suggestions such as data analysis. In response, CMS states that the cases it has seen are not limited to certain supplier types or groups, and therefore CMS cannot restrict the requirements to only large or new supplier organizations. CMS reiterates that the purpose of accreditation is to confirm quality standard compliance and not to detect fraud; these are two entirely separate activities that do not necessarily overlap. Accordingly, CMS states that the agency is not using tightened accreditation standards as a substitute for any lack of anti-fraud enforcement success.

Several commenters stated that the current 3-year cycle has benefits such as allowing DMEPOS personnel to learn and improve and restructure their business based on auditor recommendations. In response, CMS disagrees because the principal purpose of surveys is to verify the supplier's compliance, not provide educational support.

Numerous commenters requested that CMS delay enforcement of revised §424.57(c)(24). In response, CMS does not believe that the requirements can be postponed. As noted, the problem of inappropriate payments and the potential for patient harm is very real, and therefore CMS states it must implement these requirements as soon as possible.

Regarding the proposed requirement (at new §424.58(e)(8)) that AOs perform annual surveys of all supplier locations for which the supplier seeks accreditation or reaccreditation, a commenter requested that CMS define "all supplier locations". In response, CMS states that, for purposes of this requirement, the term "all supplier locations" means locations for which: (1) the supplier seeks accreditation or reaccreditation with the AO; and (2) the AO is required to perform a survey under §§424.57 or 424.58.

b. Temporary Accreditation (§424.57(c)(23))

As noted above, section 424.57(c)(23) requires all suppliers to notify their AO when a new DMEPOS location is opened. The AO may accredit the new supplier location for three months after it is operational without requiring a new site visit. To conform to the new stricter requirements for survey performance, CMS proposed that §424.57(c)(23) would be revised to

simply state that all suppliers must notify their AO when a new DMEPOS location is opened, effectively eliminating temporary accreditation.

Numerous commenters expressed concern that this proposal would prevent new locations from operating until a survey is performed, and that the survey could be delayed due to the AOs' need to perform many other surveys, resulting in negative consequences (like loss of beneficiary access and continuity of care, etc.) Commenters made alternative recommendations or suggested exceptions to the requirement that a survey be completed prior to accreditation. In response, CMS states it does not believe accreditation is appropriate without confirmation via a detailed and thorough on-site inspection of quality standard adherence. CMS also does not believe this change will cause access to care issues.

c. Unannounced Surveys

As part of its proposals for stricter and more expansive requirements regarding the performance of surveys that would be codified in new §424.58(e)(8), CMS proposed that an AO would be required to perform all surveys as unannounced.

Several commenters cited reasons why unannounced site surveys would be unproductive or cause harm. Commenters added that scheduled surveys could equally achieve CMS' goals. In response, CMS notes that unannounced DMEPOS surveys are common, so this new policy would not necessarily constitute a new requirement or dramatic change from present practice. CMS reemphasizes its obligation to protect the Trust Fund and beneficiaries and disagrees that unannounced surveys would cause harm. As explained in the proposed rule, CMS continues to believe DMEPOS supplier surveys should be unannounced so that a non-compliant supplier cannot use prior notice of a survey to remedy its deficiencies solely to pass the survey and then resume its non-adherence.

Numerous commenters stated that unannounced DMEPOS surveys would not align with all business models (for example, for staff that rotate to different sites, do home visits, or operate on an appointment-only basis) and that unannounced surveys do not allow the surveyor to confirm whether the supplier will have staff on-site when the surveyor arrives. Multiple commenters noted that an unannounced survey could interrupt patient care, causing embarrassment and rescheduling. A number of commenters raised other practical considerations and atypical situations which could make unannounced surveys impractical or problematic for suppliers. Other commenters recommended alternatives, such as providing short notice, rather than totally unannounced or surprise surveys. In response, CMS states that the agency will closely follow this issue as it implements the new requirement, but reiterated its belief that unannounced surveys will best align with the agency's obligation to ensure compliance. CMS also notes that surveys would not be a year-round burden, as they are only required at least once every 12 months.

d. AO Requirements and Related Provisions in §§424.57 and 424.58

A commenter generally supported the proposed rule's efforts to achieve greater consistency with certain provisions in 42 CFR part 488 while also noting that DMEPOS suppliers differ

significantly from institutional providers. As such, the commenter stated that certain part 488 procedures may require adaptation to reflect the operational realities of the DMEPOS sector. In response, CMS agrees with this assessment and notes its belief that it is not possible to incorporate many aspects of existing part 488 certified provider/supplier accreditation procedures into §424.58.

Several commenters opposed aspects of CMS' conflict of interest and consulting provisions, stating that CMS should not restrict an AO's ability to provide education and training prior to an organization's survey. Commenters asked CMS to clarify the difference between "consulting" and supplier education. In response, CMS believes that the surveying AO's prior aid (or "coaching") in helping the supplier achieve compliance is antithetical to CMS' goals for achieving assurance of compliance. CMS believes that its proposed conflict of interest provisions will assist in ensuring impartial surveys. Further, CMS states that should the AOs seek elucidation on the scope of these provisions (for instance, whether forms of education fall within §424.58(m) and (n)), CMS will consider issuing guidance.

Several commenters requested that the 2-calendar-day timeframe for notifying CMS of an immediate jeopardy situation be changed to 2 business days. Other commenters recommended revisions to the timing of other activities (such as changing the requirement that the AO notify CMS within 3 business days of any decision related to a supplier's accreditation status to 10 days). In response, CMS agrees with the suggestion to modify "2 calendar days" to "2 business days" and will therefore modify its proposal. However, CMS declines to make other requested changes in its proposed timelines because the agency believes they are reasonable and feasible.

A commenter questioned whether the 10-day period in §424.58(c)(1)(xxiii)(E) for notifying CMS of CAPs begins on the date when the AO makes its determination to apply a CAP or the date on which the AO requests the CAP. In response, CMS states that section 424.58(c)(1)(xxiii)(E) requires the notification to be made within 10 days of the AO's decision, which, for purposes of this paragraph, CMS equates to the date the determination is made.

Multiple commenters stated that CMS should have all AO probation, suspension, and termination notices publicly available on the CMS website. In response, CMS states that all AO suspensions and terminations will indeed be posted on the CMS website. Probations will not be posted because an AO on probation would normally be able to continue its activities without interruption.

Regarding the surveys and reviews addressed in §424.58(f)(2) and (f)(4), a commenter asked if they would be announced or scheduled. Another stated that "lookback" surveys are not a reliable or meaningful method of validation, and others recommended alternative approaches. In response, CMS notes that these surveys have been included in the regulation since 2006 and the agency continues to believe they can be beneficial. Whether they will be announced is a matter on which CMS will issue guidance to the AOs during the implementation of the DMEPOS accreditation provisions.

Several commenters questioned whether the AO's authorized official attestation in §424.58(c)(1)(xxiii) must be submitted annually or only with initial and reapproval applications.

Another commenter questioned whether the attestation's provision regarding patient records is a one-time requirement or will be on a cycle. In response, CMS states that the attestation (which references the use of patient records) need only be furnished when submitting an initial application or reapproval application under, respectively, §424.58(c) and (d). However, the agreements contained therein remain in effect so long as the organization is a DMEPOS AO.

Several commenters expressed concern about proposed §424.58(e)(5)(ii), under which CMS could direct an AO to deny or terminate a supplier's accreditation. The commenter recommended that CMS limit its enforcement mechanisms to enrollment revocation and payment suspensions; should CMS finalize this proposal, the commenter urged a robust appeals process, during which any termination would be stayed. In response, CMS stresses that any such CMS direction would occur extremely rarely (if ever) and only in the most exigent of circumstances, in part because the agency does not wish to hinder the AO's independence. The supplier's appeal rights regarding the accreditation (and whether the denial or termination would be stayed) would be consistent with the AO's existing procedures.

A commenter expressed concern with respect to the volume of CAP data that must be reported (which the commenter stated goes beyond what AOs must report for other Medicare providers and suppliers). In response, CMS acknowledges the AO burden involved but reiterates its previous statements that certified provider/supplier accreditation is different from DMEPOS supplier accreditation; consequently, the policies for the latter cannot be dictated by the former. CMS emphasizes that the CAP reporting requirement is intended to help CMS exercise closer monitoring of DMEPOS accreditation.

Several commenters expressed concern that: (1) there are too few AOs for certain types of DMEPOS suppliers (such as those providing mastectomy and lymphedema services); (2) the removal of one or more AOs could be harmful to the accreditation process; and (3) the metrics that CMS will use to take action against an AO (and what those actions might be) are unclear. In response, CMS notes that it anticipates requiring existing AOs to undergo the reapproval process very soon after the final rule's publication. The agency is unable to predict the number of AOs that will remain after this process is completed or that may be added in the future (if any) to accredit different types of suppliers. The grounds for action are proposed in §424.58(h), (i), and (j). CMS believes it would be more harmful to DMEPOS accreditation to retain such an AO than to remove it from the program.

Several commenters stated that CMS must provide definitions and guidance to the AOs on CAPs and deficiencies before implementing its proposed changes regarding potential disciplinary action against AOs for survey finding disparities. In response, CMS declines to delay implementation but states it anticipates issuing sub-regulatory guidance to the AOs as promptly as possible.

Several commenters opposed CMS' proposed 36-month rule expansion to include DMEPOS suppliers. A commenter stated that the delays involved in reenrolling as a new supplier (as well as becoming accredited again) could prove very burdensome and delay patient care and noted that there is already a process for notifying CMS of a change in majority ownership. In response, CMS notes this provision is intended to confirm that the supplier's new ownership is fully

committed to quality standard compliance. While CMS recognizes the burden involved and the potential for delays in application processing and patient care, the agency reiterates the need to ensure that taxpayer dollars are only paid to compliant suppliers. CMS further does not believe patient access to care will be harmed due to the vast number of other DMEPOS suppliers from which beneficiaries can receive services and items.

Several commenters believed that AOs should not be held responsible for future non-compliance by a supplier (existing §424.58(b)(3) which CMS proposed to redesignate as §424.58(f)(2)(ii)). A commenter contended that if a supplier becomes non-compliant and a survey is needed, it should be at the supplier's expense and not the AO's. In response, CMS agrees with this comment and has decided not to finalize this provision at this time. CMS may reconsider this issue in future rulemaking. Proposed § 424.58(f)(2)(iii), (iv), and (v) will be finalized and redesignated as §424.58(f)(2)(ii), (iii), and (iv).

e. General/Miscellaneous Comments

Several commenters supported CMS' proposed DMEPOS accreditation provisions, generally, stating that CMS is rightly concerned that some AOs may be accrediting suppliers that do not meet the quality standards. Others made recommendations for additional requirements. In response, CMS expressed appreciation for the support and additional suggestions which the agency will take into consideration for future rulemaking or subregulatory guidance.

A commenter stated that CMS did not furnish evidence to support its proposals and urged CMS to withdraw its changes and engage with stakeholders to identify targeted, evidence-based improvements that may be needed. Several commenters expressed concern related to the overall burden and impact on DMEPOS suppliers. In response, CMS states the agency has witnessed deficiencies among AOs and that the regulations contain numerous gaps that hinders the agency's oversight. CMS states it estimated supplier burden in the collection of information and regulatory impact analysis sections of the final rule. CMS plans to conduct extensive outreach and provide guidance to DMEPOS suppliers to help them understand and transition to the new requirements. Moreover, CMS plans to monitor implementation of the new requirements and address any issues that arise.

Many commenters offered other suggestions that CMS determined were out of scope, such as those related to reimbursement, or repeated similar comments to those summarized above. These can be reviewed in the preamble of the final rule.

A commenter requested that CMS share DMEPOS data on issues such as targeted states, supplier newness, accreditation organizations, supplier size, multi locations, poor survey outcomes, etc. In response, CMS notes that the agency regularly posts DMEPOS accreditation-related information and guidance at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/durable-medical-equipment-prosthetics-orthotics-supplies-dmepos and will continue to do so.

6. Final Provisions

CMS is finalizing all of its proposals without modification except as follows:

- When reporting immediate jeopardy situations (see §424.58(e)(1)(iii)), the AO must do so within 2 business days instead of the proposed 2 calendar days. CMS is making this revision based on requests from several commenters.
- In response to several commenters, CMS is not finalizing proposed §424.58(f)(2)(ii) which would have required the AO to bear the expense for a survey if a supplier becomes non-compliant and a survey is needed. As a result, proposed §424.58(f)(2)(iii), (iv), and (v) will be redesignated and finalized as §424.58(f)(2)(ii), (iii), and (iv).
- AOs are currently required to submit, on a monthly basis, certain written information to CMS. CMS has decided not to finalize its proposal to revise the requirement to submit "no later than the last day of the month". Instead, CMS will retain the language in the opening paragraph of §424.58(c)(1) (which is redesignated as new paragraph (e)(1)(i)) that states such submissions must be made "on a monthly basis". This is because the monthly reports currently required under existing paragraph (c)(1) are not necessarily due at the end of each month.

C. Exemption Process for Prior Authorization of Certain DMEPOS Items (§414.234(c)(1) and (c)(1)(ii))

1. Background

Medicare pays for DMEPOS items 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. Additional conditions must be met for payment of DMEPOS items which vary by item and are specified in statute and regulations.[62] These conditions are further detailed in CMS manuals and in local and national coverage determinations.

For certain DMEPOS items, CMS requires 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. CMS provides history on the establishment of CMS' process for prior authorization of DMEPOS items frequently subject to unnecessary utilization found at §414.234.[63]

CMS notes that in the 2019 ESRD PPS & DMEPOS final rule,[64] the agency finalized technical corrections and updates to §414.234 which included the establishment of authority to exempt compliant suppliers from the prior authorization process at §414.234(c)(1)(ii). Specifically, §414.234(c)(1)(ii) states that CMS may elect to exempt suppliers from prior authorization upon

[62] Scope of payment for medical suppliers, appliances, and devices is described at 42 CFR 410.36(a) and scope and condition for payment for DMEPOS is described at §410.38.
[63] Published in the Federal Register and titled "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (80 FR 81674), this rule established a permanent prior authorization program nationally, based on authorities outlined in section 1834(a)(15) of the Act.
[64] 84 FR 60648

demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process. At that time, CMS did not provide specifics on this exemption process in the regulatory text, however, the agency 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. In response, CMS indicated that it would consider this suggestion in future rulemaking.

2. Provisions of the Proposed Rule

CMS proposed adding technical language to §414.234 (c)(1) that provides for the exemption process. Additionally, at §414.234 (c)(1)(ii)(A), CMS proposed to exempt a supplier from the mandatory prior authorization process when the supplier achieves a rate of payable claims submitted of at least 90 percent during an initial or periodic review. This exemption would remain in effect until CMS withdraws the exemption. An exemption is withdrawn if the rate of non-payable claims submitted becomes higher than 10 percent. Finally, at §414.234 (c)(1)(ii)(B), CMS proposed to provide at least 60-day notice to the supplier of an exemption or withdrawal of an exemption.

3. Comment/Response and Final Action

Several commenters supported the proposed prior authorization exemption process. Some commenters, while supportive, objected generally to the burden imposed by prior authorization requirements. In response, CMS notes appreciation for the support of their proposals and that issues beyond the proposals are out of scope.

A few commenters made recommendations or suggested alternatives. For example, one commenter suggested that suppliers be provided with a choice to be exempt from prior authorization. A few commenters requested that CMS develop criteria that would avoid creating a two-tiered system favoring larger suppliers. In response, CMS clarifies that suppliers that find value in the prior authorization program may decline the exemption. CMS believes the agency has achieved equity and transparency in the exemption process by providing CMS' metrics in this rule and by applying it consistently to all suppliers.

A few commenters suggested modifications on sample sizes and CMS' analyses on compliance approval ratings. In response, the agency states it will continue to assess its methodologies and adjust in the future, if needed.

After consideration of public comments, CMS is finalizing all of its proposals to clarify circumstances under which CMS would exempt a DMEPOS supplier from the prior authorization process, including its proposal to provide notice of the exemption, or the withdrawal of the exemption, from prior authorization requirements.

VII. DMEPOS Competitive Bidding Program

In this section, CMS finalizes provisions from the proposed rule that will be applicable in the next round of competitive bidding – the timeline for the next round has recently been published by CMS and contracts and single payment amounts (SPAs) will be in effect no later than January 1 2028.[65] The next competitive bidding program (CBP) round will include seven remote item delivery (RID) DMEPOS CBP product categories: (1) Class II continuous glucose monitors **(**CGMs) and insulin pumps, (2) urological supplies, (3) ostomy supplies, (4) hydrophilic urinary catheters, (5) Off-the-Shelf (OTS) back braces, (6) OTS knee braces, and OTS upper extremity braces.

Highlights of provisions finalized from the proposed rule include the following:

- SPAs will now be calculated using the 75th percentile of winning bids instead of the maximum winning bids. These SPAs will be updated at the beginning of the second and third year of the contract period by an inflationary update.
- RID CBP program was established wherein contract suppliers are responsible for furnishing remote item delivery items under a product category to all Medicare beneficiaries regardless of where they live in the competitive bidding area (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.
- Regulatory definition of medical equipment is modified to include supplies related to ostomy care and urological supplies. CMS states that tracheostomy supplies are "supplies related to ostomy care." This change results in CMS being able to include these product categories into the CBP.
- For competitions for the first time after 2023, the number of contracts offered for each product category will be based on 125 percent of the number of suppliers furnishing at least 3 percent of the total national allowed services for the lead item in 2025.
- CGMs and insulin pumps will be reclassified under the frequent and substantial servicing payment category and thus will be made on a continuous, monthly rental basis with payment for all necessary supplies and accessories included in the monthly rental rates beginning on the first day of the contract period. Payment based on this method will be phased-in at the same time that class II CGMs and insulin pumps are phased in under the DMEPOS CBP (no later than January 1, 2028 or the start of the next CBP) to give suppliers time to prepare for the transition to the new monthly rental business model.
- Special payment limits were established for class III CGMs and insulin pumps used in conjunction with class III CGMs. Rates will be the same as class II CGMs and insulin pumps if all the conditions are met by CMS in using its inherent reasonableness authority.

A. Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated the establishment and implementation of CBPs in CBAs throughout the United States

[65] See DEMPOS Fact Sheet.

for contract award purposes for the furnishing of competitively priced DMEPOS items and services.[66] These items include:

- 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.

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.

Under the DMEPOS CBP, suppliers who want to furnish designated products in a CBA submit a bid. These bids are evaluated based on the supplier's eligibility, financial stability, and bid price. Contracts are awarded to those suppliers who offer the best prices and meet the applicable quality and financial standards. Payment amounts are based on single payment amounts (SPAs). Prior to round 2021, the SPA for each item in the product category was calculated based on the median of the winning contract suppliers' bid amounts for each item. Effective January 1, 2019, and beginning with Round 2021, CMS implemented a "lead item" pricing methodology for submitting bids (a bid for each item within a product category was no longer required, only the "lead item" or the item with the highest Medicare allowed charges). CMS also changed its methodology for calculating SPAs 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 then used to calculate the SPAs for all items in the product category.

The statute (Section 1847(b)(3)(B) of the Act) mandates that the contracts awarded to suppliers under the CBP must be recompeted not less often than once every 3 years. 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. 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. CMS has initiated several rounds of the DMEPOS CBP, as summarized in table FF-25 in the final rule (reproduced here). There have been temporary gap periods when no rounds of competitive bidding were active.

[66] Amended section 1847(a) of the Social Security Act

<table>
<tr><th colspan="3">Table FF-25. Competitive Bidding Rounds and Contract Periods</th></tr>
<tr><th>Calendar Year</th><th>Round 1 Areas (9 Metropolitan Statistical Areas (MSAs))</th><th>Round 2 Areas (90 MSAs) and National Mail Order</th></tr>
<tr><td>2011</td><td rowspan="3">Round 1
1/11/2011 -
12/31/2013</td><td rowspan="2">--</td></tr>
<tr><td>2012</td></tr>
<tr><td>2013</td><td rowspan="3">Round 2 & National Mail Order
7/1/2013 - 6/30/2016</td></tr>
<tr><td>2014</td><td rowspan="3">Round 1 Recompete
1/1/2014 - 12/31/2016</td></tr>
<tr><td>2015</td></tr>
<tr><td>2016</td><td rowspan="3">Round 2 & National Mail Order Recompetes
7/1/2016 - 12/31/2018</td></tr>
<tr><td>2017</td><td rowspan="2">Round 1 2017 (recompete)
1/1/2017 - 12/31/2018</td></tr>
<tr><td>2018</td></tr>
<tr><td>2019</td><td colspan="2" rowspan="2">Temporary Gap Period</td></tr>
<tr><td>2020</td></tr>
<tr><td>2021</td><td colspan="2" rowspan="3">Round 2021 (recompetes for Round 1 and Round 2)
1/1/2021 - 12/31/2023</td></tr>
<tr><td>2022</td></tr>
<tr><td>2023</td></tr>
<tr><td>2024</td><td colspan="2" rowspan="2">Temporary Gap Period</td></tr>
<tr><td>2025</td></tr>
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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 sub-divided 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 CMS refers 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.

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

In this section, CMS modifies 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. In addition, CMS discusses its finalized policy, in lieu of self-reported supplier capacity, to estimate supplier capacity using data on actual contract supplier capacity from previous rounds of the DMEPOS CBP.

1. Background

Under the DMEPOS CBP Medicare-enrolled DMEPOS suppliers submit bids and compete to receive a limited number of contract(s) to furnish DMEPOS items and services in different CBAs throughout the nation. These bids are used to calculate the SPAs to pay contract suppliers in lieu of the payment amount they would otherwise receive under the standard DMEPOS fee schedule. Medicare payment for competitively bid items and services is equal to 80 percent of the applicable SPA and the contract supplier collects a coinsurance payment from the beneficiary of 20 percent of the applicable SPA.

a. Rules in Effect Prior to Round 2021 of the DMEPOS CBP

Prior to Round 2021, bidding entities submitted a bid amount for each item within a product category. The number of items within a product category (such as standard mobility equipment and related supplies) can vary from less than ten items to hundreds of individual items, as identified by HCPCS codes.[67] For each product category, these bid amounts were combined into one composite bid for each bidding entity. The composite bid was computed by assigning weights to each item within the product category based on the national volume of that item relative to the national volume of all items in the product category.

CMS arrayed the composite bids from lowest to highest and awarded a contract to the supplier with the lowest composite bid and then awarded contracts to the next supplier in the array until there were enough suppliers to meet the projected demand in the CBA for the items in the product category. The pivotal bid is the bidding entity where the cumulative capacity of the bidding entities for furnishing the items and services meets or exceeds projected demand. Those bidding entities below the pivotal bid are referred to as the winning contract suppliers – if a bid is above the pivotal bid then the supplier was not awarded a contract. The bids for the winning

[67] For example, in the Round 2 Recompete, the Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies product category had 5 items and the Standard Mobility Equipment and Related Accessories (includes walkers, standard power and manual wheelchairs, scooters, and related accessories) had 152 items.

contract suppliers were then used to calculate the SPA for the items and services in the product category for each CBA.

Prior to Round 2021, CMS calculated the SPA for each item in the product category based on the median of the winning contract suppliers' bids for each item. CMS notes that using the median of the winning bids resulted in 40 to 80 percent reductions in the payment amounts under the program. Suppliers also accepted their contract offers at the median of the winning supplier bids approximately 92 percent of the time consistently from round to round.

b. Changes Implemented with Round 2021 of the DMEPOS CBP

CMS made significant changes to the DMEPOS CBP as part of the 2018 ESRD/DMEPOS final rule (83 FR 56922) that were implemented with Round 2021 of the DMEPOS CBP. These included the following:

- Lead item pricing methodology. Instead of submitting bid amounts for each item in a product category, the bidding entity submits a bid amount for a "lead item" – the item with the highest total nationwide Medicare allowed charges within that product category – and this bid amount represents the bidding entity's "composite bid" for furnishing all items in the product category.

- Calculation of the SPA. The methodology for calculating SPAs was changed from the median of the winning contract supplier's bid for each item in the product category to the maximum winning contract supplier bid amount for a "lead item" in the product category. The SPAs for the non-lead items within the product category are determined by multiplying the lead item SPA by a relative ratio based on historic differences in the fee schedule amounts (using 2015 data prior to competitive bidding) for the lead item and non-lead item.[68]

CMS states that the lead item pricing methodology was adopted to prevent "unbalanced bidding" and to simplify the bidding process and reduce the burden for bidding entities. Unbalanced bidding occurred in the rounds prior to 2021 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. The lead item pricing also greatly simplified the bidding process because bidding entities only have to submit one bid amount for each competition (product category and CBA) whereas previously the bidding entity had to submit bid amounts for every item in the product category. This process had resulted in errors by bidding entities that resulted in some bids being disqualified.

[68] 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.

c. Projecting Demand for Items and Services and Estimating Supplier Capacity for Furnishing Items and Services.

CMS states that in determining the number of contract suppliers for a competition, it aims to limit the number of contract suppliers to ensure they are incentivized to submit a competitive bid. Awarding too many contracts decreases the incentive for a bidding entity to submit a competitive bid as they are more likely to be awarded a contract regardless of the submitted amount. 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 has remained virtually unchanged since its inception.

CMS states that 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. 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.

To estimate projected demand, CMS first calculates 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. 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).[69]

CMS argues that this approach has 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. CMS states that this process 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.

[69] 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.

After determining the projected beneficiary demand, CMS then calculates 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.

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. A bidder that does not meet the minimum financial threshold for a bidder to receive additional capacity beyond its historic amount would be limited to the historic amount. In contrast, if a bidder meets the minimum financial threshold then CMS accepts the bidder's capacity at the greater of its estimated or historical capacity (based on claims data). However, if a bidder's capacity is greater than 20 percent of the projected demand in the CBA, then CMS adjusts the bidder's capacity to 20 percent of the projected beneficiary demand to ensure that at least five contracts are awarded for each competition, in accordance with current regulations at 42 CFR 414.414(h).

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. 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. 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. CMS emphasizes 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).

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. CMS also has special rules in place for small suppliers – defined as a supplier with a gross revenue of $3.5 million — with a goal of awarding them at least 30 percent of the total number of contracts. CMS first determines which percentage of bidders in the winning array 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.

2. Current Issues

CMS implemented the lead pricing and the maximum bid amount SPA methodologies under Round 2021 of the DMEPOS CBP. CMS competed 15 product categories in 130 CBAs, 13 were included in previous rounds of the CBP, while OTS back and knee braces were competed for the

first time.[70] Within these CBAs there were over 2,000 competitions and CMS received and reviewed over 49,000 bids. CMS did not award competitive bidding contracts for any of the 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings. The Round 2021 contracts went into effect in 127 CBAs for the OTS back braces and OTS knee brace categories resulting in estimated Medicare savings of $934 million.

CMS believes that 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. This resulted in 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).

CMS provides an example (Table FF-26 in the final rule) using actual bid amounts submitted for a Round 2021 competition to illustrate the impact of outlier pricing on the SPA that results when using the maximum winning bid methodology. In this example, the maximum winning bid of $189 is $39 and 26 percent higher than the next highest bid of $150, demonstrating that just adding one additional bidding entity has significant impact on the amount that all the contract suppliers would be paid. Contracts were not awarded for this product category because the total payments made based on this maximum winning bid of $189 greatly exceeds the payments amounts that would have otherwise been paid at $74.25 (without competitive bidding).

CMS states that its goal 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.

3. Provisions of the Regulation

a. Determination of SPAs for Lead Items

CMS finalizes its proposal to change the methodology used for determining SPAs for lead items under the program (revision of §414.416(b)(1)) so that the SPA for the lead item in the product category will be based on the 75th percentile of bid amounts (instead of the maximum bid) for the lead item that are equal to or below the pivotal bid for the product category.

Under the 75th Percentile approach, CMS will use 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. CMS also

[70] Round 2021 initially had 16 product categories but the product category for non-invasive ventilators was removed in April 2020 due to the COVID-19 PHE.

believes that reducing the number of contracts awarded will help ensure that the bid amount will be closer in value to the median bid option (described in more detail below).

CMS also revises §414.416(b)(1) to indicate 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 will be determined by going 75 percent of the way between the 2 bid amounts, rounded to the nearest cent. In the final rule, CMS provides an illustrative example in Table FF-28 (reproduced below). For this example, 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) * 75 percent] + $6.50).

Table FF-28 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 final rule also discussed two other potential options (not adopted) including using the median of winning bids (the "median bid" option) and using the maximum winning bid amount and limiting the number of contract suppliers ("maximum bid" option).

Median Bid Option. This option would 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.

Maximum Bid Option. This option would maintain the current methodology that establishes SPAs based on the maximum winning bid amount. Based on analysis of past bidding rounds, CMS believes that reducing the number of contracts awarded would be needed 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. CMS believes 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.

All of the options CMS explored were informed by simulations CMS's contractor conducted using bid and contracting information from previous rounds of the DMEPOS CBP.[71]

Comment/response: Many commenters supported the current methodology which establishes SPAs based on maximum winning bid amounts, while some suggested other methodologies such as the 90th percentile. Commenters were concerned that use of the 75th percentile of winning bid amounts combined with bid limits and reduction of number of contract suppliers would result in payment amounts that are too low and not sustainable. In response, CMS reiterates that the maximum bid methodology was not feasible as it did not reliably result in total payments to contract suppliers that are less than the total amounts that would otherwise be paid under the DMEPOS fee schedule. In addition, CMS believes that the 90th percentile option suggested by some commenters would include a high risk of outlier pricing and would not be representative of bids from the suppliers as a whole. CMS also made some technical changes to §414.416(b)(1).

b. Determination of SPAs for Non-Lead Items

CMS finalizes its proposal to change the way 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)(2). Specifically, the calculation will involve multiplying the lead item SPA by a relative ratio, which will be based on (i) the 2015 fee schedule amount for the non-lead items in the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands) to (ii) the 2015 fee schedule amount for the lead item for the same area.

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, CMS will 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, CMS would still need to use the average of the fee schedule amounts since these CBAs would include multiple areas with different fee schedule amounts.

[71] 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.

c. Methodology for Calculating the Number of Contract Suppliers

CMS finalizes its proposal (with a few corrections to technical errors) to 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, CMS will select at least 2 contract suppliers to furnish items and services. The total number of contract suppliers chosen could be 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 will 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 not more than 75 percent of the total number of contract suppliers that furnished the lead item in 2018 or 2023 rounded down to the nearest whole number.

Table FF-30 in the final rule (reproduced below) provides 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 CMS proposed and including the 75th percentile option (shaded) that CMS is finalizing in this rule.

Table FF-30: 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.
75th 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.

CMS provides an illustrative example in the final rule on how this would work for the 75th Percentile option finalized by CMS. 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, then CMS would do the following:

- Double the number of contract suppliers in 2018:

  9 x 2 = 18

- Adjust the result by the 5 percent decrease in Part B enrollment since 2018:

  18 x 0.95 = 17.1 rounded to the nearest whole number, 17.

- Determine the fewest number of contracts to award:

  29 x 0.50 = 14.5 rounded up to the nearest whole number, 15.

- Determine the highest number of contracts to award:

  29 x 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.

After the first time a competition is recompeted after 2023, CMS finalizes that the number of contract suppliers selected to furnish items and services will 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 selected to furnish items and services is 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, unless there is less than 2 contract suppliers, in which case the number of contract suppliers will be 2.

CMS also will use 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. CMS states that 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, CMS 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.

For new product categories and CBAs, CMS will 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. CMS believes 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 CMS' 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.

Using 2024 Medicare claims data,[72] CMS illustrates how it would determine the number of contracts to award for new product categories being phased into the DMEPOS CBP using 2024 Medicare claims data. If competitions were held today for a nationwide remote item delivery (RID) CBP as finalized under section F using the 75th percentile methodology and using those product categories specified, CMS would award the following numbers of RID CBP contracts:

- eight for urological supplies;
- eight for ostomy supplies;
- ten for class II continuous glucose monitors (CGMs);
- six for OTS upper extremity braces;
- four for OTS back braces; and
- six 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.

In situations where CMS is not able to award enough contracts to meet the target number of contracts in a competition, 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 the bidding entities are able to meet beneficiary demand. Once the

[72] These estimates were updated in the DMEPOS fact sheet published on November 28, 2025.

competition is implemented, CMS states that it 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 indicate that contracts are generally awarded to at least five suppliers satisfying the conditions for awarding contracts. CMS believes that as the program is implemented in additional areas throughout the United States, that five contract suppliers would be excessive for some areas and product categories. CMS finalizes that this number can be no lower than 2 for any competition as the statute mandates multiple contract suppliers (at least 2).

In accordance with the special rules at §414.414(g), CMS has a goal of awarding at least 30 percent of the total number of contracts to small suppliers. CMS 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.

Comment/response: Commenters generally opposed CMS' proposed method for determining the number of contract suppliers needed to meet demand for items and services in a CBA stating that the approach was arbitrary and capricious and did not ensure that contract suppliers would be able to meet projected demand. CMS, in response, disagreed, stating that the proposed methodology for previously bid categories and areas relies on actual contract supplier capacity from previous rounds to inform the program on the number of contract suppliers needed to meet demand for the items and services in the same areas for the same product categories in subsequent rounds of competition. It also believes that about half of the number of contracts awarded in past competitions were not needed. Some commenters were also concerned about the change in the minimum number of contract suppliers from five to two and how it was possible to meet the 30 percent small supplier target. In response, CMS replies that if there are only two winning suppliers for a competition and one of them is a small supplier, then the 30 percent small supplier target is met. If neither supplier is small, then the steps under current regulations at 42 CFR 414.414(g) would be followed and potentially more contracts offered in an attempt to meet the 30 percent small supplier target.

CMS finalizes its proposed changes with a few corrections to technical errors in the regulation text at §414.414(h)(1) and §414.414(h)(3)(i).

d. Methodology for Evaluating Bids

CMS finalizes its proposal to change the methodology for evaluation of bids by revising §414.414(e). Specifically, CMS will 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.

C. Adjustments to SPAs

As a result of the COVID-19 PHE, supply chain disruptions, and recent years' higher than normal inflation, CMS believes 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 states that this would also reduce burden for bidding entities since they would no longer need to factor standard inflationary cost increases into their bid calculation and ensure better access to items and services under the program in the event that costs do increase significantly during the contract period.

Specifically, CMS amends §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. CMS finalizes 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 the state or area that includes the CBA where the SPA is applied.

Commenters were supportive of the proposed change to apply an annual update factor to SPAs.

D. Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected

1. Background

CMS believes that further changes are needed to the bid limit provisions and conditions for awarding contracts to ensure both the continued viability of the DMEPOS CBP and adherence to the requirement for savings as stipulated at section 1847(b)(2)(A)(iii). This provision prohibits the awarding of contracts to any entity unless the total amounts to be paid to contracted suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. CMS also states 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 latter have not yet been adjusted based on rates established under the DMEPOS CBP.

CMS also states that, in addition to price savings, the DMEPOS CBP must also take into consideration guaranteed access for beneficiaries and reduction in improper utilization. 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. CMS states that the evidence suggests a 10 to 20 percent reduction in waste, fraud, and abuse is associated with the DMEPOS CBP.[73]

CMS concludes that 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, CMS believes that it is appropriate 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.

2. Provisions of Regulations

a. Limits on SPAs

CMS finalizes its proposal to modify §414.414(f) to specify that a contract will not be awarded for a competition if the SPA for the lead item is no greater than the lesser of 110 percent of the adjusted fee schedule amount for the lead item, if applicable, or the unadjusted fee schedule amount for the lead item. It believes 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 latter have not yet been adjusted based on rates established under the DMEPOS CBP.

b. Submission of Bids

For similar reasons, CMS finalizes several modifications to §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. These are summarized in the table below. CMS states that bidding entities will be educated (no detail provided on by what means) and provided with guidance to ensure that they did not enter bids that are higher than these limits.

Modifications to 42 CFR 414.412 Regarding Bid Amounts.		
Product Included in Prior CBP	**Regulation Cite**	**Finalized Policy**
First time	42 CFR 414.412(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.

[73] CMS cites as evidence findings from a 2014 GAO study (GAO-14-156) which showed decreases of 10 to 20 percent in utilization across product categories attributable to the CBP without evidence of any difficulties in beneficiary access. CMS believes this difference is attributable to waste, fraud, and abuse.

Modifications to 42 CFR 414.412 Regarding Bid Amounts.		
Product Included in Prior CBP	**Regulation Cite**	**Finalized Policy**
Included in prior competition	42 CFR 414.412(b)(3)	The bid amount 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.
Included in prior competition with a temporary gap in CBP	42 CFR 414.412(b)(4)	If it has been more than one year since the most recent SPA was last paid due to a temporary gap in the CBP, 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. Inflation adjustment will be based on the 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.
Included in prior competition but made under a bid for a new CBA	42 CFR 414.412(b)(5)	The bid amount submitted for each lead item and product category must not exceed the lesser of the most recent SPA for the item plus 10 percent or the unadjusted fee schedule amount for the item.

As discussed in section VII.F.3., certain products such as OTS back braces and OTS knee braces, class II CGMs, and insulin pumps are currently delivered to beneficiaries from remote supplier locations that, on average, are hundreds of miles from the beneficiary's residence. Relatedly, CMS is finalizing its proposal to amend §414.412(b) to establish bid limits for lead items in a product category in a remote item delivery CBP for the first time with specific regulatory provisions for class II CGMs, insulin pumps, and OTS back braces or OTS knee braces.

Amendments to 42 CFR 414.412(b) to Establish Bid Limits for Lead Items		
Product category in a remote item delivery CBP for first time	**Regulation Cite**	**Finalized Policy**
Class II Continuous Glucose Monitors (CGMs)	42 CFR 414.412(b)(9)	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 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.
Insulin infusion pumps	42 CFR 414.412(b)(10)	Must not exceed the nonrural payment amount that would otherwise apply to the supplies and accessories for the insulin pump for a 1-month period plus the total nonrural rental fee schedule amounts that would otherwise apply to rental of

Amendments to 42 CFR 414.412(b) to Establish Bid Limits for Lead Items		
Product category in a remote item delivery CBP for first time	**Regulation Cite**	**Finalized Policy**
		the insulin pump for 13 months of continuous use divided by 60.
OTS back brace or OTS knee brace	42 CFR 414.412(b)(11)	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.
All other items included as a lead item in a product	42 CFR 414.412(b)(12)	Must not exceed the average payment amount that would otherwise apply for the areas included in the remote item delivery CBP.

CMS discuses that for OTS back braces and OTS knee braces that the fee schedule amounts vary for nonrural and rural areas.[74] The average of the 2025 fee schedule amounts for nonrural areas within the contiguous United States is $124.53 compared with $184.76 for rural areas within the contiguous United States and outside the contiguous United States. CMS argues, however, that these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations and the cost of shipping to a beneficiary residing in a rural and non-rural area is comparable. CMS acknowledges that shipping costs may be incurred for items that are shipped to an area outside of contiguous United States, such as Alaska, Hawaii, or Puerto Rico, but states there are few beneficiaries living in these areas compared to areas within the contiguous United States. CMS sets the bid limits based on the average nonrural payment amount for OTS back braces, OTS knee braces, and insulin pumps.

Comment/response: CMS received 107 comments from individuals, manufacturers, suppliers, and industry associations on its proposal to amend the regulations at § 414.412(b)(2) through (5) and (9) through (12) to establish limits on bids submitted to better ensure savings under the DMEPOS CBP and at § 414.414(f). Many commenters expressed concern that the bid limit would force prices in the DMEPOS CBP to continue to decrease with each successive round to unsustainably low levels. Many also believe that savings should be measured based off the unadjusted fee schedule amounts and that bid limits should be similarly tied to unadjusted fee schedule amounts. Another commenter proposed that savings be considered at the national level instead of being considered at the level of each competitive bidding area. A few commenters expressed concern that tying bid limits to the adjusted fee schedule amount with only a 10 percent margin does not reflect the true cost pressure suppliers have faced in recent years.

In response, CMS does not agree. CMS states that the bid limit helps to ensure that the DMEPOS CBP fulfills the statutory requirement for savings. In addition, where items have been previously bid, the bid limit would allow prices to increase over time by as much as ten percent from the previous round (as long as it does not exceed the amount CMS would otherwise pay under the DMEPOS fee schedule). CMS also states that considering savings at the national level in establishing bid limits would not be consistent with the statute (section 1847(b)(A)(iii) of the Act) that specifically refers to payments in a competitive acquisition area in defining the

[74] This issue also applies to insulin pumps.

requirement for savings. CMS also does not agree that the 10 percent margin is insufficient as this adjustment is in addition to the annual inflation update for SPAs. It also notes that acceptance of contracts is voluntary and any supplier whose bid is above the median bid faces no penalty for refusing a contract.

E. Revising the Definition of "Item" Related to Medical Supplies

CMS proposed to include ostomy, tracheostomy, and urological supplies in the CBP by amending the regulatory definition of "item" in §414.402 to include those products. It also proposed a conforming amendment to the payment rules at §414.408(g) to specify other medical equipment, including ostomy, tracheostomy, and urological supplies are purchased items for which the SPA is calculated based on the bids submitted and accepted.

The proposals are finalized with what CMS describes as a technical modification to align the language of the regulation text to that of the statute in section 1861(m)(5) of the Act. Specifically, instead of the proposed language "including ostomy, tracheostomy, and urological supplies," the final regulation text reads "including supplies related to ostomy care and urological supplies." It states that tracheostomy supplies are "supplies related to ostomy care."

As it did in the proposed rule, the agency reiterates the factors it applies in determining whether to include a new item in the CBP, including annual allowed charges, annual growth in expenditures, number of suppliers, savings under demonstrations, and various reports and studies conducted by CMS and other federal agencies. With respect to ostomy, tracheostomy, and urological supplies, it notes the demonstration programs that began in 1999 under which urological supplies were competitively bid and savings were realized without significant impact on beneficiary access to the items. CMS also cites a MedPAC report[75] and an OIG report[76] that both noted higher Medicare payment rates for these items than private-payer rates and recommended paying less for them. The agency also notes significant growth in allowed charges for these items as well as high improper payment rates for urological supplies (including intermittent urinary catheters) in reviews performed by OIG and CMS contractors.[77]

Reactions to the proposal were mixed. Those in support welcomed what they anticipate to be a substantial reduction in costs to taxpayers and beneficiaries. Others were pleased by the potential savings but were concerned about the impact of the CBP on patient choice and the availability of certain brands, the quality of the products selected, issues with access, and diminished support from suppliers. They noted many ostomy products are similar but not identical, with variations in chemical composition and features critical for individual use. Some suggested phasing in these items to the CBP. Several commenters believe the competitive bidding demonstrations in Polk County, Florida prove that urological supplies are not well-suited for competitive bidding.

CMS seeks to reassure readers that the CBP includes safeguards to address the concerns commenters raised. It disagrees with the conclusion that the Polk County demonstrations show

[75] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/defaultsource/reports/jun18_ch6_medpacreport_sec.pdf
[76] https://oig.hhs.gov/oei/reports/OEI-04-20-00620.pdf
[77] https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf

that ostomy, tracheostomy and urological supplies are not well suited for the CBP, pointing to findings that beneficiary access and quality of services were "essentially unchanged" under those demonstrations.

Commenters opposed to the proposal raised legal arguments against adding these items to the CBP, but the preamble does not provide any specific description of the legal arguments made by those commenters. CMS reiterates the position it expressed in the proposed rule. It believes there is no ambiguity in the statute and that these items may be included in the CBP. Specifically, it argues the CBP applies with respect to covered items for which payment is otherwise made under section 1834(a) of the Act. The definition of covered item in section 1834(a)(13) of the Act includes a cross-reference to section 1861(m)(5) (relating to the definition of what is included in home health services), which mentions medical supplies including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care. Finally, section 1834(h)(1)(E) of the Act[78] indicates that payment for these items is made pursuant to section 1834(a) of the Act.

F. Remote Item Delivery (RID) CBP

In this section, CMS finalizes its 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 CMS 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. GAO noted that the MMA of 2003 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 CMS stated that it 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.

CMS implemented a national mail order CBP for diabetes testing supplies (supplies for blood glucose monitors) from July 1, 2013, through December 31, 2018. CMS established definitions for "mail order item" and "non-mail order item" in §414.402.[79] These definitions were

[78] Section 1834(h) of the Act sets forth the payment rules for prosthetic devices and orthotics and prosthetics, including ostomy supplies, tracheostomy supplies, and urologicals.

[79] These definitions were established 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).

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)(1)(H) of the Act.

2. Current Issues

CMS details its analysis of Medicare claims data showing 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 FF-32 (reproduced here), 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.[80]

Table FF-32: Categories of Items Furnished From Remote Supplier Locations

Category	2024 Allowed Charges for the Category	Lead Item	Average Distance (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

CMS states that 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.

CMS lists in table FF-33 (a modified version show below) the current HCPCS Level II codes for several product categories that it believes 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. CMS notes, however, that this table is for illustration purposes only and that the actual product

[80] 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.

categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means.

Examples of RID CBP Product Categories and HCPCS Codes (compiled from Table FF-33)	
Product Category	**HCPCS Level II Codes**
Class II CGMs and Insulin Pumps	E0784, E2103, A4224, A4225, A4239
OTS Back Brace	L0450, L0455, L0457, L0467, L0469, L0621, L0623, L0625, L0628, L0641, L0642, L0643, L0648, L0649, L0650, L0651
OT Knee Brace	L1812, L1830, L1833, L1836, L1850, L1851, L1852
OTS Upper Extremity Brace	L3650, L3660, L3670, L3675, L3678, L3710, L3761, L3762, L3809 L3908, L3912, L3916, L3918, L3924, L3925, L3927, L3930
Ostomy Supplies	A4331*, A4357*, A4361, A4362, A4363, A4364, A4366, A4367, A4368, A4369, A4371, A4372, A4373, A4375, A4376, A4377, A4378, A4379, A4380, A4381, A4382, A4383, A4384, A4385, A4387, A4388, A4389, A4390, A4391, A4392, A4393, A4394, A4395, A4396, A4398, A4399, , A4402*, A4404, A4405, A4406, A4407, A4408, A4409, A4410, A4411, A4412, A4413, A4414, A4415, A4416, A4417, A4418, A4419, A4420, A4422, A4423, A4424, A4425, A4426, A4427, A4428, A4429, A4430, A4431, A4432, A4433, A4434, A4435, A4436, A4437, A4450*, A4452*, A4455*, A4456*, A5051, A5052, A5053, A5054, A5055, A5056, A5057, A5061, A5062, A5063, A5071, A5072, A5073, A5081, A5082, A5083, A5093, A5102*, A5120, A5121, A5122, A5126, A5131*
Urological Supplies**	A4217, A4295, A4296, A4297, A4310, A4311, A4312, A4313, A4314, A4315, A4316, A4320, A4322, A4326, A4327, A4328, A4331*, A4332, A4333, A4334, A4336, A4338, A4340, A4344, A4346, A4349, A4351, A4352, A4353, A4354, A4355, A4356, A4357*, A4358, A4360, A4402*, A4450*, A4452*, A4455*, A4456*, A5102*, A5105, A5112, A5113, A5114, A5131*, A5200,
* HCPCS Level II codes included in product categories for ostomy supplies and urological supplies **Note, CMS states in its November 28, DMEPOS fact sheet that the urological supplies category will not include hydrophilic catheters. A separate product category was created for these items.	

CMS identified lower volume items under the OTS Upper Extremity Braces and OTS Back Braces product categories, where less than the average delivery distances were less than 100 miles, as shown in tables FF-34 and FF-35 of the final rule. (A modified table is included below that lists the HCPCS codes for these lower volume items.)

CMS sought comment 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 nonmail order basis. The alternative would be to exclude these codes. CMS is concerned that

excluding the items, which would mean that contract suppliers would not be required to furnish these braces, could potentially affect access to these items.

National Average Delivery Distance for OTS Upper Extremity Braces (2024) With an Average Distance Less than 100 Miles (compiled from Tables FF-34 & Table FF-35)		
HCPCS Level II Code	**Average Distance**	**Allowed Charges**
OTS Upper Extremity Braces		
L3678	13	$974
L3710	32	$50,676
L3912	59	$21,253
L3925	41	$100,324
L3927	52	$112,892
L3930	84	$10,240
OTS Back Braces		
L0450	16	$10,903
L0455	12	$5,570
L0467	4	$1,911
L0469	4	$1,629
L0625	57	$46,479
L0628	39	$11.732
L0643	13	$3,341

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. CMS states that items may be furnished to beneficiaries who come into the local storefront of a contract supplier, but it believes that most contract suppliers would have a limited number of local storefronts and therefore these occurrences would be rare. 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.

CMS notes 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 the replacement supplies were needed, and the claim denial could potentially be overturned on appeal.

3. Provisions of the Final Regulation

CMS finalizes its proposal that the term "Remote item delivery competitive bidding program" is defined under §414.402 to mean "a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under a 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."

CMS finalizes that the term "Remote item delivery item" is 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.

CMS clarifies that the product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means. 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.

CMS also finalizes its policy to continue using the claims appeal process to determine whether payment can be made for replacement of supplies by non-contract suppliers in cases where replacement of supplies is needed and the supplies cannot be delivered on a timely basis by a contract supplier.

4. Comment/response

Commenters had many concerns on a wide range of issues regarding the RID CBP, which are briefly described below.

Closure of small DME suppliers. Several commenters were concerned the proposal would cause small DME suppliers to close, change long-standing supplier relationships, make it difficult for suppliers to meet beneficiary demand at lower prices, and potentially result in beneficiary access issues. CMS notes that it requires contract suppliers to furnish items to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who request these items from that contract supplier. It also points to it special rules at §414.414(g) to establish a goal of awarding at least 30 percent of the total number of contracts to small suppliers.

Quality concerns. Others expressed concern about the potential quality of items and services and what actions beneficiaries could take if they were concerned about the quality. CMS acknowledges the concerns and shares the goal of ensuring beneficiary access to quality DMEPOS items and services. CMS also notes that suppliers participating in the RID CBP must continue to follow the DMEPOS Quality Standards.

Access and other issues for local suppliers and beneficiaries in rural and underserved areas. Several commenters expressed concerns about potential negative effects the remote method of delivery under the RID CBP may have on local suppliers and beneficiaries in rural and underserved areas. Many commenters were concerned that the RID CBP may hurt beneficiaries who rely on in-person fittings or education on proper usage, including beneficiaries who use off-the-shelf (OTS) orthotics, intermittent catheters, or ostomy items. Another commenter asked if contract suppliers would be required to maintain local storefronts and furnish the items on a non-mail order basis in addition to furnishing the items on a mail order basis. CMS states that the RID CBP is a way to ensure access for all beneficiaries, including those in rural areas, and it plans to closely monitor access and health outcomes under the RIB CBP. In response, to beneficiary education, CMS states that it is important to distinguish between custom-fitted and custom-fabricated orthotics, which require clinical expertise and in-person fitting, and OTS orthotics, which require minimal self-adjustment for appropriate use. The RID CBP proposal is limited to OTS orthotics that are appropriate for remote delivery. CMS also reminds readers that physicians, treating practitioners, and hospitals may furnish competitively bid OTS orthotics without submitting a bid and being awarded a contract under the DMEPOS CBP, provided that certain conditions are satisfied.[81] With regards to a storefront, CMS states that under a RID CBP, a contract supplier would not be required to furnish the items in local storefronts in addition to furnishing them from remote locations, but they can voluntarily maintain local storefronts to furnish these items as well as furnishing them from remote locations to beneficiaries in all parts of the country.

Definition of region. One commenter sought clarification on what "region" means with respect to the remote item delivery competitive bidding program. CMS states that it did not specify which specific areas would be include under a RID CBP in the proposed rule, but if regional RID CBPs are established, they could cover smaller regions such as a State, territory, or the District of Columbia, or they could cover larger areas such as a group or combination of States, territories, and/or the District of Columbia.

Lost or misplaced supplies. Many commenters commented on CMS' proposal regarding situations where a beneficiary loses or is temporarily without supplies that Medicare has already paid for. CMS states that it believes these situations where beneficiaries lost or misplaced supplies is rare and can continue to be handled adequately through the claims appeals process under a RID CBP.

State licensure issues. Several commenters opposed the proposal because of concerns with licensing as state licensing requirements vary from state to state, and could impact a suppliers' ability to serve beneficiaries in specific states. CMS replies that it is the supplier's obligation to confirm and obtain the necessary state-specific licenses needed and that if there is a state

[81] This applies when the items are furnished by the physician or treating practitioner to their own patients as part of their professional service or by a hospital to its own patients during an admission or on the date of discharge, and if the items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

requirement to maintain a physical location that would also be their responsibility. CMS notes that similar concerns were overcome with mail diabetic testing supplies.

Separate from the final rule, CMS announced in the DMEPOS fact sheet the next round RID DMEPOS CBP product categories. CMS cited the following 7 product categories:

- Class II Continuous Glucose Monitors (CGMs) and Insulin Pumps
- Urological Supplies[82]
- Ostomy Supplies
- Hydrophilic Urinary Catheters
- Off-The-Shelf (OTS) Back Braces
- OTS Knee Braces
- OTS Upper Extremity Braces

CMS also provided this additional information. For beneficiaries transitioning from non-contract suppliers to contract suppliers during the initial three months of the contract period, if the non-contract supplier does not transfer the beneficiary's medical necessity documentation to the contract supplier, then the contract supplier has six months to obtain new orders from the patient's physician or treating practitioner. As part of this transition, contract suppliers must furnish the brand of items ordered by the patient's physician in compliance with the physician authorization process and DMEPOS supplier standards. This six-month grace period does not apply to the purchase of OTS braces, as these items will not involve such transitions.

G. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

In this section, CMS discusses its payment policies for CGMs and insulin infusion pumps (referred to as insulin pumps). These include (1) reclassifying CGMs and insulin pumps under the frequent and substantial servicing payment category; (2) establishing bid limits for CGMs and insulin pumps for the first time they are phased in as the lead item in a product category; (3) making 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; (4) determining SPAs for non-lead items for Class II CGMs, Insulin Pumps, and Supplies and Accessories; (5) continuing to make separate payment for replacement of supplies and accessories necessary for the effective use of a CGM or insulin pump owned by the beneficiary as items are phased in under the DMEPOS CBP; (6) excluding insulin pumps used in conjunction with a class III CGM the DMEPOS CBP; (7) establishing special payment limits for Class III CGMs and insulin pumps used in conjunction with Class III CGMs; and (8) allowing contract suppliers to bill for up to 3 months of rental for CGMs and insulin pumps in advance. This section also includes a table summarizing all of the finalized policies.

[82] CMS states that the urological supplies category will not include hydrophilic catheters.

1. Payment Reclassification of CGMs and Insulin Pumps

a. Background

CMS is concerned that two types of DME — CGMs and insulin 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.

CGMs are currently classified as routinely purchased equipment.[83] 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. Class III CGMs are not accurate enough to be classified as an integrated CGM system. Class III devices are also statutorily excluded from the CBP.

- The 2025 average Medicare fee schedule amount for purchase of a new, class II CGM receiver is $286.03.
- A 90-day supply for replacement supplies for the operation of a class II CGM totals $803.76.[84]

Over 5 years, the supplies used with class II CGMs account for over 98 percent of the total CGM costs over 5 years.

Insulin pumps are classified as other covered items of DME. Medicare payment for insulin 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 (such as Alaska, Hawaii, and Puerto Rico).
- A 90-day supply for replacement supplies necessary for the operation of the insulin pump totals approximately $403.68 for nonrural areas and $447.06 for rural and noncontiguous area.[85]

[83] 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 (FR 86 73900)
[84] 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.
[85] 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

Total payments for the ongoing replacement of supplies used with insulin pumps account for 60 percent of the total insulin pump costs, not including the cost of insulin, over 5 years.

CMS states that it 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.

CMS believes payment for CGMs and insulin pumps, as discussed below, should be on a continuous rental basis like other DME items requiring frequent and substantial servicing.

b. Reclassify CGMs and Insulin Pumps

CMS finalizes its proposal to reclassify all CGMs and insulin pumps under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, as implemented under §414.222(a). CMS will pay for all CGMs and insulin pumps on a monthly rental basis under both the DMEPOS CBP and in non-CBAs under the fee schedule payments. Thus, the reclassification as described by CMS will apply to all insulin pumps regardless of whether they are paid for under the DMEPOS CBP or under the fee schedule. The monthly rental payments will include payment for any necessary supplies and accessories. As discussed above, this will be a departure from how these items are currently classified and paid for under the Medicare DMEPOS fee schedule.

Based on a comment response, CMS notes that payment based on a continuous monthly rental basis for these items should be phased-in at the same time that class II CGMs and insulin pumps are phased in under the DMEPOS CBP to give suppliers time to prepare for the transition to the new monthly rental business model. CMS further states that it will announce the effective date of this payment classification through program instructions.

CMS believes this reclassification is necessary as the technology for CGMs and insulin pumps, which are often used in conjunction with CGMs, will continue to change very rapidly in future years. 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. CMS states 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 changes in diet and equipment activated changes in insulin.

CMS states that both CGMs and insulin pumps require software updates to ensure they are functioning properly and are protected from hacking or cyberattacks. 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.

CMS also states that an added benefit to this payment category reclassification will be that beneficiaries will have greater access to the latest technological equipment. This eliminates 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.[86] With purchased equipment, 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.[87] CMS also emphasizes that 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. The contract supplier of the rented equipment will 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 will also be responsible for addressing recalls of the rented equipment and furnishing replacement equipment, as necessary.

2. Bids Submitted for Class II CGMs or Insulin Pumps included as a Lead Item in a Product Category for the First Time

CMS finalizes its proposal to establish bid limits for CGMs and insulin pumps for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). These bid limit amounts for CGMs and insulin pumps will be calculated by converting the current equipment and supply costs to a monthly amount. CMS finalizes its proposal to divide the total fee schedule amount for the equipment items by 60 for the number of months over a 5 year period – the reasonable useful life of the equipment as part of this calculation. CMS will use the nonrural payment amount in the current fee schedule to calculate the bid limits for insulin pumps noting that 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. The bids submitted for rental of CGMs and insulin pumps cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under the DMEPOS fee schedule.

[86] CMS does not specify how frequently a beneficiary could switch in the final rule to new rental equipment but in posting to the social media platform X on November 28, 2025 announcing the release of the HH/DMEPOS final rule, CMS stated that CGMs and insulin pumps could upgrade their CGMs and insulin pumps as often as every 30 to 90 days. The 90-day minimum period corresponds with the billing for CGM and insulin pump supplies that are billed in 90-day increments.

[87] In accordance with regulations at 42 CFR 414.210(f)(a).

CMS uses 2025 fee schedule amounts to demonstrate how the bid limits will be calculated. The monthly rental calculations are as follows:

- **Non-Adjunctive, Class II CGMs: $272.69**
  - Purchase fee schedule amount for the non-adjunctive CGM receiver (E2103): $286.03/60 months = $4.77
  - Monthly fee schedule for CGM supplies (A4239): $267.92
  - $267.92 + $4.77=$272.69

- **Insulin Pumps (based on nonrural amounts): $226.22**
  - Monthly fee schedule amount for insulin pump (E0784): $5,702.34/60 months =$95.04
  - Monthly fee schedule for infusion set supplies (A4224): $25.19 x 4=$100.76
  - Monthly fee schedule for insulin cartridges (A4225): $3.38 x 9=$30.42
    CMS notes that in 2024, Medicare paid for seven to nine units of A4225 (insulin cartridges) per month, on average, for beneficiaries using insulin pumps (E0784) and is seeking comments on this assumption.
  - $95.04 + $100.76+$30.42=$226.22

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 these bid limits to be considered. The actual monthly rental SPAs for CGMs and insulin pumps will be determined by CMS after evaluating all the bids it receives from the bidding entities.

CMS also discusses the potential impact on beneficiaries using the bid limits, not factoring in reduced pricing under the DMEPOS CBP.

Impact of Monthly Rental Amounts for CGMs and Insulin Pumps, not factoring in reduced pricing under the DMEPOS CBP	
Product	**Impact on Beneficiary Coinsurance Payments**
CGM receiver and supplies	Same total but coinsurance payments for the CGM receiver will now be lower and spread out over 60 months rather than paid all at once in one lump sum.
Insulin Pumps (new users)	Same total for the insulin pumps and supplies, but the coinsurance payments for the insulin pump will now be lower and spread out over 60 months rather than over 13 months.
Supplies Only (user owns an insulin pump)	Coinsurance payments will remain approximately the same unless they elect to obtain a new insulin pump,
Insulin pump (beneficiary in the middle of the 13-month capped rental period when phased into the DMEPOS CBP)	Coinsurance payments will increase since they will transition to the new monthly payments with coinsurance payments which will not be reduced by the amounts attributed to the monthly rental payments already made under the capped rental rules.

3. Payment for CGMs and Insulin Pumps Furnished by Contract Suppliers Under the DMEPOS CBP and by Grandfathered Suppliers

CMS finalizes its 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. Payment will 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 will no longer be made and contract suppliers will retain ownership of the rental equipment. Rental agreements for covered CGMs and insulin pumps entered into before the application of the DMEPOS CBP will be continued once the items are phased in under the program, on a bundled monthly rental basis.

In accordance with section 1834(a)(1)(F)(ii) and (iii) of the Act, CMS also finalizes that fee schedule amounts for class II CGMs or insulin pumps will 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). Specifically, the payment for CGMs and insulin pumps and necessary supplies and accessories that are not furnished under the DMEPOS CBP will also be made on a bundled monthly rental basis with payments limited to the amounts established for CGMs and insulin pump under the DMEPOS CBP.

CMS plans to announce the effective date of this payment classification through program instructions.

4. 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

CMS finalizes its 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 receive replacement supplies and accessories for the CGM or insulin pump from a contract supplier for the CBA where they reside.

CMS states that this is a temporary transition rule that will phase out once all beneficiary-owned CGMs or insulin pumps are replaced by rented equipment after they are lost, stolen, irreparably damaged, or 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 will be established in accordance with the payment rules for non-lead items. The beneficiary will 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.

5. 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

Given the possibility that CGMs and insulin pumps could be included in the same product category (with CGMs being the lead item) in a remote item delivery CBP,[88] CMS finalizes its proposal to calculate what the unadjusted fee schedule amounts for CGMs would have been in 2015 so it 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. This is necessary because Medicare did not start paying for class II CGMs until after 2015.

Using this approach, CMS will determine 2015 fee schedule amounts for the monthly rental of a class II CGM by 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. CMS will 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.

CMS makes 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 nonlead items. The SPAs for the rental of a non-lead item in a product category including CGMs and insulin 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. CMS' 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. CMS uses 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.

CMS also finalizes its proposal that the 2015 fee schedule amounts for the monthly rental of an insulin pump used for the purpose of calculating SPAs for non-lead items will be calculated using the average 2015 fee schedule amounts for the insulin 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 pump multiplied by nine for the nonrural areas included in the RID CBP plus the average 2015 fee schedule amounts

[88] In the November 28 2025 DMEPOS Fact Sheet, CMS includes CGMs and insulin pumps in the same product category.

for the weekly insulin pump supplies multiplied by four for the nonrural areas included in the RID CBP.

6. Insulin Infusion Pumps Used in Conjunction with Class III CGM

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. The 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 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. In addition, there are some insulin pumps that are approved by the FDA for use in conjunction with a class III CGM. In instances where an insulin pump that has been approved by the FDA for use in conjunction with a class III CGM, CMS finalizes its proposal that the insulin pumps used in conjunction with a class III CGM should be excluded from the DMEPOS CBP.

7. Special Payment Limits for Class III CGMs and Insulin Infusion Pumps Used in Conjunction with Class III CGMs

CMS finalizes its proposal to use its authority at section 1842(b)(8) of the Act to establish special payment limits for class III CGMs and insulin pumps used in conjunction with class III CGMs if the bundled monthly rental amounts for class II CGMs and/or insulin 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 pumps and related supplies. In accordance with its regulations at §405.502(g)(1)(ii), CMS can determine that a payment amount is grossly excessive if it is determined that an overall payment adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount.

CMS believes 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. Further, CMS states it believes 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. CMS believes 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.

CMS believes 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. CMS notes that 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.

Specifically, CMS finalizes the following:

- Monthly rental fee schedule payment amounts for class III CGMs will be limited to the monthly rental SPAs established for class II CGMs under the DMEPOS CBP.
- Monthly rental fee schedule payment amounts for insulin pumps used in conjunction with class III CGMs will be limited to the monthly rental SPAs established for insulin pumps under the DMEPOS CBP.
- Monthly fee schedule payment amounts for supplies used in conjunction with beneficiary-owned class III CGMs will be limited to the monthly SPAs established for supplies used in conjunction with beneficiary-owned class II CGMs under the DMEPOS CBP.
- 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 will 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)(9)(A) of the Act, the Secretary is required to 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) also require CMS to publish in the Federal Register proposed and final notices announcing a special payment limit before it adopts the limit. CMS sought 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.

Further, 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.

CMS believes the reductions would level the playing field and avoid providing class III CGM suppliers and manufacturers with an unfair advantage. CMS notes that Class III CGMs currently make up about 25 percent of the total charges for CGMs under Medicare and thus believes 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. Beneficiary cost-sharing for class II CGMs, insulin pumps would be reduced as a result of the special payment limit and method. CMS does not believe that assignment rates and participation rates would likely be affected.

8. 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 pump is currently made for these items in quantities necessary for a 90-day period. CMS finalizes its proposal to allow contract suppliers to bill for up to 3 months of

rental for CGMs and insulin pumps in advance to be consistent with this policy.

9. Summary of Provisions

The following is a summary list of the provisions under this section.

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 will 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 will 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 will 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 will 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 will 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 will 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.

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 will be classified as items requiring frequent and substantial servicing for the purpose of implementing the payment rules under section 1834(a) of the Act. Payment will 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 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)
Special payment limits will be established in accordance with regulations at 42 CFR 405.502(g) and section 1842(b)(8) and (9) of the Act to limit payment for class III CGMs and insulin pumps used in conjunction with class III CGMs as well as supplies and accessories for beneficiary owned class III CGMs and insulin pumps used in conjunction with class III CGMs to the payment amounts established for class II CGMs and insulin pumps as well as supplies and accessories for beneficiary owned class II CGMs and insulin pumps under the DMEPOS CBP.
Payment for replacement of supplies and accessories only for beneficiary-owned equipment will 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, or is more than 5 years old, or in cases where the beneficiary elects to obtain newer equipment.

10. Comment/Response:

Commenters had many concerns on a wide range of issues related to payment for CGMs and insulin infusion pumps which are briefly described below.

Patient access to care and associated outcomes. Many commenters expressed concern over the implication of the proposals on access to care and associated outcomes, emphasizing the complications and side effects that occur due to unmanaged diabetes, such as diabetic ketoacidosis, kidney failure, heart disease, neuropathy, amputation, and vision loss. Commenters note that the integration of CGMs and pumps for insulin therapy is associated with positive health outcomes, including lower A1c (HbA1c) levels, increased glycemic control, and reduced time managing the disease. CMS agrees with the comments and states that its proposals are designed to provided beneficiaries with the latest CGM and/or insulin pump technologies and prevent beneficiaries from being locked into a device for five years.

Elimination of suppliers from creating a bundled category of CGMs and insulin pumps. Commenters expressed concern that creating a bundle category of CGMs and insulin pumps has the potential to eliminate suppliers who have a strong history of supplying specific types of diabetes technologies. CMS replies that under the physician authorization process at 42 CFR 414.420, a contract supplier must furnish the specific brand of CGM and/or insulin pump prescribed by the physician or treating practitioner if the physician or treating practitioner believes the specific brand is needed to avoid adverse health outcomes. Once folded into the DMEPOS CBP, contract suppliers are required to furnish any brand of class II CGM or insulin pump included under the product category if the beneficiary requests the item from the contract supplier and the physician authorizes use of a specific brand CGM or insulin pump as part of their order. CMS states it is confident that manufacturers of CGMs and insulin pumps will work closely with the contract suppliers to educate and train them on the brands of class II CGMs and insulin pumps they have not carried in the past.

Furnishing CGMs and insulin pumps on a rental basis. Many commenters expressed concern that suppliers lack the expertise to furnish CGMs and insulin pumps on a rental basis, including

repairing and servicing equipment, managing returns and replacements of equipment, including recalls, refurbishing equipment for reuse, and providing technical support, software updates, and device training that manufacturers are currently providing for this equipment. Commenters also stated that certain CGMs and insulin pumps are single patient use devices and cannot be reused. Others expressed concern that suppliers would not be able to absorb the upfront costs of purchasing equipment that may quickly be replaced and thus recoup their investments.

CMS notes that all DME items are required to be able to withstand repeated use and asserts that these items can be rented to another patient once the patient is finished renting the item. The DMEPOS standards also require suppliers to answer questions and respond to complaints a beneficiary has about any DMEPOS item that is sold or rented. The supplier may not pass this responsibility off to the manufacturer of the equipment but suppliers may subcontract with manufacturers to perform repairs or maintenance and servicing of rented CGMs and insulin pumps. CMS also points out that insulin pumps are currently being paid for on a rental basis for a period of continuous use during which time suppliers must maintain and repair the equipment as needed and provide all services necessary for the equipment to function properly. With respect to CGMs, CMS believes that suppliers will be able to absorb the upfront cost of purchasing CGMs they rent from the money they receive for supplies for the rented CGMs. CMS further provides a comparison to blood glucose monitors and believes that manufacturers will have an incentive to significantly reduce the cost of their brand of CGM receiver to obtain profits from their brand of CGM supplies.

Effective date of the change in payment methodology. One commenter believed that the change in payment methodology should be implemented before the items are phased-in under the DMEPOS CBP. CMS disagrees and states that payment on a continuous monthly rental basis (i.e., the frequent and substantial servicing payment classification) for these items should be phased in at the same time that class II CGMs and insulin pumps are phased in under the DMEPOS CBP to give suppliers time to prepared for the transition to the new monthly rental business model. This would apply for the phase in of class II CGMs and insulin pumps under the DMEPOS CBP and the concurrent classification of CGMs and insulin pumps paid for on a fee schedule basis as items requiring frequent and substantial servicing. Until the next round of CBP begins, the payment classification under the DMEPOS fee schedule for CGMs and insulin pumps will remain the same. That is, payment for insulin pumps will be 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, and CGMs will continue to be classified as routinely purchased equipment.

CMS states that it will announce the effective date of this payment classification through program instructions.

Recouping costs of the equipment. Several commenters suggested changes to how the monthly equipment payment should be calculated by changing the useful life of the equipment from 5 years to 3 years or changing how the equipment costs are amortized over 5 years. These changes would help the supplier to be fully paid for the equipment if the beneficiary decides to upgrade to newer technology equipment before the 5-year period is over. CMS does not agree and states that Medicare payment for DME is based on payment for new items expected to last for 5 years. In

addition, CMS states that the equipment acquisition costs can be recouped over 5 years by renting the equipment to multiple patients.

Using inherent reasonableness authority to limit monthly rental fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. Many commenters did not agree that the inherent reasonableness authority and process for adjusting grossly excessive fee schedule amounts should be used to limit monthly rental fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. CMS did not agree and does not believe that it would be inherently reasonable for Medicare payment amounts for less accurate and less expensive CGMs to be higher than the Medicare payment amounts for other CGMs that are more accurate.

Process outlined in statute and regulations for establishing special payment amounts using the inherent reasonableness authority has not been followed. Some commenters believe that CMS did not follow the proper process for establishing special payment limits for class III CGMs and insulin pumps used in conjunction with class III CGMs. In addition, these commenters believe that CMS did not believe the requirements for use of valid data and reliable data in determining an appropriate payment amount for these items have been met.

CMS disagrees and believes it followed the proper process outlined in statute and regulations. This includes consulting with representatives of supplier or other individuals who furnish class III CGMs, publishing the notice of proposed determination in the Federal Register (as part of the proposed rule), and allowing public comment for the proposed determination. It states that it did not need to do a pricing survey as its determination was based on other factors. It also provides in the response to comments a more detailed explanation of the factors and other data considered in making the inherent reasonableness determination, including the economic justification for a uniform/fee payment limit. CMS states that publication of this final rule is notice of the final determination needed to establish these special payment limits.[89]

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

Section 1847(b)(2) of the 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.

CMS is finalizing its 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. CMS believes 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. Bidding entities will no longer require the submission of a tax return extract, income statement, balance sheet, and statement of cash flows.

[89] The justification and detailed explanation provided by CMS in the final rule was not as transparent in the proposed rule and could be subject to interpretation of whether the proper process was followed in establishing these payment limits.

Each bidding entity must 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. The date each document was prepared cannot be 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.

CMS will 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 its business, changes the name of a credit report, and/or revises the numerical score/rating ranges.

CMS will 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. A bidding entity that receives a minimum score of 12 or higher as passing – meets the financial sustainability threshold. If deemed as passing, the bidding entity will continue to be evaluated for a potential contract offer. CMS notes that its analysis of Round 2021 data showed that only 1.7 percent (19 out of 1,133) of suppliers' TINs received a credit score rating of 8 or lower. In the final rule, CMS includes a detailed description of each business credit report to help suppliers understand the difference between the business credit reports as well as the score required for each of the tiers of five-tier credit report scoring system (see table FF-36, reproduced below).

Table FF-36. 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

Table FF-36. Credit Report Scoring List					
Credit Report Name	**Tiers and Scoring**				
	20	**16**	**12**	**8**	**4**
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

With respect to the financial scoring methodology, CMS will 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 will also 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. 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. 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. 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.

Comment/response: Many commenters had concerns that a credit report and credit score would not be sufficient in determining if a supplier could increase their capacity to meet beneficiary demand. Commenters argued that such documentation is critical to assessing a supplier's ability to scale operations and meet demand, and some expressed concern that credit scores could be manipulated. CMS responds that bidding entities that manipulate credit scores may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program, and those entities that manipulate credit scores could be referred to the Office of Inspector General or the Department of Justice for further investigation.

CMS also states in response to comments that it will review Medicare FFS claims to verify bidding entities are small suppliers. In addition, CMS agrees that all locations/billing numbers that are part of a single corporate entity for a DMEPOS supplier should count as a single supplier for the purposes of the competition.

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

Since the inception of the DMEPOS CBP, within either 45 (for Round 1 bids) or 90 days (for subsequent round bids) after the Covered Document Review Date **(**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. CMS is finalizing its proposal 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 policy 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.

CMS states that this policy 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 will identify the universe of bidding entities that submitted at least one covered document by the CDRD and then determine if they have a missing covered document(s) by the close of the bid window. CMS will 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 required in the current process. Additionally, CMS states that 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.

Comment/response: Commenters were in support of the proposal. CMS finalizes its proposal as proposed, with the exception of technical changes to the regulation text. CMS is finalizing the regulation text with the technical change to redesignate paragraphs (d)(2) to (d)(3) .and the rest of the proposal without changes, which is reflected in 42 CFR 414.414(d)(3)(ii)(B).

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. 114–10) (MACRA), requires a bid surety bond for bidders. CMS' 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.

2. Provisions of the Regulation

CMS applied the bid surety bond rider process during bid evaluation for Round 2021 of the DMEPOS CBP, and is now finalizing its proposal to codify this process in regulation. Additionally, CMS corrects a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph re-designation in 83 FR 57072.

In the final rule, CMS gives examples of the types of deficiencies that could be corrected by a bid surety bond rider. These include correcting the name of the bidder as the principal/obligor, missing or an illegible name or the National Association of Insurance Commissioners (NAIC) number of the authorized surety, not naming CMS obligee, the omission of the conditions of the bid surety bond language, an incorrect or missing CBA name, a missing or illegible bond surety bond number, a missing or illegible date of issuance, or fixing a bid surety bond value other than $50,000. CMS also gave examples of the types of deficiencies that a bidder may have on its bid surety bonds that cannot be corrected by a bid surety bond rider, which included a late bid submission (e.g. did not meet the bid submission deadline), a bidder that submitted a document other than a bid surety bond (e.g. Medicare enrollment bond), and a missing bid surety bond.

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 will be provided to a bidder in this situation. 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.

Bidders will be notified by CMS of the deficiency (that is, the incorrect, incomplete, or missing requirement), and will 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 will send 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 finalizes its proposal 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. CMS states that a 10 business day timeframe was utilized for Round 2021, which provided bidders with

ample time and also anticipates that extending this timeframe could result in some bid evaluation processes being delayed.

CMS is also finalizing revisions in 42 CFR 414.412(g)(1) to clarify that, for each round of the DMEPOS CBP, a bidding entity must obtain a bid surety bond for each CBA included on a bid(s) from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provide proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission. CMS corrects a technical error created in 83 FR 57072 where CMS redesignated paragraphs (e) through (h) as paragraphs (d) through (g), respectively. This correction will 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.

Comment/response: Commenters generally supported the proposal of allowing bidders with a single, 10-day business day timeframe to submit a bid surety bond rider correcting certain deficiencies on their bid surety bond(s). Other commenters suggested CMS clarify when a supplier can decline a contract offer(s) without forfeiting its bid surety bond. CMS replies that in accordance with 42 CFR 414.412(g)(3)(i), when a bidding entity is offered a contract for a competition, its composite bid (the bid submitted by the supplier for the lead item in the product category) for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition, and the bidding entity does not accept the contract offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond.

K. Tribal Exemption from Participating in the DMEPOS CBP

1. Background

The Indian Health Care Improvement Act (IHCIA) (Pub. L. 94-437, September 30, 1976) amended the Act to permit payment by Medicare and Medicaid for services provided to American Indians/Alaska Natives (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, (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.

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 (IHCIA), 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.

2. Provisions of the Regulation

CMS finalizes its proposal to use the authority at section 1862(a)(17) of the Act to add an exception to §414.408(e)(2) that will 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.

Commenters were supportive of this proposal and CMS finalizes all provisions without changes.

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

1. Background

CMS reiterates that 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 their contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. In the 2006 proposed rule (71 FR 25682),[90] 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.

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. Nevertheless, CMS is 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

[90] "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. (71 FR 25654).

in CBAs or defined area(s) within CBAs specified in the contracts and affected by the PHE (the PHE-impacted area).

CMS believes it is prudent for the agency 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 encompass 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.

2. Provisions of the Regulation

CMS finalizes its proposal, in §414.422, that if it 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, the agency has 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. CMS provides these options:

Items and Services/Geographic Areas Impacted by the PHE	**CMS Policy at §414.422**
Encompass all competitions referenced in a DMEPOS CBP supplier contract	Unilaterally terminate the DMEPOS CBP supplier contract.
Encompass only a portion of the items and services and geographic areas referenced in a DMEPOS CBP supplier contract	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.

CMS finalizes its proposal, in §414.422, that after termination and/or modification of all applicable DMEPOS CBP supplier contracts, it would revert back to the general fee-for-service program requirements. 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.

CMS also finalizes its proposal 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.

Comment/response: Commenters were supportive of the proposal. One commenter had concerns about the risk of over-consolidation and indicated that replacement providers will not be staffed or stocked to absorb a sudden surge, leaving patients vulnerable. CMS clarifies that this proposal has no impact on DMEPOS supplier consolidation and that any enrolled DMEPOS supplier will be permitted to provide services to Medicare beneficiaries who live in a competitive bidding area if DMEPOS CBP contracts are terminated during a Public Health Emergency.

M. Technical Changes to §414.408(h)(8)

CMS finalizes its proposal to make 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). CMS received no comments on this issue.

N. Definitions of "Competition" and "Adjusted Fee Schedule Amount" and "Unadjusted Fee Schedule Amounts" under §414.402

CMS finalizes its proposal that *Adjusted fee schedule amount* and *Unadjusted payment amount* mean 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.[91] These references refer to Medicare fee schedule amounts for enteral nutrition, DME and medical supplies and OTS orthotics, and lymphedema compression treatment items.

Similarly, for the purpose of streamlining regulation text, rather than continuing to write out "competitive bidding area and product category combination," CMS adds 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."

O. DMEPOS CBP Burden Estimates and Regulation Impact

This section summarizes the DMEPOS CBP collection of information requirements in section VIII and the regulatory impact of these provisions described in section IX of the final rule.

[91] Subpart C of Part 414 is Fee Schedules for Parenteral and Enteral Nutrition (PEN) Nutrients, Equipment and Supplies, Splints, Casts, and Certain Intraocular Lenses (IOLs); Subpart D is Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices; and Subpart Q is Payment for Lymphedema Compression Treatment Items

1. DMEPOS CBP Collection of Information Requirements

CMS calculates the increase or decrease in administrative burden for bidding entities in the DMEPOS CBP associated with information collection requirements required by CMS. Overall, CMS calculates that the changes results in an annual reduction in burden or savings to bidding entities of $30.5 million in total.

Regulatory Section in Title 42 of the CFR	**Form**	**Change in Annualized Costs**
Submission of Financial Documents (§ 414.402)	Form A	$(178,946)
Adjustments to Single Payment Amounts (§ 414.408(b))	Form B	$(10,109,340)
Determining the Number of Contracts Awarded (§ 414.414(h))	Form B	$(10,109,340)
RID CBA and Revising the Definition of Item Related to Medical Supplies (§ 414.402)	Form B	$(10,109,340)
TOTAL	N/A	$(30,506,966)

2. DMEPOS CBP Regulatory Impact

CMS believes that the provisions of this 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. Nevertheless, CMS provides additional information on these provisions.

Changes to the Calculation of SPAs and Number of Contracts to be Awarded. CMS expects that the combination of setting the SPA at 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 would result in zero net expenditure.

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, CMS expects 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.

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.

Other Provisions. CMS states that the other provisions of this rule are purely an administrative effort with no impact on Medicare coverage or expenditure, and, for this reason, have no cost or transfer associated with them.

VIII. Regulatory Impact Analysis

CMS estimates that the net impact of the HH PPS policies in this final rule is a decrease in Medicare payments to HHAs of 1.3 percent, or $220 million, for 2026. The permanent and temporary adjustments—needed to ensure aggregate spending neither increased nor decreased as a result of the 30-day episode of care and elimination of therapy thresholds beginning in 2020—are the primary contributors to the decrease in Medicare payments to HHAs. The overall impact of the changes in the HH PPS system on payments to HHAs in 2026 is summarized in the following table.

Summary of Overall Impact of HH PPS Changes		
Policy	**2026 impact**	
	Percentage	**Dollars**
HH PPS update	+2.4%	+$405 million
Permanent adjustment	-0.9%	-$150 million
Temporary adjustment	-2.7%	-$460 million
Updated fixed dollar loss (FDL)	-0.1%	-$15 million
Net impact	**-1.3%**	**-$220 million**

Table 51, reproduced below from the final rule, provides details on the impact by facility type and ownership, by rural and urban area, by census region and by facility size. The combined effects of all changes vary by specific types of providers and by location. The table breaks out the payment effects of the permanent adjustment, the case-mix weights recalibration budget neutrality factor, the 2026 wage index update, the 2026 update percentage, the FDL update, and the temporary adjustment. The permanent behavior adjustment impact reflected in column 3 does not equal the -1.023 percent permanent adjustment. CMS explains that the -0.9 percent reflected in column 3 includes all payments, while the -1.023 percent adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods that are LUPAs. Proprietary free-standing HH agencies (about 83 percent of all agencies) would experience an average decrease of payments of 1.6 percent. Voluntary/Non-profit HHAs would experience a 0.7 percent decrease. Government-based agencies would experience a 1.0 percent decrease.

Table 51: 2026 Estimated HHA Impacts by Facility Type and Area of the Country								
	Number of Agencies	**Permanent Adjustment**	**2026 Case-Mix Weights Recalibration**	**2026 Updated Wage Index (with 5% cap)**	**2026 HH Payment Update %**	**Fixed-Dollar Loss (FDL)**	**Temporary Adjustment**	**Total**
All Agencies	**9,851**	**-0.9%**	**0.0%**	**0.0%**	**2.4%**	**-0.1%**	**-2.7%**	**-1.3%**
Facility Type and Control								
Free-Standing/Other Vol/NP	718	-0.9%	0.1%	0.5%	2.4%	-0.1%	-2.7%	-0.7%
Free-Standing/Other Proprietary	8,140	-0.9%	0.0%	-0.2%	2.4%	-0.1%	-2.8%	-1.6%
Free-Standing/Other Government	101	-0.9%	-0.1%	0.3%	2.4%	-0.1%	-2.6%	-1.0%
Facility-Based Vol/NP	388	-0.9%	0.1%	0.3%	2.4%	-0.1%	-2.6%	-0.8%
Facility-Based Proprietary	24	-0.9%	0.1%	-0.9%	2.4%	-0.1%	-2.7%	-2.1%
Facility-Based Government	167	-0.9%	0.2%	0.4%	2.4%	-0.1%	-2.7%	-0.7%
Subtotal: Freestanding	9,033	-0.9%	0.0%	0.0%	2.4%	-0.1%	-2.7%	-1.3%
Subtotal: Facility-based	580	-0.9%	0.1%	0.3%	2.4%	-0.1%	-2.6%	-0.8%
Subtotal: Vol/NP	1,106	-0.9%	0.1%	0.5%	2.4%	-0.1%	-2.6%	-0.6%

Table 51: 2026 Estimated HHA Impacts by Facility Type and Area of the Country								
	Number of Agencies	Permanent Adjustment	2026 Case-Mix Weights Recalibration	2026 Updated Wage Index (with 5% cap)	2026 HH Payment Update %	Fixed-Dollar Loss (FDL)	Temporary Adjustment	Total
Subtotal: Proprietary	8,164	-0.9%	0.0%	-0.2%	2.4%	-0.1%	-2.8%	-1.6%
Subtotal: Government	268	-0.9%	0.1%	0.4%	2.4%	-0.1%	-2.6%	-0.7%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	166	-0.9%	0.1%	0.8%	2.4%	-0.1%	-2.7%	-0.4%
Free-Standing/Other Proprietary	796	-1.0%	0.0%	0.0%	2.4%	-0.1%	-2.8%	-1.5%
Free-Standing/Other Government	62	-0.9%	-0.2%	1.2%	2.4%	-0.1%	-2.6%	-0.2%
Facility-Based Vol/NP	153	-0.9%	0.2%	1.2%	2.4%	-0.1%	-2.6%	0.2%
Facility-Based Proprietary	8	-0.9%	0.4%	0.7%	2.4%	-0.1%	-2.7%	-0.2%
Facility-Based Government	120	-0.9%	0.1%	0.6%	2.4%	-0.1%	-2.6%	-0.5%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	552	-0.9%	0.1%	0.5%	2.4%	-0.1%	-2.7%	-0.7%
Free-Standing/Other Proprietary	7,342	-0.9%	0.0%	-0.2%	2.4%	-0.1%	-2.8%	-1.6%
Free-Standing/Other Government	39	-0.9%	0.0%	-0.1%	2.4%	-0.1%	-2.6%	-1.3%
Facility-Based Vol/NP	235	-0.9%	0.1%	0.2%	2.4%	-0.1%	-2.5%	-0.8%
Facility-Based Proprietary	16	-0.9%	-0.1%	-1.5%	2.4%	-0.1%	-2.7%	-2.9%
Facility-Based Government	47	-0.9%	0.3%	0.2%	2.4%	-0.1%	-2.7%	-0.8%
Facility Location: Urban or Rural								
Rural	1,362	-0.9%	0.0%	0.3%	2.4%	-0.1%	-2.8%	-1.1%
Urban	8,459	-0.9%	0.0%	-0.1%	2.4%	-0.1%	-2.7%	-1.4%
Facility Location: Region of the Country (Census Region)								
New England	302	-0.9%	-0.1%	1.6%	2.4%	-0.1%	-2.7%	0.2%
Mid Atlantic	370	-0.9%	0.2%	-0.3%	2.4%	-0.1%	-2.7%	-1.4%
East North Central	1,372	-0.9%	0.0%	0.6%	2.4%	-0.1%	-2.8%	-0.8%
West North Central	548	-0.9%	0.0%	0.9%	2.4%	-0.1%	-2.7%	-0.4%
South Atlantic	1,573	-0.9%	0.0%	0.6%	2.4%	-0.1%	-2.8%	-0.8%
East South Central	357	-1.0%	0.0%	0.1%	2.4%	-0.1%	-2.8%	-1.4%
West South Central	1,961	-0.9%	-0.1%	-0.5%	2.4%	-0.1%	-2.8%	-2.0%
Mountain	699	-0.9%	0.0%	0.2%	2.4%	-0.1%	-2.7%	-1.1%
Pacific	2,627	-0.9%	0.0%	-1.1%	2.4%	-0.1%	-2.7%	-2.4%
Outlying	42	-0.9%	1.1%	-0.1%	2.4%	-0.1%	-2.7%	-0.3%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,285	-0.9%	-0.2%	-0.5%	2.4%	-0.1%	-2.7%	-2.0%
100 to 249	1,573	-0.9%	-0.2%	-0.5%	2.4%	-0.1%	-2.7%	-2.0%
250 to 499	1,767	-0.9%	-0.1%	-0.4%	2.4%	-0.1%	-2.7%	-1.8%
500 to 999	1,920	-0.9%	-0.1%	-0.3%	2.4%	-0.1%	-2.7%	-1.7%
1,000 or More	2,306	-0.9%	0.1%	0.1%	2.4%	-0.1%	-2.7%	-1.1%

Source: 2024 Medicare claims data for periods with matched OASIS records ending in 2024 (as of July 11, 2025).
Notes: The estimated 0.9 percent decrease related to the final permanent adjustment includes all payments, while the -1.023 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 2.7 percent decrease related to the final temporary adjustment includes all payments, while the -3.000 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 "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 0.37. 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 9,851).

CMS examined alternatives to the finalized -1.023 percent permanent adjustment including finalizing the calculated permanent adjustment of -4.162 percent. CMS considered another alternative that would calculate and only finalize the remaining permanent adjustment needed to account for behavior change attributable to PDGM implementation for 2020 through 2021 claims, rather than through 2022 claims. CMS' utilization trends showed that most of the effects related to the implementation of PDGM occurred by the end of 2022 and that several factors make it difficult to separate the effects of PDGM and non-PDGM-related behaviors on estimated aggregate expenditures, such as changes to the OASIS assessment which started in 2023.

CMS also considered not applying a temporary adjustment, as in prior rules, or finalizing the -5.0 temporary adjustment as proposed or finalizing a different percentage to begin to recoup the calculated temporary adjustment dollar amount. CMS stated that it considered commenters' concerns about the magnitude of a -5.0 percent temporary adjustment in tandem with any finalized permanent adjustment. As such, CMS believes it is most appropriate to finalize implementing a smaller 3.0 percent reduction in 2026. 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.