

RULE SUMMARY

JULY 2025

MEDICARE HOME HEALTH PROSPECTIVE PAYMENT SYSTEM

Overview and Resources

On June 30, 2025, the Centers for Medicare & Medicaid Services (CMS) released its proposed calendar year (CY) 2026 payment rule for the Medicare Home Health Prospective Payment System (HH PPS). The proposed rule includes updates to the Medicare fee-for-service (FFS) HH PPS payment rates based on changes set forth by CMS and those previously adopted by the US Congress. Among the proposed updates are:

- Recalibration of the Patient-Driven Groupings Model (PDGM) case-mix weights, low utilization payment adjustment (LUPA) thresholds, functional levels, and comorbidity adjustment subgroups;
- Payment adjustments to reflect the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate payment expenditures under the HH PPS;
- Updates to the HH quality reporting program (QRP);
- Updates to the Expanded Home Health Value-Based Purchasing (HHVBP) Model;
- Updating HHA Conditions of Participation (CoPs);
- Updates to face-to-face encounter policies;
- Strengthening policies related to Medicare and Medicaid provider enrollment; and
- Updates to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) related policies.

Program changes will be effective for discharges on or after January 1, 2026, unless otherwise noted. CMS estimates the overall impact of this proposed rule to be a decrease of \$1.135 billion in aggregate payments to Home Health Agencies (HHAs) in CY 2026 over CY 2025, which includes a \$425 million increase due to the proposed home health payment update, a \$655 million decrease due to the proposed permanent behavior adjustment, a \$815 million decrease due to the proposed temporary adjustment, and a \$90 million decrease due to the proposed fixed-dollar loss (FDL) amount for outlier payments. Please note that CMS has a different estimate of \$786 million for the proposed temporary adjustment recoup for CY 2026 in their discussion in the rule. We have reached out to CMS for clarification since this does not match the impact of \$815 million stated in Table 1 of the proposed rule.

A link to this proposed rule and other resources related to the HH PPS are available on the CMS <u>website</u>. An online version of this proposed rule is available <u>here</u>.

Comments on this proposed rule are due to CMS by August 29, 2025 and can be submitted electronically at http://www.regulations.gov by using the website's search feature to search for file code "CMS-1828-P."

Request For Information (RFI) - Deregulation

"On January 31, 2025, President Trump issued Executive Order (EO) 14192 'Unleashing Prosperity Through Deregulation,' which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on

approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. CMS has made available an RFI. Please submit all comments in response to this RFI through the provided weblink."

HH PPS Payment Rates

The table below shows the proposed CY 2026 30-day period standard payment rate compared to the final CY 2025 30-day standard payment rate:

	Final CY 2025	Proposed CY 2026	Percent Change
30-Day Period Standard Payment Rate	\$2,057.35	\$1,933.61	-6.01 %

The following table provides details for the proposed annual updates to the HH 30-day period standard payment rate for CY 2026.

Proposed CY 2026 Update Factor Component	Change to 30-Day Period Standard Rate		
Market Basket (MB) Update	+3.2%		
Affordable Care Act (ACA)-Mandated Productivity Adjustment	-0.8 percentage points (PPTs)		
Permanent Behavior Assumption Adjustment	-4.059%		
Wage Index and Labor-Related Share Budget Neutrality	+0.19%		
Case-Mix Weights Recalibration Budget Neutrality	+0.51%		
Temporary Adjustment	-5.00%		
Net Rate Update	-6.01%		

The proposed market basket update percentage is based on IHS Global Inc.'s first quarter 2025 forecast with historical data through 4Q 2024.

Behavioral Assumptions and Adjustments

Since CY 2020, CMS has been required by the Bipartisan Budget Act of 2018 to use a 30-day period of care as the unit of payment in place of the prior 60-day episode of care. Part of this statute requires CMS to make assumptions about behavior changes that could occur as a result of implementing a 30-day unit of payment and case-mix adjustment factors that eliminated the use of therapy thresholds when calculating the CY 2020 standard payment amount.

The Consolidated Appropriations Act (CAA) of 2023 requires CMS to determine the differences between assumed and actual behavior on estimated aggregate expenditures, beginning in CY 2020 and ending with CY 2026, and make permanent and temporary adjustments as necessary through notice and rulemaking. CMS is also required to provide both the data sets underlying the simulated 60-day episodes as well as time in order for stakeholders to make comments on the development of the HH PPS payment rate.

In the CY 2023 HH PPS final rule, CMS adopted the methodology to determine the impact on estimated expenditures between assumed and actual behavioral changes, which are used for evaluating the budget



neutral 30-day payment rates for CYs 2020–2026 under the PDGM. These rates will be compared to what they would have been under the 153-group case-mix system and 60-day unit of payment that was in place prior to the establishment of the PDGM.

After analyzing 30-day period standard payment rates for CYs 2020–2023 to account for changes in actual versus assumed behavior, CMS found that the actual rates should have been lower than the adopted rates (which were calculated using assumed behavior).

Using this same methodology with CY 2024 claims, CMS has determined that the 30-day base payment rate for CY 2024 should have been \$1,916.77 based on actual behavior, rather than the adopted rate of \$2,038.13 based on assumed behaviors, including all behavior adjustments that were applied to the CY 2023 30-day base payment rate. This results in an updated total permanent adjustment of –5.954% that needs to be applied to the CY 2026 payment rate to account for expenditures for CYs 2020–2024. Since a portion of this adjustment has already been accounted for in the CYs 2023, 2024, and 2025 rates, CMS is proposing that the remaining permanent adjustment for CY 2026 will be –4.059%. In past years, CMS only applied half of this full permanent behavioral adjustment to reduce burden for providers. In order to mitigate continued accrual of the temporary adjustment and to reduce the need for large permanent adjustments in the future, CMS is proposing to apply this full adjustment to the CY 2026 30-day base payment rate.

The same CMS analysis also found that, by updating the HH PPS payments rates for actual behaviors in CYs 2020–2024, total estimated payments for these five years were higher than they should have been. CMS estimates these overpayments to be:

- \$873 million for CY 2020
- \$1.211 billion for CY 2021
- \$1.405 billion for CY 2022
- \$971 million for CY 2023
- \$840 million for CY 2024

This results in a combined \$5.301 billion in temporary payment reconciliation, requiring an additional temporary adjustment to the 30-day payment rate. Analyses by CMS and MedPAC have shown that home health payments under the PDGM continue to be higher than those of the prior 153-group system and are also in excess of costs. Due to this, CMS is proposing to begin recoupment of these overpayments through a temporary adjustment to the CY 2026 base payment rate. Rather than collecting the full temporary dollar amount in year, which would require an approximate 34% reduction to the CY 2026 base payment rate, CMS is proposing to apply this temporary adjustment in numerous smaller adjustments beginning with CY 2026. This temporary adjustment proposed for CY 2026 would be -5.0% and would credit approximately \$786 million to the temporary dollar amount. Note that the estimated \$786 million anticipated to be collected is based on an estimate of the number of 30-day periods that would occur in CY 2026, and may not reflect the actual dollar amount if the actual number of 30-day periods and other utilization trends in CY 2026 differ from the estimated. CMS will continue to analyze the data each year through CY 2026 to determine if more temporary adjustments are warranted and will apply these adjustments in future rulemaking as appropriate.

National Per-Visit Amounts

CMS uses national per-visit amounts by service discipline to pay for LUPA periods of care as well as to compute outliers. LUPA payments are made when the number of visits is less than the LUPA threshold for their PDGM classification. This threshold is set at either two visits, or the 10th percentile value of visits,



whichever is higher. CMS typically uses the most current utilization data available to set LUPA thresholds at the time of rulemaking.

CMS proposes to update LUPA thresholds using CY 2024 home health claims data. Of these thresholds, 395 case-mix groups will have no change in threshold, 20 groups will increase by one visit, and 17 groups will have their threshold decrease by one visit. A list of all proposed LUPA thresholds can be found here. The proposed CY 2026 national per-visit rates compared to the final CY 2025 national per-visit rates are shown below. These rates are not subject to the permanent behavior adjustment, temporary adjustment, or case-mix budget neutrality.

Per-Visit Amounts	Final CY 2025	Proposed CY 2026	Percen t Change	Proposed CY 2026 with LUPA Add-On
Home Health Aide	\$78.20	\$80.11	+2.44%	N/A
Medical Social Services	\$276.85	\$283.61		N/A
Occupational Therapy (OT)	\$190.08	\$194.72		\$335.66 (1.7238 adj.)
Physical Therapy (PT)	\$188.79	\$193.40		\$313.79 (1.6225 adj.)
Skilled Nursing	\$172.73	\$176.95		\$304.35 (1.7200 adj.)
Speech Language Pathology (SLP)	\$205.22	\$210.23		\$351.00 (1.6696 adj.)

The LUPA add-on is used for OT, PT, SN, or SLP visits in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes.

Outlier Payments

Outlier payments are intended to mitigate the risk of caring for extremely high-cost cases. An outlier payment is provided whenever an HHA's cost for an episode of care exceeds a fixed-loss threshold, defined as the HH PPS payment amount for the episode plus an FDL amount.

Currently, there is a cap of eight hours or 32 units per day (one unit = 15 minutes), summed across the six disciplines of care, on the amount of time per day that will be counted toward the estimation of an episode's costs for outlier. The discipline of care with the lowest associated cost per unit is first discounted in the calculation of episode cost, in order to cap the estimation of an episode's cost at eight hours of care per day.

The FDL amount is the home health FDL ratio multiplied by the wage index-adjusted 30-day period payment. This is added to the HH PPS payment amount for that episode. If the calculated cost exceeds the threshold, the HHA receives an additional outlier payment equal to 80% of the calculated excess costs over the fixed-loss threshold.

Each HHA's outlier payments are capped at 10% of total PPS payments. By law, a limit of 2.5% of total HH PPS payments is set aside for outliers. CMS is proposing an FDL ratio of 0.46 for CY 2026, based on CY 2024 claims data.

Wage Index and Labor-Related Share

As has been the case in prior years, CMS proposes to use the most recent inpatient hospital wage index, which is the Federal Fiscal Year (FFY) 2026 pre-rural floor and pre-reclassification hospital wage index, to adjust payment rates under the HH PPS. The wage index is applied to the labor-related portion of the HH payment rate. CMS previously adopted the use of a labor-related share of 74.9% for CY 2024 and onwards.

In the CY 2025 final rule, CMS adopted that counties that have a different wage index value than the CBSA or rural area into which they are designated after applying the 5% wage index cap will use a five-digit wage index transition code, beginning with "50". This will apply until the county's new CBSA-based wage index is at least 95% of the county's wage index from the previous year. This is in addition to the permanent 5% stop loss on wage index previously finalized.

The wage index and labor-related share budget neutrality factors for CY 2026 are proposed to be 1.0019 for the standard rate and 1.0004 for the per-visit rates. These factors ensure that aggregate payments made under the HH PPS are not greater or less than will otherwise be made if wage adjustments had not changed.

A complete list of the wage indexes proposed for CY 2026 is available here.

Patient-Driven Groupings Model

CMS assigns HH stays into PDGM 30-day period of care groupings that are consistent with how clinicians differentiate between patients and the primary reasons for needing home health care. Case-mix adjustments for home health payments are based solely on these patient characteristics, relying more heavily on clinical characteristics and other patient information to place patients into 432 clinically meaningful payment categories.

Each year CMS recalibrates the PDGM case-mix weights in a budget neutral manner to ensure that the case-mix weights reflect current home health resource use and changes in utilization patterns. For CY 2026, CMS is proposing to recalibrate case-mix weights based on CY 2024 claims data as of March 13, 2025. Compared to CY 2025 weights, 421 groups will see a difference between -5% and 5%, and 11 groups will change between +5% and +10% for CY 2026. CMS is proposing a case-mix budget neutrality factor of 1.0051 to be applied to the standardized 30-day period payment rate.

The proposed case-mix weights for CY 2026 are listed in Table 25 and on the CMS website are available here.

CMS is proposing to update functional impairment levels and functional points by clinical group using CY 2024 claims data. Tables 20 and 21 show the proposed Outcome and Assessment Information Set (OASIS) points and thresholds for functional levels by clinical group, respectively, for CY 2026. CMS is also proposing that the comorbidity adjustment applicable to 30-day periods of care be calculated using CY 2024 home health OASIS data, which would result in 20 low comorbidity adjustment subgroups and 100 high comorbidity subgroups. These groups are listed on Tables 22 and 23, respectively.

Expanded HHVBP Model

CMS previously adopted eight measure removal factors to be considered when determining whether to remove measures from the expanded HHVBP Model's applicable measure set. CMS is proposing to add



an additional measure, Factor 9: It is not feasible to implement the measure specifications, to these removal factors for situations where it is no longer feasible to continue implementing a quality measure. CMS is proposing to remove the following HHCAHPS Survey-based measures from the HHVBP beginning CY 2026:

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

Removal of these three measures are dependent on their removal from the HHCAHPS Survey as well as adopting the Factor 9 removal factor since these measures would no longer be able to be calculated.

Additionally, CMS is proposing to add the following measures to the HHVBP applicable measure set beginning in CY 2026:

- Medicare Spending Per Beneficiary Post-Acute Care
- OASIS-Based Function Measures:
 - o Improvement in Bathing (based on OASIS item M1830)
 - o Improvement in Upper Body Dressing (based on OASIS item M1810)
 - o Improvement in Lower Body Dressing (based on OASIS item M1820)

Due to these proposed revisions, CMS also proposes to update the weights of individual measures starting with the CY 2026 performance period as well as to the measure category weights. The current and proposed weights can be found in Table 34.

CMS is considering two alternative options for revising the HHVBP measure weights. Table 35 shows these alternatives compared to the proposed measure weight update for the larger volume cohort.

HHVBP Quality Measure Concepts Under Consideration For Future Years - RFI

CMS requests comment on the following measure and other future model concepts for possible inclusion in future updates to the HHVBP:

- Falls with Major Injury Measure
- Measuring HHA performance on forthcoming HHCAHPS items based only on HHA achievement
- Adding to the applicable measure set for the Expanded HHVBP Model the three remaining items in the Specific Care Issues Measure as single item measures

Home Health Quality Reporting Program

CMS collects quality data from HHAs on processes, outcomes, and patient experience of care. HHAs that do not successfully participate in the HH QRP are subject to a 2.0 percentage point reduction to the market basket update for the applicable year. CMS lists the measures currently in place for CY 2026 in Table 30, which are also listed below.

Measures	Data Source
Improvement in Ambulation/Locomotion (CBE #0167)	OASIS
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674)	OASIS
Improvement in Bathing (CBE #0174)	OASIS
Improvement in Bed Transferring (CBE #0175)	OASIS



COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (proposed to be removed CY 2026+)	OASIS
Drug Regimen Review Conducted with Follow-Up for Identified Issues— Post Acute Care (PAC) HH QRP	OASIS
Discharge Function Score	OASIS
Improvement in Dyspnea	OASIS
Influenza Immunization Received for Current Flu Season	OASIS
Improvement in Management of Oral Medications (CBE #0176)	OASIS
Changes in Skin Integrity PAC	OASIS
Timely Initiation of Care (CBE #0526)	OASIS
Transfer of Health Information to Provider-PAC	OASIS
Transfer of Health Information to Patient-PAC	OASIS
Discharge to Community-PAC HH QRP (CBE #3477)	Claims-based
Total Estimated Medicare Spending Per Beneficiary (MSPB)—PAC HH QRP	Claims-based
Potentially Preventable 30-day Post-Discharge Readmission Measure for HH Quality Reporting Program	Claims-based
Home Health Within Stay Potentially Preventable Hospitalization	Claims-based
How well did the home health team communicate with patients	HHCAHPS
How do patients rate the overall care from the home health agency	HHCAHPS
How often the home health team gave care in a professional way	HHCAHPS
Did the home health team discuss medicines, pain, and home safety with patients	HHCAHPS
Will patients recommend the home health agency to friends and family	HHCAHPS

Beginning with the CY 2026 HH QRP, CMS is proposing to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure due to continued costs and burden to providers. This would be effective with assessments completed on or after the date completed on or after the publication date of the CY 2026 HH PPS final rule. This measure would be removed from OASIS effective Apr. 1, 2026, as it is not technically feasible to remove the item earlier. Due to this, HHA would still need to submit a valid response to the OASIS assessment in order for the assessment to not be rejected until the measure is removed. CMS also proposes to end public reporting of this measure with the January 2026 Care Compare refresh.

CMS is proposing to remove four items under the social determinants of health category of the OASIS-E Data Set, beginning with the CY 2026 HH QRP:

- Living Situation "What is your living situation today?"
- Food "Within the past 12 months, you worried that your food would run out before you got money to buy more."
- Food "Within the past 12 months, the food you bought just didn't last and you didn't have money to get more."
- Utilities "In the past 12 months, has the electric, gas, oil, or water company threatened to shut off services in your home?"



In an effort to update and shorten the HHCAHPS survey, CMS is proposing a number of measure updates, revisions, and removals. These can be found in Table 31. Since the Summary Star Rating is currently based on the Overall Rating of Care and the three composite measures, CMS is proposing to calculate the Summary Star rating based on the Overall Rating of Care, the two modified composite measures (Care of Patients and Communications Between Providers and Patients), and the three new stand-alone measures related to talking about home safety, reviewing prescribed and over-the-counter medicines, and talking about medicine side effects. The Overall Rating of care and two composite measures would each have a weight of one and the three new stand-alone measures would have a weight of 1/3. CMS proposes to continue reporting the Overall Rating Willingness to Recommend the Agency measure in the transition period between the current and new surveys. CMS is proposing to wait to publicly report the new versions of Care of Patients and Communications Between Providers and Patients, as well as the three new stand-alone measures, until four quarters of data are available.

CMS currently applies a case-mix adjustment to HHCAHPS survey scores prior to public reporting for the following variables: patient age, patient education, self-reported overall health, self-reported mental health, diagnosis of schizophrenia or dementia, whether the patient lives alone, whether the patient or proxy answered the survey, and the language in which the survey was completed. Recent CMS testing has shown that case-mix variables do not need to be added and the diagnosis adjustments are no longer significant. As such, CMS proposes to drop the case-mix adjustment for diagnosis of schizophrenia or dementia. This testing also showed that the mode of survey administration impacted survey responses. CMS is proposing to add a mode adjustment after the application of the case-mix adjustment before public reporting each quarter. More information on the survey mode adjustments can be found here.

Currently, HHAs can request exceptions and extensions to report data for the HH QRP when there are certain extraordinary circumstances outside the control of the HHA so that the HHA would not be subject to the 2.0 PPT reduction of their HH PPS payments. Since this rule, CMS has become aware of inconsistencies in the regulation text regarding these requests. In order to clarify this process, CMS proposes that HHA submit a request for an extension to file a reconsideration request to CMS via email no later than 30 calendar days from the date of the written notification of non-compliance. The extension request must contain the HHA's:

- CCN;
- Business name;
- Business address;
- Contact information for the chief executive officer or designated personnel;
- Statement of the reason for the request for extension; and
- Evidence of the impact of the extraordinary circumstances.

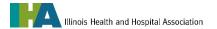
CMS would notify the HHA in writing, via email, regarding this request once a decision is made. CMS is also considering proposing similar modifications across all post-acute care setting QRPs.

To support the transition to OASIS all-payer submission requests as outlined in the CY 2023 HH PPS final rule, CMS is proposing to replace instances of the word "beneficiary" with the term "patient" in the OASIS assessment.

HH QRP Measure Concepts Under Consideration For Future Years - RFI

CMS is seeking input on the following four concepts for future years of the HH QRP:

Interoperability



- Cognitive Function
- Well-being
- Nutrition

Potential Revision of the Final Data Submission Deadline Period From Months to 45 Days - RFI

CMS is seeking feedback on the potential future reduction of the HH QRP data submission deadline from 4.5 months to 45 days. Specifically, CMS is requesting comment on the following:

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

Advancing Digital Quality Measurement in the HH QRP - RFI

CMS is considering opportunities to advance Fast Healthcare Interoperability Resources® (FHIR®)-based reporting of patient assessment data for the submission of the OASIS. CMS seeks to identify challenges and/or opportunities that may arrive during this integration, and determine the support needed to complete and submit quality data in ways that protect and enhance care delivery. CMS seeks input on future measures under consideration including applicability of interoperability as a future concept in post-acute settings. CMS also seeks feedback on the current state of health IT use in HHAs.

Face – To – Face Encounters

The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 allows for NPs, CNSs, and PAs to order and certify patients for eligibility for the home health benefit and establish a plan of care. Since the passing of this act, CMS has received requests to change the current face-to-face encounter policy to allow any practitioner to perform the face-to-face encounter, citing that the language of the CARES Act allows for this. CMS agrees and is proposing to revise regulations to state that face-to-face encounters can be performed by a physician, NP, CNS, PA, or certified nurse-midwife.

Home Health Cops Changes

In the CY 2023 HH PPS final rule, CMS finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period. In order to align HH CoPs with the OASIS all-payer submission requirements, CMS is proposing to replace all mentions of "beneficiary" in the OASIS instrument with the term "patient".

Medicare and Medicaid Provider Enrollment

Consistent with past rulemaking, CMS is proposing to strengthen certain components of the provider enrollment process as well as allow for more action to be taken against providers engaging (or potentially engaging) in fraudulent or abusive behavior: providers who present a risk of harm to Medicare beneficiaries or the Medicare Trust funds, or that are otherwise unqualified to furnish Medicare services or items. CMS is proposing clarifications and revisions to Medicare provider enrollment provisions as follows:

- False or misleading information revocation and denial ground;
- Authority to prescribe drugs;
- Pattern or practice of prescribing;
- Modifications to provider enrollment paragraph references and enrollment provisions; and
- Abuse of billing privileges.



Currently, there are a number of situations where CMS can revoke a provider's Medicare enrollment retroactively, typically back to the date on which the provider's non-compliance commenced. CMS is proposing to further expand the bases for which a retroactive revocation can be applied, including revocations based on:

- A lapse in an independent diagnostic testing facility's comprehensive liability insurance, the date the insurance lapsed;
- 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;
- 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;
- 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;
- 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;
- 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); and
- 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.

CMS is also proposing to update regulatory policies regarding:

- New deactivation authority;
- Stay of enrollment;
- Submission of documentation;
- Reassignment effective dates;
- DMEPOS liability insurance;
- Deactivation reason clarification; and
- Adverse legal action.

Lastly, CMS is proposing updates to statutory and regulatory Medicaid and the Children's Health Insurance Program (CHIP) provider enrollment requirements. Specifically, CMS is proposing 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.

Certain DMEPOS Accreditation Policies, and DMEPOS Prior Authorization

In an effort to reduce fraudulent activity among DMEPOS suppliers and accrediting organizations (AOs), CMS is proposing various regulatory changes to the current DMEPOS accreditation process with the goal to improve and strengthen the process. CMS outlines six scenarios where a strengthened accreditation program could help limit or prevent the activities in question.

CMS is proposing several new definitions in order to clarify the regulatory provisions to which they relate, which includes:

• "Complaint" as an allegation from any party that one of the AO's accredited suppliers may be non-compliant with one or more quality standards or other applicable CMS requirement.



- "Immediate jeopardy" as a situation where the supplier's non-compliance with one or more quality standards or other applicable CMS requirement has cause, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public.
- "Reasonable assurance" as meaning that an AO has demonstrated to CMS's satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements; the suppliers the AO accredits meet or exceed Medicare requirements; and the AO is compliant with all provisions of § 424.58.
- "Unannounced survey" as meaning a survey conducted without any prior notice of any type (through any means of communication or forum) to the supplier to be surveyed, such that the supplier does not expect the survey until the surveyors arrive; and the AO schedules its surveys so that suppliers cannot predict when they will be performed.

CMS is proposing updates to regulatory language and policies on the following topics:

- Separating the processes by which an entity may apply or reapply to become an AO for ease of comprehension, noting that the two processes are very similar.
- Procedures involving an AO's application for reapproval of its DMEPOS accreditation program.
- Changes to the activities an approved AO must undertake on an ongoing basis, including changes to:
 - Monthly data submission concerning the AO's activities;
 - Submission of the acknowledgement, cross walk, and explanation in response to a change in CMS requirements;
 - Allowing the AOs' surveyors to serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation determination.
 - Notification to CMS within two calendar days of a supplier's immediate jeopardy deficiency;
 - Within 10 calendar days of receiving CMS notice that CMS intends to withdraw the AO's approval, provide written notice of the withdrawal to all the AO's accredited DMEPOS suppliers; and
 - Annually furnish CMS-specified summary information regarding the prior year's accreditation activities and trends.
- Revising the regulatory language for the criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved DMEPOS AO.
- Procedures via which an DMEPOS AO's accreditation program could be voluntarily terminated or involuntarily terminated.
- Creation of AO suspensions and probations for situations where AO non-compliance are not severe enough to warrant termination under the proposed expansion of termination criteria.
- Steps CMS would take in exercising their discretion to determine what actions should be taken to address AO non-compliance.
- Reconsiderations and rebuttals with respect to actions taken due to non-compliance.
- Defining and allowances or an AO acting as a consulting service.
- AO relationships which could result in a conflict of interest.
- AO changes of ownership.
- Requirements for suppliers to be accredited in order to enroll in Medicare.

CMS also seeks comments on the topics from AOs, DMEPOS, and other stakeholders.



Lastly, CMS is proposing to clarify circumstances under which CMS would exempt a supplier from the prior authorization process under the newly proposed regulatory updates. These circumstances would be when a supplier achieves at least a 90% prior authorization provisional affirmation threshold during an initial or periodic assessment. This exemption would be withdrawn if claims-based evidence showed that the supplier began submitting claims not payable under Medicare in excess of 10% of claims during the periodic assessment. Notice would be given 60-days prior to either the start or end of the exemption period.

DMEPOS Competitive Bidding Program

Currently, competitive bidding programs (CBPs) in competitive bidding areas throughout the United States are established in order to award contracts for the furnishing of competitively priced DMEPOS items and services, including certain DME and medical supplies; enteral nutrients, equipment, and supplies; off-the-shelf orthotics; and lymphedema compression treatment items.

CMS plans to update the DMEPOS CBP with proposals on the following topics:

- Determining payments amounts and the number of contracts awarded for the DMEPOS CBP;
- Adjustment of single payment amounts (SPAs);
- Bid limits and conditions for awarding contracts if savings are not expected;
- Revising the definition of "item" related to medical supplies;
- Remote item delivery CBP;
- Payment for continuous glucose monitors and insulin infusion pumps;
- Revising the submission of financial document requirements for the DMEPOS CBP;
- Revising the covered document review date evaluation and notification process for the DMEPOS CBP;
- Bid surety bond review process;
- Tribal exemption from participating in the DMEPOS CBP;
- Addition of a termination clause for DMEPOS CBP supplier contracts;
- Technical changes to regulatory text § 414.408(h)(8); and
- Definitions of "competition", "adjusted free schedule amount", and "unadjusted free schedule amount" under § 414.402.

Within each of the preceding sections, CMS includes detailed background information and what issues the proposals are meant to address.

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