Small Entity Compliance Guide

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

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The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121, as amended by Pub. L. 110-28, May 25, 2007) contains requirements for issuance of "small entity compliance guides." Guides are to explain what actions affected entities must take to comply with agency rules. Such guides must be prepared when agencies issue final rules for which agencies are required to prepare a Final Regulatory Flexibility Analysis under the Regulatory Flexibility Act.

This final rule is estimated to have a significant economic impact on a substantial number of small entities. The complete text of this final rule can be found on the CMS website by clicking on the link to "CMS-1828-F" at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-prospective-payment-system-regulations-and-notices/cms-1828-f .

Summary

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

The overall impact of the Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) final rule, as detailed in the Regulatory Flexibility Analysis (RFA) section of the final rule and discussed below, reflects an estimated $220 million (1.3 percent) decrease in payments to home health agencies (HHAs).

We have prepared this guide to address the following provisions of the final rule have prepared this guide to address the following provisions of the final rule:

Home Health Prospective Payment System (HH PPS)

This final rule updates the payment rates for HHAs for CY 2026, as required under section 1895(b) of the Social Security Act (the Act), effective January 1, 2026. This final rule also finalizes permanent and temporary adjustments to the CY 2026 home health base payment rate to account for the difference between assumed versus actual behavior changes on estimated aggregate expenditures for home health payments as a result of the change in the unit of payment to 30 days and the implementation of the Patient Driven Groupings Model (PDGM). Additionally, this rule finalizes the recalibrated PDGM case-mix weights and updates the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2026; updates the CY 2026 fixed-dollar loss ratio (FDL) for outlier payments; and finalizes changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v) to align with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we consider all HHAs small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' on a "substantial" number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the provisions in this final rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that the HH PPS final rule would have a significant economic impact on a substantial number of small entities.

The overall impact of the CY 2026 HH PPS final rule, as detailed in the Regulatory Flexibility Analysis (RFA) section of that rule and discussed below, reflects an estimated decrease in payments to home health agencies (HHAs).

The overall impact in estimated total home health payments in CY 2026 is a decrease of approximately 1.3 percent. The net decrease in CY 2026 is mostly driven by the impact of the permanent and temporary adjustments. Free-standing non-profit HHAs are estimated to see a 0.7 percent decrease and facility-based non-profit HHAs are estimated

to see a 0.8 percent decrease in payments in CY 2026. Free-standing proprietary HHAs are estimated to see a 1.6 percent decrease and facility-based proprietary HHAs are estimated to see a 2.1 percent decrease in payments in CY 2026. Urban HHAs are estimated to see a 1.4 percent decrease in payments while rural HHAs are estimated to see a 1.1 percent decrease in payments for CY 2026. Based on the number of first periods of care, smaller HHAs (with less than 100 home health periods of care) are estimated to experience a 2.0 percent decrease in payments for CY 2026. Larger HHAs (with 1,000 or more home health periods of care) are estimated to experience a 1.1 percent decrease in payments for CY 2026. HHAs in the Pacific regions are estimated to receive a 2.4 percent decrease in payments, and HHAs in the East South Central regions are estimated to receive a 1.4 percent decrease in payments in CY 2026.

We provide the following online manuals that present compliance information regarding our home health regulations. The manuals are frequently updated to reflect the latest changes in Medicare home health policy. These manuals serve, in part, as a system of small entity compliance guides that meet the letter and spirit of SBREFA.

Medicare Benefit Policy Manual; Chapter 7- Home Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c07.pdf.

Medicare Claims Processing Manual; Chapter 10- Home Health Agency Billing: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c10.pdf.

Home Health Quality Reporting Program (HHQRP)

We finalized the proposal to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure. We also finalized the proposal to remove four assessment items: one Living Situation item, two Food items, and one Utilities item. We finalized the proposal to implement a revised Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey beginning with the April 2026 sample month. Additionally, we finalized the proposal to revise the policy to allow providers to submit a request for reconsideration of an initial determination of non-compliance with the HH QRP data submission requirements. They can request this if they believe that they can demonstrate full compliance. We also finalized that, in very limited circumstances, the HHA could request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA, (that is, a natural disaster or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day period for requesting reconsideration of the initial determination.

We summarized input received on a series of requests for information (RFIs). In the CY 2026 HH PPS proposed rule, we sought information on a change to the final data submission deadline period from 4.5 months to 45 days. We also sought feedback on the digital quality measurement (dQM) transition for HHAs. We solicited feedback from the

public on current adoption of health IT and standards, including Fast Healthcare Interoperability Resources (FHIR), and what related challenges or barriers HHAs are facing. Finally, we sought input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

The total economic impact of the policies in this final rule including the removal of one Living Situation item, two Food items, and one Utilities item as well as the proposal to remove the patient COVID-19 vaccination item, which is proposed for implementation in CY 2026 will result in a reduction in costs of $17,810,282.

To support HHAs in implementing this final rule, there are several resources that are available to remain in compliance with new and current HH QRP requirements. An Outcome and Assessment Information Set (OASIS) Guidance manual is available to support coding guidance related to OASIS-E2 implementation found at: Guidance Manual for the Outcome Assessment Information Set Version E (OASIS-E) of the OASIS data set, effective April 1, 2026:
https://www.cms.gov/medicare/quality/home-health/oasis-user-manuals .
To support the appropriate submission of assessment data, users may reference the most up to date information available at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/homehealthqualityinits/dataspecifications .

To assist users in outlining current quality measures and the most updated calculation of measures, users can reference information at: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/homehealthqualityinits/home-health-quality-measures .

To help providers address a range of questions, troubleshoot problems, and request guidance and support, the following website outlines contact information for Help Desks related to the HH QRP: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/homehealthqualityinits/help-desk .

We also conduct Open Door Forums (ODFs) to improve transparency in our policies. These forums provide small entities with an opportunity to obtain information, as questions, and express their views to senior CMS officials on nearly all major HH QRP regulatory issues, especially those that might affect providers in a new or burdensome way. As such, information on Home Health, Hospice, and Durable Medical Equipment ODFs can be found at https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/ODF_HHHDME.html

Home Health Value Based Purchasing (HHVBP) Model

In January 2021, CMS announced that the original HHVBP Model had met the statutory requirements for model expansion described in paragraphs (1) through (3) of section 1115A(c) of the Act. In the CY 2022 HH PPS final rule we finalized the decision to expand the Model to all Medicare certified HHAs nationwide beginning January 1, 2022.

CY 2022 was a pre-implementation year with the first performance year being CY 2023 and the first payment year being CY 2025.

This final rule adds a new measure removal factor for the HHVBP Model, makes changes to the HHVBP Model applicable measure set, and makes changes to the HHVBP Model measure weights. This final rule also summarizes comments received in response to a Request for Information (RFI) on Future Performance Measure Concepts for the Expanded HHVBP Model that build on input from the Model's Implementation and Monitoring technical expert panel (TEP), which met in November 2023, June 2024, and December 2024. Discussions included potential future measure concepts that could fill measurement gaps in the expanded HHVBP Model.

For more information about the Model, we provide a Web page for the expanded HHVBP Model webpage. https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model .

Provider Enrollment

In our ongoing efforts to prevent Medicare fraud, waste, and abuse, CMS finalized several new and revised provider enrollment provisions. Our principal provisions include, but are not limited to, the following: (1) increasing the number of reasons for which CMS can revoke a Medicare provider retroactively; and (2) expand the grounds for which CMS can deny, revoke, or deactivate a provider's Medicare enrollment. We estimated that these provisions would result in $2.2 billion dollars in annual savings to the Medicare program, since Medicare would no longer be paying these providers due to their non-compliance with Medicare requirements.

We furnish provider enrollment outreach and education via our website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification. This website contains links to, among other things, downloadable provider enrollment applications, regulations, and subregulatory guidance. We have regular contact with provider and supplier organizations via various vehicles. If warranted, we will conduct additional outreach on our enrollment provisions in this final rule.

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Accreditation Process

We finalized a number of enhancements to CMS' DMEPOS supplier accreditation program. The provisions center around two general principles. First, DMEPOS suppliers have long been required to be resurveyed and reaccredited every 3 years. The final rule changed this to require annual re-surveys and reaccreditations. Second, we strengthened the requirements that DMEPOS accrediting organizations (AOs) must meet to become and remain an AO (for instance, submission of more data to CMS to allow us greater oversight of the AOs).

We estimated an annual cost burden to DMEPOS suppliers and the AOs of $128.3 million. However, this would be more than offset by the over $660 million in savings to the Medicare program from the revocation of suppliers that our more frequent surveys/accreditations would ascertain are non-compliant with Medicare requirements.

CMS is currently conducting outreach to DMEPOS AOs and the DMEPOS supplier community regarding these new requirements.

Exemption Process for Prior Authorization of Certain DMEPOS Items

CMS finalized additional specificity to the DMEPOS prior authorization exemption process. Modeled on a similar exemption process in the hospital outpatient department prior authorization program (42 CFR 419.83(c)), suppliers achieving a target approval rate of 90 percent will be offered an exemption from required prior authorization. To determine supplier eligibility for continued exemption, the DME Medicare Administrative Contractors (MACs) would complete a post payment medical review sample. From this claim sample, suppliers must again meet a claim approval rate of 90 percent or greater to continue their exemption. Suppliers who did not meet the compliance rate threshold must continue submitting prior authorization requests as required. By achieving the compliance rate percentage, the supplier has demonstrated an understanding of the requirements for submitting accurate claims. The DME MACs will provide suppliers notice of an exemption or withdrawal of an exemption at least 60 days prior to the effective date. They will conduct outreach and education to the DMEPOS supplier community to provide more information on this initiative. We have regular contact with the DMEPOS supplier community and will conduct additional outreach, if needed. More information can be located via our website at http://go.cms.gov/DMEPOSPA. This website contains updated information, as well as downloadable operational guide and frequently asked questions.

DMEPOS Competitive Bidding Program (CBP)

This rule revised DMEPOS CBP to enhance its effectiveness in achieving the objectives of the program as mandated by section 1847(a) of the Act. It also revised how SPAs mandated by section 1847(b)(5)(A) of the Act were calculated and how CMS determined the number of contracts it would award in each competitive bidding area (CBA) for every product category, taking into account the ability of bidding entities (bidders) to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the CBA on a timely basis as mandated by section 1847(b)(4)(A) of the Act. Additionally, it applied annual inflation update factors to the SPAs.

Moreover, the final rule established special payment rules for class II continuous glucose monitors and insulin infusion pumps to pay for these items and all related supplies and accessories on a 90-day rental basis under DMEPOS CBP. This rule classified class III continuous glucose monitors and insulin infusion pumps used in conjunction with class III continuous glucose monitors as items that required frequent and substantial servicing

and made payment for the items using the same 90-day rental method and payment amounts established for class II continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

The final rule also established the definition of "remote item delivery competitive bidding area" under DMEPOS CBP. In addition, it revised the methodology used to establish bid limits and addressed the conditions for determining when contracts could not be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act because the total amounts to be paid to contractors in a CBA were expected to be less than the total amounts that would otherwise be paid. The final rule also revised the definition of "item" to clarify that items that could be included in a CBP included medical supplies, including ostomy, tracheostomy, and urological supplies in accordance with section 1847(a)(2)(A) of the Act.

Also, this rule streamlined the requirements and evaluation of the DMEPOS CBP financial standards as well as the processes for evaluating and notifying a bidder of any applicable covered document(s) not submitted by the covered document review date (CDRD). In addition, this rule codified the DMEPOS CBP bid surety bond rider process. This rule also added a Tribal exception to the DMEPOS CBP. Lastly, it added a termination clause to DMEPOS CBP supplier contracts that could be utilized during a public health emergency.

To assist suppliers, including small businesses, in understanding these changes related to the DMEPOS CBP, we have posted information on the CMS.gov website: https://www.cms.gov/newsroom/fact-sheets/durable-medical-equipment-prosthetics-orthotics-supplies-competitive-bidding-program-updates .