Small Entity Compliance Guide

Medicare Program; Calendar Year (CY) 2025 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare 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 were 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-1803-F" at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-prospective-payment-system/cms-1803-f

Summary

The overall impact of the Calendar Year (CY) 2025 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 $85 million (0.5 percent) increase in payments to home health agencies (HHAs).

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

<u>Home Health Prospective Payment System (HH PPS)</u>

This final rule updates the payment rates for HHAs for CY 2025, as required under section 1895(b) of the Social Security Act (the Act), effective January 1, 2025. It also updates the CY 2025 payment rate for disposable negative pressure wound therapy (dNPWT) devices. This rule finalizes a crosswalk for mapping the Outcome and Assessment Information Set-D (OASIS-D) data elements to the equivalent OASIS-E data elements for use in the methodology to analyze the difference between assumed versus actual behavior change on estimated aggregate expenditures and finalizes a permanent adjustment to the CY 2025 home health base payment rate. In addition, it finalizes the recalibrated patient-driven groupings model (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 2025; finalizes the proposal to adopt the most recent Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) delineations for the home health wage index; and finalizes an occupational therapy (OT) LUPA add-on factor and updates the physical therapy (PT), speech-language pathology (SLP), and skilled nursing (SN) LUPA add-on factors. This rule also updates the CY 2025 fixed-dollar loss ratio (FDL) for outlier payments and the CY 2025 rate for the intravenous immune globulin (IVIG) items and services payment under the home IVIG benefit.

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 will not result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. The Secretary certifies that this final rule will not have significant economic impact on a substantial number of small entities.

The overall impact of the CY 2025 HH PPS final rule, as detailed in the Regulatory Flexibility Analysis (RFA) section of that rule and discussed below, reflects an estimated increase in payments to HHAs.

The overall impact in estimated total home health payments in CY 2025 is an increase of approximately 0.5 percent. A substantial amount of the variation in the estimated impacts of the policies finalized in this rule in different areas of the country could be attributed to changes in the CY 2025 wage index methodology, which is used to adjust payments under the HH PPS. Free-standing non-profit HHAs are estimated to see a 0.1 percent decrease and facility-based non-profit HHAs are estimated to see a 0.0 percent change in payments in CY 2025. Free-standing proprietary HHAs are estimated to see a 0.7 percent increase and facility-based proprietary HHAs are estimated to see a 1.2 percent increase in payments in CY 2025. Urban HHAs are estimated to see a 0.4 percent increase in payments while rural HHAs are estimated to see a 2.0 percent increase in payments for CY 2025. 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 0.5 percent increase in payments for CY 2025. Larger HHAs (with 1,000 or more home health periods of care) are also estimated to experience a 0.5 percent increase in

payments for CY 2025. HHAs in the Pacific regions are estimated to receive a 1.5 percent decrease in payments, and HHAs in the East South Central regions are estimated to receive a 3.2 percent increase in payments in CY 2025.

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.

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 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 Quality Reporting Program (HH QRP)

We finalized the collection of four new items as standardized patient assessment data elements in the social determinants of health (SDOH) category and modify one item collected as a standardized patient assessment data element in the SDOH category beginning with the CY 2027 HH QRP. The four assessment items finalized for collection are: one Living Situation item, two Food items, and one Utilities item. In addition, we finalized a policy to modify the current Transportation item beginning with the CY 2027 HH QRP. We also finalized an update to the removal of the suspension of OASIS all-payer data collection to change all-payer data collection to begin with the start of care OASIS data collection timepoint instead of discharge timepoint. Lastly, we summarized input on future HH QRP measure concepts.

The total economic impact of these proposals including the addition of one Living Situation item, two Food items, and one Utilities item, and the modification of the current Transportation item finalized for implementation in CY 2027 is an estimated increase of $12,604,895.

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

OASIS Guidance manual is available to support coding guidance related to OASIS-E implementation found at:
Guidance Manual for the Outcome Assessment Information Set Version E (OASIS-E) of the OASIS data set, effective January 1, 2023:
https://www.cms.gov/files/document/oasis-e-guidance-manual51622.pdf

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

Medicare Home Intravenous Immune Globulin (IVIG) Items and Services

In accordance with section 4134 of the Consolidated Appropriations Act of 2023 (CAA, 2023), we are finalizing an update to the payment rate for items and services related to administration of IVIG in a patient's home for a patient with a diagnosed primary immune deficiency disease (PIDD).

We provide the following online manuals that present compliance information regarding the IVIG regulations. These manuals are frequently updated to reflect the latest changes in Medicare IVIG 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 15 – Covered Medical and Other Health Services:
https://www.cms.gov/medicare/prevention/prevntiongeninfo/downloads/bp102c15.pdf

Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS):
https://www.cms.gov/files/document/r12252cp.pdf

Home Health Agency Condition of Participation (CoP) Changes

This rule finalized a new standard at § 484.105(d) requiring HHAs to develop, implement, and maintain an acceptance to service policy that is applied consistently to each prospective patient referred for home health care. The policy must address, at minimum, the following criteria related to the HHA's capacity to provide patient care: (1) the anticipated needs of the referred prospective patient; (2) the HHA's case load and case mix; (3) the HHA's staffing levels; and (4) the skills and competencies of the HHA staff. It also finalized the requirement that HHAs must make specified information available to the public that is reviewed as frequently as services are changed, but no less often than annually.

To develop, implement and maintain an annual review of the acceptance to services policy, we expect a one-time cost to develop the policy at a total of $6,156,799 for all HHAs and $395,800 for an annual review. To make specified information publicly available, we estimate a one-time cost of $199,430 for all HHAs and $398,861 for annual updates.

We provide the following online guidance to assist facilities here: Home Health Statue Operation Manual Appendix B: chrome extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf

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 well as ask questions, and express their views to senior CMS officials on home health CoP 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.

Medicare Provider and Supplier Enrollment Requirements

We finalized expansion of the definition of "new provider or supplier" in § 424.527(a) for purposes of applying a provisional period of enhanced oversight (PPEO) to providers and suppliers. The expanded definition includes providers and suppliers that are reactivating their Medicare enrollment and billing privileges under § 424.540(b).

We were unable to establish an estimate of any potential burden associated with this provision for two main reasons. First, we do not have sufficient data upon which we can

formulate a burden projection. Second, we cannot predict the scope, extent, and length of any future PPEO or the provider or supplier type(s) to which it may apply.

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.