Small Entity Compliance Guide

Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements

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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-1780-F" at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-prospective-payment-system/cms-1780-f.

Summary
The overall impact of the Calendar Year (CY) 2024 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 increase in payments to home health agencies (HHAs).

We 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 2024, as required under section 1895(b) of the Social Security Act (the Act), effective January 1, 2024. This rule sets forth the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2024; updates the LUPA thresholds, functional impairment levels, comorbidity adjustment subgroups for CY 2024, and the fixed-dollar loss ratio (FDL) used for outlier payments.

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'' 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. The Secretary has determined that this final rule will have a significant economic impact on a substantial number of small entities.

The overall impact of the CY4 2024 HH PPS final rule, as detailed in the 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 2024 is an increase of approximately 0.8 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 2024 wage index methodology, which is used to adjust payments under the HH PPS. This rule finalizes a permanent prospective payment adjustment to the CY 2024 home health 30-day period payment rate to account for any increases or decreases in aggregate expenditures as a result of the difference between assumed behavior changes and actual behavior changes, due to the implementation of the Patient-Driven Groupings Model (PDGM) and 30-day unit of payment as required by the Bipartisan Budget Act of 2018. This rule also finalizes proposals to rebase and revise the home health market basket; revise the labor-related share; recalibrate the PDGM case-mix weights; update the low utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups for CY 2024; codify statutory requirements for disposable negative pressure wound therapy (dNPWT); and establish regulations to implement payment for items and services under the home intravenous immune globulin (IVIG) benefit.

Free-standing non-profit HHAs are estimated to see a 0.8 percent increase and facility based non-profit HHAs are estimated to see a 1.2 percent increase in payments in CY 2024. Free-standing proprietary HHAs are estimated to see a 1.0 percent increase and facility based proprietary HHAs are estimated to see a 0.8 percent increase in payments in CY 2024. Urban HHAs are estimated to see a 0.9 percent increase in payments while rural HHAs are estimated to see a 0.4 percent increase in payments for CY 2024. 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 1.2 percent increase in payments for CY 2024. In contrast, larger HHAs (with 1,000 or more home health periods of care) are estimated to experience a 0.4 percent increase in payments for CY 2024. HHAs in the Mid Atlantic are estimated to see a 1.5 percent increase in payments while HHAs in the New England and Mountain regions are estimated to receive a -0.1 percent increase in payments in CY 2024.

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)

This final rule finalized the following proposals for the HHQRP: CMS finalized the addition of two quality measures to the HH QRP: the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date and the Discharge Function measures; the removal of two Outcome and Assessment Information Set (OASIS)-based data elements: M0110-Episode Timing and M2200-Therapy Need; the codification of the previously finalized 90 percent OASIS data completion threshold policy in the Code of Federal Regulations (CFR); and the public reporting of four measures: Transfer of Health (TOH) Information to the Provider-Post-Acute Care(PAC), TOH Information to the Patient-PAC, HH QRP COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date, and the Discharge Function measures. CMS also summarized feedback on its request for information on future HHQRP measure concepts and an update on health equity in the HHQRP.

The total economic impact of these proposals including the addition of the COVID-19 QM, removal of the Application of Functional Assessment/Care Plan, and the removal of the M0110 – Episode Timing and M2200- Therapy Need OASIS items proposed for implementation in CY 2025 is an estimated reduction in cost of $5,123,430 or on average $437 per HHA annually.

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

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Expanded 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 rule finalized the codification of the HHVBP Measure removal factors; an additional opportunity for HHAs to request a review of a reconsideration of the annual total performance score and payment adjustment; an updated applicable measure set; changes to the weight of each measure within the OASIS-based category and the claims-based category. In addition, we have provided a reminder to HHAs and other stakeholders that public reporting of HHVBP performance data and payment adjustments will begin in December 2024; and an update which lets stakeholders know that we are committed to developing approaches to meaningfully incorporate the advancement of health equity into the Model.

To assist HHAs in understanding and adapting to changes due to the expanded HHVBP Model, we developed a Web page for the expanded HHVBP Model.

https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model

Medicare Home Intravenous Immune Globulin (IVIG) Items and Services

As required under Division FF, section 4134 of the CAA, 2023, CMS is finalizing regulations, as proposed, to implement permanent coverage and payment of items and services related to administration of IVIG in a patient's home for a patient with a diagnosed primary immune deficiency disease (PIDD). Currently, Medicare pays for the IVIG product using the average sales price (ASP) methodology, and the items and services needed for in-home administration of IVIG for the treatment of PIDD are paid under a Medicare Demonstration program. This Demonstration program will end on December 31, 2023, and the CAA, 2023, establishes permanent coverage and payment of the items and services needed for in-home administration beginning on January 1, 2024.

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

To assist providers in understanding the new benefit, we have released two Change Requests:

- Manual Updates for Coverage of Intravenous Immune Globulin (IVIG) For Treatment of Primary Immune Deficiency Diseases in the Home
- Implementation of the New Home Intravenous Immune Globulin (IVIG) Items and Services Payment

Hospice Informal Dispute Resolution and Special Focus Program

A new Informal Dispute Resolution (IDR) process for hospice providers has been finalized in this rule and will align with the IDR for home health agencies. Information on this program is being updated in the CMS State Operations Manual (SOM) Chapter 10 – CMS Enforcement Process for Home Health Agencies and Hospices guidance manual.

Additionally, CMS finalized the hospice Special Focus Program (SFP) that, through increased regulatory oversight, would address issues that place hospice beneficiaries at risk of receiving both unsafe and poor-quality care.

This rule imposes no direct Federal compliance requirements with significant economic impacts on small entities beyond the usual Conditions of Participation for all hospices,

regardless of size, as noted in 42 CFR 418 Subpart D, and the SOM Appendix M. Economic impacts on all hospices (including small entities) continue as established, if and when enforcement action is taken, which may include a number of actions that could have a financial impact, up to and including termination from Medicare participation (see 42 CFR 488.1210).

More information on the hospice IDR process will be available in the revisions to the SOM Chapter 10 in early 2024 at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.

Additional information on the hospice SFP may be found at: https://www.cms.gov/medicare/health-safety-standards/certification-compliance/hospice-special-focus-program.

Changes Regarding Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule Adjustments

Section 3712 of the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act (Pub. L. 116-136, March 27, 2020) https://www.govinfo.gov/link/plaw/116/public/136 requires that Medicare payment rates for durable medical equipment (DME) in areas other than rural and noncontiguous areas during the coronavirus disease 2019 (COVID-19) public health emergency (PHE) be equal to 75 percent of the adjusted payment amounts (based on the DME competitive bidding program information), and 25 percent of the unadjusted fee schedule amounts. The regulations at § 414.210(g)(9)(v) codified these payment rates for the duration of the PHE. Section 4139 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328, December 29, 2022) requires payment based on these rates through the end of the COVID-19 PHE or December 31, 2023, whichever is later. Medicare codified these payment rates through the end of the COVID-19 PHE or unless otherwise specified by law.

Lymphedema Compression Treatment Items

Section 4133 of the CAA, 2023 establishes a Medicare Part B benefit for standard and custom-fitted gradient compression garments and other compression treatment items for the treatment of lymphedema that are prescribed by an authorized practitioner. Compression garments for treatment of lymphedema have not been previously covered by Medicare because, prior to the enactment of the CAA, 2023, there was no statutory benefit category for such items. This rule addresses the scope of the new benefit by defining what constitutes a standard- or custom-fitted gradient compression garment and identifying other compression items used for the treatment of lymphedema that fall under the new benefit category, beginning January 1, 2024. The rule sets forth Medicare payment for gradient compression garments for both daytime and nighttime use as well as ready-to-wear, non-elastic, gradient compression wraps with adjustable straps and compression bandaging systems applied in a clinical setting as part of phase one decongestive therapy as well as during phase two maintenance therapy. In response to

concerns by commenters, this rule establishes that Medicare will pay for an increase in daytime garments over the amount previously proposed. As such, Medicare will pay for three daytime garments every 6 months and two nighttime garments every 2 years for each affected extremity or part of the body. This rule establishes the initial Healthcare Common Procedure Coding System (HCPCS) codes and the payment methodology for these items and outlines how future coding, benefit category, and payment determinations for these items will be made. The payment basis that we are finalizing for lymphedema compression treatment items approximates the payment methodology by the Department of Veterans Affairs, which is the average Medicaid State agency payment amounts plus 20 percent. In the event that Medicaid State agency payment rates are not available, payment rates will be based on the average of payment amounts established by TRICARE and internet retail prices. If neither Medicaid nor TRICARE payment amounts are available, Medicare payment rates will be based on the average internet retail prices for a lymphedema compression treatment item. All suppliers must meet Medicare DMEPOS supplier standards in order to furnish DMEPOS items.

We provide an online manual that presents policy and compliance information regarding DMEPOS regulations. These manuals are frequently updated to reflect the latest changes in Medicare DMEPOS 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

We also conduct biannual HCPCS Level II Public Meetings to improve transparency in our establishment of DMEPOS benefit categories and payment determinations. These forums provide small entities with an opportunity to request Medicare DMEPOS benefit category and payment determinations for devices, services and supplies they are bringing to the U.S. market. (https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/public-meetings)

To assist suppliers in understanding the new benefit, we have posted information on the CMS.gov website:

- https://www.cms.gov/medicare/payment/fee-schedules/dmepos-fee-schedule/lymphedema-compression-treatment-items
- https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2023-transmittals/r12359cp

Medicare Definition of Brace

This rule also codifies the longstanding Medicare definition of brace to provide clarification on the scope of the Medicare Part B benefit for leg, arm, back, and neck

braces and, as a result, classifies certain exoskeleton-type devices as braces for Medicare payment purposes.

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https://www.cms.gov/medicare/prevention/prevntiongeninfo/downloads/bp102c15.pdf
- Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS):
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Please visit the fact sheet page on cms.gov for more information on the rule:
https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-home-health-prospective-payment-system-final-rule-cms-1780-f.

Documentation Requirements for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Products Supplied as Refills to the Original Order

This rule codifies our long-standing refill policy, with some changes. We require documentation indicating that the beneficiary has confirmed their need for the DMEPOS refill within the 30-day period prior to the end of their current supply. We also finalized our requirement that delivery of DMEPOS items (that is, date of service) be no sooner than 10 calendar days before the expected end of the current supply.

Provider and Supplier Enrollment Requirements

Regarding Medicare provider enrollment, we finalized several regulatory changes to help prevent and address hospice fraud, waste, and abuse in the future. The hospice enrollment-related regulatory changes in this final rule include all of the following:

- Subjecting hospices to the highest level of provider enrollment application screening, which includes fingerprinting all 5 percent or greater owners of hospices.

- Expanding the HHA change in majority ownership provisions in 42 CFR 424.550(b) to include hospice changes in majority ownership.

- Clarifying that the definition of "Managing Employee" in 42 CFR 424.502 includes the administrator and medical director of a hospice.

To further protect the Trust Funds and Medicare beneficiaries, we also finalized additional provider enrollment provisions, which include, but are not limited to, the following:

- Reducing the period of Medicare non-billing for which a provider or supplier can be deactivated under § 424.540(a)(1) from 12 months to 6 months.

- Strengthening the program integrity safeguards associated with a provisional period of enhanced oversight under section 1866(j)(3) of the Act.

We projected an annual burden of our provisions over the first 3 years of this rule of $1,081,782. This involves the costs to providers associated with completion of the Form CMS-855A, fingerprinting, and payment of the application fee.

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.