

Small Entity Compliance Guide

CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations

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The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, Pub. L. 104-121, March 29, 1996, 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 (RFA). The overall impact of the Calendar Year (CY) 2019 Home Health Prospective Payment System (HH PPS) final rule with comment period, as detailed in the Regulatory Flexibility Analysis (RFA) section of that rule and discussed below, reflects an estimated increase in payments to home health agencies. This final rule with comment also implements temporary, transitional payments for eligible home infusion therapy providers in CY 2019. This final rule with comment period is estimated to have a significant economic impact on a substantial number of small entities. The complete text of this final rule with comment period can be found on the CMS website by clicking on the link to “CMS-1689-F” at <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

Home Health

As required under section 1895(b)(3)(B) of the Social Security Act (the Act), this final rule with comment period updates the HH PPS rates under the Medicare prospective payment system for home health agencies (HHAs) effective January 1, 2019. In accordance with sections 1895(b)(4)(B) and 1895(b)(4)(C) of the Act, this rule updates the case-mix weights and wage index used under the HH PPS. In addition, this rule finalizes a rebasing of the home health market basket, which includes a decrease in the labor-related share. Lastly, this rule finalizes the methodology used to determine rural add-on payments for CYs 2019 through 2022, as required by section 50208 of the Bipartisan Budget Act of 2018.

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 with comment period will have a significant economic impact on a substantial number of small entities.

The overall impact in estimated total payments from CY 2018 to CY 2019 is an increase of approximately 2.2 percent. A substantial amount of the variation in the estimated impacts of the policies finalized in this rule in different areas of the country can be attributed to variations in the CY 2017 wage index used to adjust payments under the HH PPS, the effects of the updated case-mix weights, changes to the labor-related share of the home health market basket, and the methodology to calculate the rural add-on provision.

Proprietary agencies are anticipated to fare slightly better than non-profit agencies as a result of the provisions of this final rule with comment period. Non-profit HHAs are estimated to see a 2.1 percent increase in payments, while proprietary HHAs are estimated to see a 2.3 percent increase in payments in CY 2019. Freestanding HHAs are estimated to see a 2.2 percent increase in payments while facility-based HHAs are estimated to see a 2.3 percent increase in payments for CY 2019. Based on the number of first episodes, smaller HHAs (with less than 100 home health episodes of care) are estimated to experience a 2.9 percent increase in payments for CY 2019. In contrast, larger HHAs (with 1,000 or more home health episodes of care) are estimated to experience a 2.0 percent increase in payments for CY 2019. HHAs in the New England are estimated to see a 1.4 percent increase in payments while HHAs in the West South Central are estimated to receive a 3.0 percent increase in payments in CY 2019.

We provide the following on-line 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, ask 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.

We also inform the public about the changes we are proposing or making in the programs that it administers. We post the Quarterly Provider Update at the beginning of each quarter at

<https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Policies/QuarterlyProviderUpdates/>.

Home Infusion Therapy

This final rule with comment period implements health and safety standards for home infusion therapy suppliers and regulations for the approval and oversight of accrediting organizations of these suppliers as required by the 21st Century Cures Act. In addition, this rule includes information on the implementation of home infusion therapy temporary transitional payments, required by the Bipartisan Budget Act of 2018. The provision of home infusion therapy services will provide the opportunity for patients to receive certain infusion drugs in their own home rather than at an outpatient center or their doctor's office.

In accordance with section 50401 of the Bipartisan Budget Act of 2018, this final rule with comment period also implements temporary, transitional payments for CYs 2019 and 2020 for eligible home infusion therapy suppliers. The overall impact of this policy is an estimated \$60 million in increased payments to home infusion therapy suppliers in CY 2019 which includes \$48 million in Medicare payments and \$12 million in beneficiary cost-sharing.

We inform the public about changes we are proposing to home infusion therapy services, including links and downloads to relevant legislation, reports, and other CMS sites at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html>.