

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Small Entity Compliance Guide

[CMS-1730-F, CMS-1744-IFC, and CMS-5531-IFC]

RINs 0938-AU06, 0938-AU31, and 0938-AU32]

Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission 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 (RFA).

The overall impact of the Calendar Year (CY) 2021 Home Health Prospective Payment System (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 home health agencies (HHAs). This final rule also implements the changes to the home health regulations regarding the use of telecommunications technology in providing services under the Medicare home health benefit as described in the “Medicare and Medicaid Programs, Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” interim final rule with comment period (March 2020 COVID–19 IFC). In addition, this rule implements the permanent home infusion therapy services benefit and supplier enrollment requirements for CY 2021 and finalizes conforming regulations text changes excluding home infusion therapy services from coverage under the Medicare home health benefit.

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-1730-F” at <https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html>.

Home Health

This final rule updates the payment rates for HHAs for CY 2021, as required under section 1895(b) of the Social Security Act (the Act), effective January 1, 2021. 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 2021; the CY 2021 fixed-dollar loss ratio (FDL); and the loss-sharing ratio for outlier payments (as required by section 1895(b)(5)(A) of the Act). Additionally, this rule adopts the revised Office of Management and Budget (OMB) statistical area delineations as described in the September 14, 2018 OMB Bulletin No. 18–04 1 for the labor market delineations used in the home health wage index, effective beginning in CY 2021. This rule finalizes a cap on wage index decreases in excess of 5 percent and adopts the OMB statistical areas and the 5-percent cap on wage index decreases under the statutory discretion afforded to the Secretary under sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act. Lastly, this rule finalizes the changes to § 409.43(a) as set forth in the March 2020 COVID–19 IFC, to state that the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system (85 FR 19230).

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 in estimated total home health payments in CY 2021 is an increase of approximately 1.9 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 2021 wage index methodology, which is used to adjust payments under the HH PPS, and the methodology to calculate the rural add-on provision.

Non-profit and proprietary agencies are anticipated to fare approximately the same as a result of the provisions of this final rule. Both non-profit HHAs and proprietary HHAs are estimated to see a 1.9 percent increase in payments in CY 2021. Freestanding HHAs are estimated to see a 1.9 percent increase in payments while facility-based HHAs are estimated to see a 2.0 percent increase in payments for CY 2021. Based on the number of first episodes of care, smaller HHAs (with less than 100 home health episodes of care) are estimated to experience a 1.8 percent increase in payments for CY 2021. In contrast,

larger HHAs (with 1,000 or more home health episodes of care) are estimated to experience a 1.9 percent increase in payments for CY 2021. HHAs in the Mid Atlantic are estimated to see a 2.8 percent increase in payments while HHAs in the New England region are estimated to receive a 0.8 percent increase in payments in CY 2021.

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, 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.

Home Infusion Therapy

This final rule summarizes the home infusion therapy policies codified in the CY 2020 HH PPS final rule with comment period (84 FR 60615), as required by section 1834(u) of the Act. This rule also finalizes the exclusion of home infusion therapy services from coverage under the Medicare home health benefit as required by section 5012(c)(3) of the 21st Century Cures Act.

The impact due to the updated payment amounts for furnishing home infusion therapy services is determined based on the rates published in the physician fee schedule (PFS) established under section 1848 of the Act. At the time of publication of this final rule, the CY 2021 PFS rates were not available.

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 websites at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Overview.html>.

In order to implement the new Medicare home infusion therapy supplier benefit as defined in the Cures Act, the final rule requires qualified home infusion therapy suppliers

to enroll in Medicare in accordance with existing Medicare provider enrollment regulations. As part of the enrollment process, home infusion therapy suppliers must do the following:

- Complete the applicable Form CMS-855 enrollment application (OMB Control No. 0938-0685).
- Undergo the screening activities consistent with the limited risk screening category in 42 CFR 424.518.
- Pay the required application fee per 42 CFR 424.514 (which in CY 2021 will be \$599).
- Be currently and validly accredited by a CMS-recognized home infusion therapy supplier accreditation organization.
- Adhere to all other enrollment regulatory requirements applicable to all enrolling and enrolled Medicare providers and suppliers.

We estimated that approximately 700 home infusion therapy suppliers will enroll in Medicare over the first 3 years of the benefit. (Of this figure, approximately 600 would enroll in the first year.) The average annual information collection cost of home infusion therapy supplier enrollment over this 3-year period would be \$28,583; this would stem from the cost associated with completing the Form CMS-855 application. We also projected that the 700 enrolling home infusion therapy suppliers would pay a combined total of \$427,550 in application fees over this 3-year period.

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 regarding enrollment issues via the Open Door Forums and other forums. If warranted, we will conduct additional outreach.

Additional Information

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/>.