DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Small Entity Compliance Guide

[CMS-1747-F and CMS-5531-F]

RINs 0938- AU37 and 0938-AU32

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID– 19 Reporting Requirements for Long-Term Care Facilities

Federal Register Vol. 86, No. 214, Page 62240 Tuesday, November 9, 2021

[CMS–1747–F and CMS–5531–F] [RINs 0938- AU37 and 0938-AU32]

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-1747-F" at https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.

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 home health agencies (HHAs) for CY 2022, as required under section 1895(b) of the Social Security Act (the Act), effective January 1, 2022. 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 2022; updates the CY 2022 fixed-dollar loss ratio (FDL); and establishes the outpatient therapy (OT) low utilization payment adjustment (LUPA) add-on factor.

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 2022 is an increase of approximately 3.2 percent. A substantial amount of the variation in the estimated impacts of the policies finalized in this rule in different areas of the country could be attributed to changes in the CY 2022 wage index methodology, which is used to adjust payments under the HH PPS, and the methodology to calculate the rural add-on provision. This final rule also recalibrates the Patient-Driven Groupings Model (PDGM) case-mix weights, updates the fixed-dollar loss ratio and establishes the OT LUPA add-on factor.

Non-profit agencies are anticipated to fare higher than proprietary agencies as a result of the provisions of this final rule. Free-standing non-profit HHAs are estimated to see a 3.4 percent increase and facility-based non-profit HHAs are estimated to see a 3.8 percent increase in payments in CY 2022. Free-standing proprietary HHAs are estimated to see a 2.9 percent increase and facility-based proprietary HHAs are estimated to see a 3.3 percent increase in payments in CY 2022. Urban HHAs are estimated to see a 3.3 percent increase in payments while rural HHAs are estimated to see a 2.8 percent increase in payments for CY 2022. Based on the number of first episodes of care, smaller HHAs (with less than 100 home health periods of care) are estimated to experience a 3.6 percent increase in payments for CY 2022. In contrast, larger HHAs (with 1,000 or more home health periods of care) are estimated to experience a 3.2 percent increase in payments for CY 2022. HHAs in the Mid Atlantic are estimated to see a 3.3 percent increase in payments while HHAs in outlying regions are estimated to receive a 2.2 percent increase in payments in CY 2022.

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 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. We also announced that the model would be expanded no earlier than January 1, 2022.

This rule finalized to end the original Model 1 year early and not to adjust payment for the HHAs in the 9 states in CY 2022 using inconsistent CY 2020 performance data. For the expanded HHVBP Model, this rule finalized a pre-implementation year for HHAs starting in CY 2022, pushing the first performance year to CY 2023 and the first payment year to CY 2025 to provide HHAs not in the original model time to learn and prepare for expansion. This rule finalized national cohorts, a 5 percent payment adjustment and the quality measure set, as proposed. This rule finalized use of the CY 2019 baseline year.

In order to assist HHAs in understanding and adapting to changes due to the expanded HHVBP Model, we have developed a Web page for the expanded HHVBP Model. https://innovation.cms.gov/innovation-models/expanded-home-health-value-based-purchasing-model

Information on the original HHVBP model can be found at: https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model

Medicare Coverage of Home Infusion Therapy

This final rule updates the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act. The impact due to the updated payment amounts for furnishing home infusion therapy services is determined by increasing the single payment amount from the prior year (that is, CY 2021) by the percentage increase in the

Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending with June of the preceding year, reduced by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity. The CPI–U for the 12-month period ending in June of 2021 is 5.4 percent and the corresponding productivity adjustment is 0.3 percent. Therefore, the final home infusion therapy payment rate update for CY 2022 is 5.1 percent.

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.

Medicare Provider and Supplier Enrollment Changes

Regarding Medicare provider enrollment, we finalized the incorporation into regulation of various longstanding subregulatory policies; these pertain to, for instance: (1) effective dates of certain provider enrollment transactions; (2) deactivation and reactivation of a provider's/supplier's Medicare billing privileges; and (3) rejection or return of a provider's/supplier's enrollment application. Two very minor regulatory clarifications pertaining to existing home health agency capitalization requirements and changes in majority ownership were also finalized.

We did not anticipate any costs or savings associated with these provisions. However, the overall impact of our provisions will be a transfer of $54,145,000 from providers/suppliers to the federal government. This will result from our provision prohibiting payment for services and items furnished by a deactivated provider/supplier.

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 Open Door Forums and other vehicles. If warranted, we will conduct additional outreach.

Survey and Enforcement Requirements for Hospice Programs

This final rule summarizes the hospice survey and enforcement changes to increase and improve transparency, oversight, and enforcement for hospice programs and implement the provisions of Division CC, section 407(b) of CAA 2021.

These provisions enhance the hospice program survey process by requiring the use of multidisciplinary survey teams, prohibiting surveyor conflicts of interest, expanding CMS-based surveyor training to accrediting organizations (AOs), requiring AOs with CMS-approved hospice programs to begin use of the Form CMS–2567, and establishing a hospice program complaint hotline. Lastly, the finalized provisions create the authority

for imposing enforcement remedies for noncompliant hospice programs, including the development and implementation of a range of remedies and procedures for appealing determinations regarding these remedies. The Special Focus Program will be considered in future rulemaking.

For purposes of the RFA, hospices are considered small businesses if they generate revenues of $6.5 million or less, according to the Small Business Administration size schedule. There are about 5,839 deemed and non-deemed hospice programs.

As of December 14, 2021, there are three CMS-approved accrediting organizations (AOs) that accredit hospice programs: Accreditation Commission for Health Care (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). Half of all the Medicare-certified hospices are deemed by these AOs and are not considered small entities. We cannot determine if hospices that an AO does not deem generate revenues of $6.5 million or less.

This rule imposes no direct Federal compliance requirements with significant economic impacts on small entities for the AOs with CMS-approved hospice accreditation programs per the Small Business Administration size schedule.

We provide the following online website that present information regarding the hospice regulations and survey processes. State Operations Manual; Appendix M – Guidance to Surveyors: Hospice https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_m_hospice.pdf.

We also inform the public about any survey and enforcement policy changes in the hospice program. We post policy memorandums at the following website: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions. These websites are updated to reflect the latest Medicare hospice changes.