

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Small Entity Compliance Guide

42 CFR 419

[CMS-1793-F]

RIN 0938-AV18

Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022

Federal Register 88 FR 77150, November 8, 2023

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, P.L. 104-121, as amended by P.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.

The complete text of this final rule with comment period can be found on the CMS Web site at: <https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/> or <https://www.govinfo.gov/content/pkg/FR-2023-11-08/pdf/2023-24407.pdf> (88 FR 77150 through 77194).

This final rule describes the agency’s actions on remand from the United States (U.S.) District Court for the District of Columbia to craft a remedy in light of the U.S. Supreme Court’s decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022), relating to the adjustment of Medicare payment rates for drugs acquired under the 340B Program from calendar year (CY) 2018 through September 27th of CY 2022.

This final rule also establishes the methodology for calculating remedy payments, the process for which those remedy payments will be made, and the prospective adjustments to the OPPS conversion factor made to budget neutralize any changes.

The effects of this final rule with comment period may vary for hospitals based on the volume for which they were furnishing 340B acquired drugs and if the initial policy in CY 2018 through CY 2022 applied to them. Rural sole community hospitals were generally excepted from the policy and so any effects would be limited.

For purposes of the RFA, we estimate that many hospitals are considered small businesses either by the Small Business Administration's size standards with total

revenues of \$41.5 million or less in any single year or by the hospital's not-for-profit status. We estimate that most hospitals that participate in Medicare are small entities, either because their revenues fall below the Small Business Administration's size standards for small businesses, or because they are nonprofit, or both.

We estimate that the remedy payments included in this final rule will include a relatively small portion to small rural hospitals of approximately 2 percent; therefore, it should have a negligible impact on approximately 245 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the volume of drugs purchased through the 340B drug discount program billed to Medicare and whether or not the initial OPSS 340B payment policy from CY 2018 through CY 2022 applied to them.

In order to assist hospitals, we have developed a Web page for this final rule that services that includes downloadable explanatory materials at:

<https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/>.