DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Small Entity Compliance Guide

42 CFR Parts 406, 407, 410, 411, 416, 419, 435, 440, 457, 482, and 485

CMS-1809-FC

RIN 0938-AV35

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Federal Register 89 FR 93912

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA, P.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 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/

This final rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this final rule, we describe the finalized changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the OPPS for calendar year (CY) 2025.

The final rule provisions include OPPS provisions, such as changes to the wage index and market basket update. These provisions also update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. In addition, this final rule responds to the maternal health crisis, addresses health disparities, expands access to behavioral health care, improves transparency in the health system, and promotes safe, effective, and patient-centered care.

In addition, this final rule updates the revised Medicare ambulatory surgical center (ASC) payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In this rule we set forth the applicable relative payment weights and amounts for services furnished in ASCs and other pertinent rate setting information for the CY 2025 ASC payment system.

The effects of this final rule vary considerably by type of hospital, location, bed size, and other variables, as well as by type of ambulatory surgical center, location, patient population, and types of surgical procedures provided, among other factors.

With respect to payment for hospital outpatient services, overall, we estimate that payments to OPPS providers will increase by about 3.0 percent on average in CY 2025, taking into consideration the hospital market basket update factor of 3.4 percent less the required productivity adjustment of 0.5 percentage points, and a 0.1 percentage point adjustment for the reduction in estimated pass through payments. Also, as required by the statute, we will further reduce the update by 2.0 percentage points for hospitals that are required to report hospital quality data for outpatient services but that did not report quality data for outpatient services or that did not report the quality data successfully in CY 2024 for the full CY 2025 update. Because effects will vary from hospital to hospital, this rule may have a significant impact on a substantial number of small entities.

Effects on ASCs will be more complex and will depend in large part on the mix of services ASCs provide. In the CY 2019 OPPS/ASC final rule with comment period, CMS finalized a proposal to apply the hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023). The CY 2024 OPPS/ASC final rule with comment period extended the interim period for an additional 2 years (through CY 2024 and CY 2025). We are updating ASC rates by 2.9 percent for CY 2025, based on the 3.4 percent hospital market basket update factor less a multifactor productivity adjustment of 0.5 percent required under law.

For purposes of the RFA, we estimate that many hospitals and critical access hospitals (CAHs) 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. Most ASCs and most community mental health centers (CMHCs) are considered small businesses with total revenues of \$16.5 million or less in any single year. We estimate that most hospitals, CMHCs and ASCs 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 CY 2025 OPPS/ASC final rule will increase payments to small rural hospitals by approximately 3 percent; therefore, it should have a negligible impact on approximately 528 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them.

In order to assist hospitals in understanding and adapting to changes in Medicare billing and payment for procedures, we have developed a Web page for hospital outpatient services that includes substantial downloadable explanatory materials at:

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

We have a similar Web page focusing on ASCs at:

https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc