

Small Entity Compliance Guide

Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage; Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Final rule

85 FR 77898 through 77949

42 CFR Part 486

CMS-3380-F, RIN 0938-AU02

12/2/2020

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.

The complete text of this final rule can be found on the CMS Web site at: <http://www.cms.gov/SmallEntity/>.

This final rule revises the Organ Procurement Organizations (OPOs) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current outcome measures with new transparent, reliable, and objective outcome measures and increasing competition for open donation service areas (DSAs).

The Regulatory Flexibility Act (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, we estimate that most health care providers regulated by CMS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any 1 year, varying by type of provider and highest for hospitals). On average, the 58 OPOs have annual revenues of about \$50 million in a market with annual organ acquisition revenues of about \$3 billion annually. While few of these would meet SBA revenue size standards for “small,” all are, by law, non-profits. Accordingly, almost all of the direct effects on businesses that this rule would create will affect small entities.