

Small Entity Compliance Guide

Medicare Program; Durable Medical Equipment Fee Schedule Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Rural Areas and Non-Contiguous Areas

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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.

The complete text of this interim and final rule with comment period can be found at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/FederalRegulationsNoticesandManualInstructions.html>.

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (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.

Approximately 85 percent of the DME industry are considered small businesses according to the Small Business Administration’s size standards with total revenues of \$6.5 million or less in any 1 year and a small percentage are nonprofit organizations. Individuals and states are not included in the definition of a small entity. We expect the interim final rule with comment period DME provisions will have a significant impact on small suppliers. A substantial number of small suppliers will benefit from the increased fee schedule amounts. Although not legally required, this interim final rule with comment period will increase payments to small suppliers such that the beneficiaries should have improved access to items.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. The Secretary has determined that this rule does not impose

substantial direct requirement costs on state or local governments, preempt states, or otherwise have a Federalism implication.