

Small Entity Compliance Guide

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS

Federal Register 83 FR 56922 through 57073

42 CFR Parts 413 and 414

[CMS-1691-F]

RIN 0938-AT28

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 final rule can be found on the CMS Web site at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1691-F.html>

This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year (CY) 2019. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, it updates and rebases the ESRD market basket for CY 2019. This rule also updates requirements for the ESRD Quality Incentive Program, and makes technical amendments to correct existing regulations related to the Competitive Bidding Program (CBP) for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Finally, this rule finalizes changes to bidding and pricing methodologies under the DMEPOS competitive bidding program; adjustments to DMEPOS fee schedule amounts using information from competitive bidding for items furnished from January 1, 2019 through December 31, 2020; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that new payment classes for oxygen and oxygen equipment are budget neutral; payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment (DME); and revises the payment methodology for mail order items furnished in the Northern Mariana Islands. This rule also includes a summary of the feedback received for the request for information related to establishing fee schedule amounts for new DMEPOS items and services.

For DMEPOS, 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. For Section V of this final rule, we believe that using the maximum winning bid amount and lead item pricing to establish the SPAs and paying most contract suppliers more than they bid helps to ensure long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Further, lead item pricing simplifies the supplier's bidding process. We anticipate that more suppliers would compete given the simpler rules and the fact that all winning bidders would be paid at least as much as they bid for the lead item. Therefore, we believe that this final rule will have a positive economic impact on bidding suppliers. As discussed in section VI of this final rule, this rule will provide additional revenue to a substantial number of small rural entities, especially for certain items furnished outside of the former competitively bid areas. Therefore, the Secretary has determined that only sections V and VI of the final rule will have a significant economic impact on a substantial number of small entities.

In order to assist entities in understanding and adapting to changes in Medicare billing and payment procedures, we have developed web materials for this rule:

- MLN Matters Article: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10838.pdf>
- Press Release: <https://www.cms.gov/newsroom/press-releases/cms-finalizes-policies-modernize-and-drive-innovation-durable-medical-equipment-dme-and-end-stage>
- Fact Sheet: <https://www.cms.gov/newsroom/fact-sheets/cy19-esrddme-nprm-cms-1691-f-and-dmepos-competitive-bidding-program-temporary-gap-period>