

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, and End-Stage Renal Disease Treatment Choices Model

CMS-1830-F; RIN 0938-AV52

Published in the November 24, 2025, Federal Register (90 FR 53068)

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.

This final rule is estimated to have a significant economic impact on a substantial number of small entities. The complete text of this final rule can be found on the CMS website at:

<https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-payment-regulations-and-notice/cms-1830-f>

Summary

We have prepared this guide to address the following provisions of the final rule:

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the Conditions for Coverage for ESRD facilities, the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model.

For purposes of the RFA, ESRD facilities are considered small businesses if they generate revenues of \$47 million or less, according to the Small Business Administration (SBA) size schedule. In addition, ESRD facilities that are considered nonprofit organizations are also considered small entities for the purposes of the RFA. Approximately 17 percent of ESRD facilities are considered to be small entities. There are about 7,608 ESRD facilities of which 1,256 are considered small entities.

This rule imposes no direct Federal compliance requirements on ESRD facilities, and it results in an overall increase to Medicare Fee-for-Service payments of approximately 2.2 percent. In order to assist ESRD facilities in understanding and adapting to changes in Medicare billing and payment procedures, we have developed guidance available at the following locations on the CMS website:

- <https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-end-stage-renal-disease-esrd-prospective-payment-system-final-rule>
- <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf>
- <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf>
- <https://www.cms.gov/files/document/mm14313-esrd-acute-kidney-injury-dialysis-cy-2026-update.pdf>