U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

B-338892

November 16, 2026

The Honorable Mike Crapo
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Brett Guthrie
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury (AKI) Dialysis Payment, and ESRD Quality Incentive Program*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) entitled "Medicare Program; CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury (AKI) Dialysis Payment, and ESRD Quality Incentive Program" (RIN: 0938-AV81). We received the rule on October 29, 2026. It was published in the *Federal Register* on October 30, 2026. 91 Fed. Reg. 68736. The effective date of the rule is January 1, 2027.

According to CMS, this rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2027. CMS also stated this rule includes updates to the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury and updates requirements for the ESRD Quality Incentive Program.

Enclosed is our assessment of CMS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions

about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact me at (202) 512-8156.



Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; CY 2027 CHANGES TO THE END-STAGE RENAL DISEASE (ESRD) PROSPECTIVE PAYMENT SYSTEM, ACUTE KIDNEY INJURY (AKI) DIALYSIS PAYMENT, AND ESRD QUALITY INCENTIVE PROGRAM"
(RIN: 0938-AV81)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) prepared an analysis of the costs and benefits of this rule. 91 Fed. Reg. 68736, 68841–53 (Oct. 30, 2026). Among other things, CMS estimated the combined impact of the policies finalized in the rule on calendar year 2027 payments is approximately $245 million. *Id*. at 68842.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603–605, 607, and 609

According to CMS, the Secretary of HHS determined that the final policies in this rule are expected to have a significant positive economic impact on a substantial number of small entities. 91 Fed. Reg. at 68855. CMS also stated the Secretary of HHS determined that the rule is expected to have a significant positive impact on the operations of a substantial number of small rural hospitals. *Id*.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

CMS determined that this rule does not mandate any requirements for state, local, or tribal governments or the private sector. 91 Fed. Reg. at 68855.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On June 26, 2026, CMS published a proposed rule. 91 Fed. Reg. 38784. CMS stated that they received 228 public comments, of which 171 were unique. 91 Fed. Reg. at 68740. CMS responded to comments in this rule. *See generally id*. at 68750–835.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501–3520

CMS determined that this rule contains information collection requirements under the Act. *See* 91 Fed. Reg. at 68840.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1302, 1395d(d), 1395f(b), and 1395g of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the Office of Management and Budget's Office of Information and Regulatory Affairs determined that this rule is significant under the Order. 91 Fed. Reg. at 68841–42.

Executive Order No. 13132 (Federalism)

CMS determined this rule will not have substantial direct effects on the rights, roles, and responsibilities of state, local, or tribal governments. 91 Fed. Reg. at 68855.