



U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-334770

November 15, 2022

The Honorable Ron Wyden

Chairman

The Honorable Mike Crapo

Ranking Member

Committee on Finance

United States Senate

The Honorable Frank Pallone, Jr.

Chairman

The Honorable Cathy McMorris Rodgers

Republican Leader

Committee on Energy and Commerce

House of Representatives

The Honorable Richard Neal

Chairman

The Honorable Kevin Brady

Republican Leader

Committee on Ways and Means

House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: 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*

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; 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” (RIN: 0938-AU79). We received the rule on November 1, 2022. It was published in the *Federal Register* as a final rule on November 7, 2022. 87 Fed. Reg. 67136. The effective date is January 1, 2023, except for the amendment to 42 C.F.R. § 413.234 in instruction number 4, which is effective January 1, 2025.

According to CMS, the final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2023. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, CMS states the final rule updates requirements for the ESRD Quality Incentive Program and finalizes changes to the ESRD Treatment Choices Model.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The final rule was published in the *Federal Register* on November 7, 2022. 87 Fed. Reg. 67136. The *Congressional Record* does not indicate when either House of Congress received the final rule. The final rule has a stated effective date of January 1, 2023, except for the amendment to 42 C.F.R. § 413.234 in instruction number 4, which is effective January 1, 2025. Therefore, except with regard to the amendment to 42 C.F.R. § 413.234, the final rule does not have the required 60-day delay in its effective date.

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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.



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; 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”  
(RIN: 0938-AU79)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would result in annualized monetary transfers from the federal government to End-Stage Renal Disease (ESRD) care providers in the amount of \$230 million in calendar year 2023. CMS further estimated the final rule would result in increased co-insurance payments from beneficiaries to ESRD providers in the amount of \$60 million also in calendar year 2023. Additionally, CMS estimated a reduction of transfers from the federal government to ESRD providers due to changes in the ESRD Quality Incentive Program in the amounts of \$5.5 million in 2023 and \$32 million in 2025 and 2026. Finally, CMS estimated changes to the ESRD Treatment Choices Model would lead to increased transfers from the federal government to ESRD facilities and managing clinicians in the amount of \$0.03 million during the period from July 1, 2022 to July 30, 2027.

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

CMS determined the final rule would have a significant economic impact on a substantial number of small entities. CMS also determined the final rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

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

CMS determined the final rule does not mandate any requirements for state, local, or tribal governments, in the aggregate, or by the private sector of more than \$165 million in any one year.

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

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

On June 28, 2022, CMS published a proposed rule. 87 Fed. Reg. 38464. CMS received 291 comments on the proposed rule, including comments from kidney and dialysis organizations, such as large dialysis organizations, small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, a dialysis coalition, patients, healthcare providers for adult and

pediatric ESRD beneficiaries, home dialysis services and advocacy organizations, provider and legal advocacy organizations, administrators and insurance groups, a non-profit dialysis association, a professional association, alliances for kidney care and home dialysis stakeholders, drug and device manufacturers, health care systems, a health solutions company, and the Medicare Payment Advisory Commission. CMS responded to the comments in the final rule.

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

CMS determined the final rule contains information collection requirements (ICRs) subject to PRA. The ICRs are associated with Office of Management and Budget (OMB) Control Numbers 0938-1289 and 0938-1340. CMS discussed the estimated burdens for each ICR in the final rule.

**Statutory authorization for the rule**

CMS promulgated the final rule pursuant to sections 1302, 1315a, 1395d, 1395f, 1395g, 1395l, 1395x, 1395hh, 1395rr, 1395tt, and 1395ww of title 42, United States Code.

**Executive Order No. 12866 (Regulatory Planning and Review)**

CMS stated OMB determined the final rule was economically significant.

**Executive Order No. 13132 (Federalism)**

CMS determined that the final rule will not have substantial direct effects on the rights, roles, and responsibilities of states and local or tribal governments.