



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

B-336851

November 26, 2024

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

The Honorable Cathy McMorris Rodgers  
Chair  
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; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, 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, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model” (RIN: 0938-AV27). We received the rule on November 6, 2024. It was published in the *Federal Register* on November 12, 2024. 89 Fed. Reg. 89084. The stated effective date of the rule is January 1, 2025.

According to CMS, this rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2025. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury.

In addition, this rule updates requirements for the Conditions for Coverage for ESRD Facilities, ESRD Quality Incentive Program, and 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 House of Representatives received the rule on November 6, 2024. 170 Cong. Rec. H5975 (daily ed. Nov. 13, 2024). The Senate received the rule on November 7, 2024. 170 Cong. Rec. S6525 (daily ed. Nov. 12, 2024). The rule was published in the *Federal Register* on November 12, 2024. 89 Fed. Reg. 89084. The stated effective date of the rule is January 1, 2025. Therefore, the stated effective date is less than 60 days from the date of publication in the *Federal Register*.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large initial 'S' and 'J'.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Christina Kang  
Regulations Coordinator  
Department of Health and Human Services

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, CONDITIONS FOR COVERAGE FOR END-STAGE RENAL  
DISEASE FACILITIES, END-STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM,  
AND END-STAGE RENAL DISEASE TREATMENT CHOICES MODEL”  
(RIN: 0938-AV27)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) conducted a detailed economic analysis for this rule. CMS estimated the combined impact of the policies finalized in the rule on payments for calendar year 2025 to be \$260 million. 89 Fed. Reg. 89197–89209 (Nov. 12, 2024).

(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 has determined that this rule will have a significant economic impact, reflecting a positive revenue increase, on a substantial number of small entities. CMS also stated that the Secretary of HHS has certified that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals. 89 Fed. Reg. 89211.

(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 for the private sector. 89 Fed. Reg. 89211.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO’s major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: “the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act’s exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act’s requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act” in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive*

*Departments and Agencies*, Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

CMS did not discuss the Act in this rule. In its submission to us, CMS stated that it provided a statement on the Act as a separate document. However, CMS did not provide such a document to us.

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

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

On July 5, 2024, CMS published a proposed rule. 89 Fed. Reg. 55760. CMS stated that they received 212 public comments. 89 Fed. Reg. 89089. CMS responded to comments in this rule.

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

CMS determined that this rule contains information collection requirements under the Act. See 89 Fed. Reg. 89194–89195.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1302, 1315a, 1395d(d), 1395f(b), 1395g, 1395hh, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, 1395ww, and 1395ddd of title 42, United States Code, and section 1881(b)(14)(F)(i) of the Social Security Act.

Executive Order No. 12866 (Regulatory Planning and Review)

The Office of Information and Regulatory Affairs determined that this rule is significant under the Order. CMS stated that OMB has reviewed the rule. 89 Fed. Reg. 89196.

Executive Order No. 13132 (Federalism)

CMS determined that this rule does not have federalism implications. See 89 Fed. Reg. 89211.