U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

B-335735

November 20, 2023

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, 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-AV05). We received the rule on November 1, 2023. It was published in the *Federal Register* as a final rule on November 6, 2023. 88 Fed. Reg. 76344. The effective date is January 1, 2024.

According to CMS, this final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2024. CMS stated that the rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, CMS noted that the rule updates requirements for the ESRD Quality Incentive Program and 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). This final rule was received by both the House of Representatives and the Senate on November 1, 2023. Email from Regulations Coordinator, Department of Health and Human Services, to CRA Rules, GAO, *Subject: Official Submission - RIN 0938-AV05* (Nov. 1, 2023). The rule was published in the *Federal Register* on November 6, 2023. 88 Fed. Reg. 76344. The rule has a stated effective date of January 1, 2024. Therefore, 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-AV05)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) conducted an economic analysis of this final rule. This analysis included a detailed analysis of the impacts the rule will have on affected entities and beneficiaries, such as impacts of the final End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), impacts of the final payment rate for renal dialysis services furnished to individuals with acute kidney injury (AKI), impacts to the ESRD Quality Incentive Program (QIP), as well as impacts to the ESRD Treatment Choices (ETC) Model.

Regarding the benefits of the rule, CMS stated that it continues to expect that making prospective Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, CMS expressed that it expects that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished at ESRD facilities by 2.1 percent based on the calendar year (CY) 2024 ESRD Bundled market basket percentage increase reduced by the CY 2024 productivity adjustment will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in delivering renal dialysis services. In the rule, CMS estimated that overall payments under the ESRD PPS will increase by 2.1 percent.

Additionally, CMS recognized the various costs of the rule relating to the ESRD PPS and AKI as well as to the ESRD QIP. CMS stated that it is finalizing a requirement for ESRD facilities to submit data and information on ESRD PPS claims for renal dialysis services regarding the number of minutes of hemodialysis treatment received by a beneficiary in center in an ESRD facility. CMS stated that this patient-level reporting on resource use will be used to apportion composite rate costs for use in the case-mix adjustment under the ESRD PPS. Thus, CMS estimated that there will be an increase in costs for ESRD facilities associated with this final reporting requirement. In total, CMS estimated the cost of the reporting requirement to be $12,781,800 per year, but recognized that this estimate represents the upper limit of its burden estimate since some non-large-dialysis-organization ESRD facilities may choose to adopt an automated process, rather than a manual one. Regarding the ESRD QIP, CMS estimated that for plan year (PY) 2026, there would be approximately $120.9 million in information collection burden and an additional $16 million in estimated payment reductions across all facilities, for a total estimated impact of $136.9 million. CMS also estimated that for PY 2027, there would be approximately $130.5 million in information collection burden and $13.8 million in estimated payment reductions across all facilities, for a total estimated impact of $144.3 million.

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

CMS determined that the ETC Model will not have a significant impact on spending for a substantial number of small entities. Additionally, CMS stated that the Secretary of the Department of Health and Human Services certified that the rule would not have a significant 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

According to CMS, this final rule will not impose a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $177 million ($100 million, adjusted for inflation) or more in any one year.

(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.

In its submission to us, CMS stated that the Act does not apply to the rule because it meets one of the Act's exemptions. According to CMS, the Act does not apply to the rule because its direct spending increase is: (1) less than $1 billion over the next 10 fiscal years, beginning with the remainder of the current fiscal year, and (2) less than $100 million in any one of those 10 fiscal years.

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

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

On June 30, 2023, CMS published a proposed rule. 88 Fed. Reg. 42430. CMS received 344 public comments on its ESRD PPS proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations; for-profit and non-profit ESRD facilities; ESRD networks; and a dialysis coalition. CMS also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home renal dialysis services

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

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

CMS determined that this final rule contains information collection requirements (ICRs) under the Act. CMS stated that it is soliciting public comments in accordance with the Act for the sections of the rule that contain ICRs. In the rule, CMS discussed the following ICRs: ICRs Regarding the JW and JZ Reporting Requirements; Reporting Policy for Discarded Amounts of Renal Dialysis Drugs and Biological Products Paid for Under the ESRD PPS, Section II.B.1.h (OMB Control Number 0938-0997); ICRs Regarding the Proposal to Require Time on Machine Data as a Recordkeeping and Cost Reporting Requirement for Outpatient Maintenance Dialysis; Section II.B.1.j (OMB Control Number 0938-0997); ESRD QIP—Wage Estimates (OMB Control Numbers 0938-1289 and 0938-1340); Estimated Burden Associated with the Data Validation Requirements For PY 2026 and PY 2027 (OMB Control Numbers 0938-1289 and 0938-1340); and Estimated ESRD Quality Reporting System Reporting Requirements for PY 2026 and PY 2027 (OMB Control Number 0938-1289). CMS provided burden estimates for these ICRs.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to various sections of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that OMB determined this final rule to be significant within the meaning of the Order.

Executive Order No. 13132 (Federalism)

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