

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

B-333746

November 19, 2021

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  
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-AU39). We received the rule on November 8, 2021. It was published in the *Federal Register* as a final rule on November 8, 2021. 86 Fed. Reg. 61874. The effective date is January 1, 2022.

According to CMS, the final rule updates the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2022. CMS stated this rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. CMS further stated this rule updates requirements for the ESRD Quality Incentive Program (QIP), including a measure suppression policy for the duration of the coronavirus disease 2019 (COVID-19) public health emergency as well as suppression of individual ESRD QIP measures for payment year 2022 under the measure suppression policy.

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 8, 2021. The *Congressional Record* does not yet reflect the date of receipt by either chamber of Congress. The rule has a stated effective date of January 1, 2022. Therefore, based on the date of publication in the *Federal Register*, 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.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive, flowing style.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II  
Regulations Coordinator

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-AU39)

(i) Cost-benefit analysis

According to the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) payments to ESRD facilities will enhance the efficiency of the Medicare program. CMS further stated that updating ESRD PPS and Acute Kidney Injury (AKI) payments by 1.9 percent 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. CMS stated that it does not anticipate ESRD PPS and AKI rate-setting will create additional cost or burden to ESRD facilities. Finally, CMS estimated approximately \$230 million in transfers from the federal government to ESRD facilities due to increased Medicare program payments and approximately \$60 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary co-insurance payments as a result of this final rule.

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

CMS stated it determined that this final rule will not have a significant economic impact on a substantial number of small entities. CMS further stated it determined that this rule will 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

CMS stated this final rule does not mandate any requirements for state, local, or tribal governments in the aggregate, or by the private sector. CMS further stated that it does not interpret Medicare payment rules as being unfunded mandates, but rather as conditions for the receipt of payments from the federal government for providing services that meet federal standards.

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

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

On July 9, 2021, CMS published a proposed rule. 86 Fed. Reg. 36322. CMS stated it received 286 comments from kidney and dialysis organizations, patients, healthcare providers, advocacy organizations, administrators and insurance groups, drug and device manufacturers, health care systems, a health solutions company, and the Medicare Payment Advisory Commission. CMS further stated that in this final rule it provided a summary of the public comments received and its responses to them.

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

CMS stated it determined that this final rule contains information collection requirements under the PRA. CMS summarized the information collection requirements as follows:

- ESRD Quality Incentive Program – Wage Estimates, Office of Management and Budget (OMB) Control Numbers 0938-1289 and 0938-1340; burden estimates provided in the proposed rule;
- Data Validation Requirements for Payment Year (PY) 2024 and PY 2025, OMB Control Numbers 0938-1289 and 0938-1340; 1,500 estimated total annual burden hours; \$63,600 estimated total annual burden cost; and
- ESRD Quality Reporting System (EQRS) Reporting Requirements for PY 2024 and PY 2025, OMB Control Number 0938-1289; 5,085,050 burden hours for PY 2024; \$215 million total burden cost for PY 2024.

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 the Office of Information and Regulatory Affairs determined this final rule is economically significant under the Order.

Executive Order No. 13132 (Federalism)

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