



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

B-332701

November 23, 2020

The Honorable Chuck Grassley  
Chairman  
The Honorable Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Frank Pallone, Jr.  
Chairman  
The Honorable Greg Walden  
Ranking Member  
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, and End-Stage Renal Disease 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; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program” (RIN: 0938-AU08). We received the rule on November 3, 2020. It was published in the *Federal Register* as a final rule on November 9, 2020. 85 Fed. Reg. 71398. The final rule has an effective date of January 1, 2021.

According to CMS, the final rule updates and makes revisions to the End-Stage Renal Disease (ERSD) Prospective Payment System for calendar year 2021. CMS states 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 this rule updates requirements for the ESRD Quality Incentive Program.

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 Senate received the rule on November 12, 2020. 165 Cong. Rec. S6673 (daily ed. Nov. 12, 2020). The House of Representatives received the rule on November 5, 2020. 165 Cong. Rec. H5974 (daily ed. Nov. 16, 2020). It was published in the *Federal Register* on November 9, 2020. 85 Fed. Reg. 71398. 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.

A handwritten signature in cursive script that reads "Shirley A. Jones". The signature is written in black ink and is positioned above the typed name and title.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Vanessa Jones  
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, AND END-STAGE RENAL DISEASE  
QUALITY INCENTIVE PROGRAM”  
(RIN: 0938-AU08)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) estimated the End-Stage Renal Disease (ERSD) Prospective Payment System and acute kidney injuries would lead to transfers of \$250 million from the federal government and beneficiaries to ERSD providers. CMS further estimated the ERSD Quality Incentive Program would lead to a reduction in transfers of \$16 million for payment years 2023 and 2024.

(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 not 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 a substantial number of 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.

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

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

CMS published a proposed rule on July 13, 2020. 85 Fed. Reg. 42132. CMS received 114 comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses. CMS provided summaries of the comments and its responses in this final rule.

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

CMS determined the final rule does not create any new information collection requirements (ICRs); however, CMS stated the final rule impacts previously approved ICRs. According to CMS, these impacts were as follows: (1) Office of Management and Budget (OMB) Control Number 0938-1289 will have an estimated burden of 750 hours at cost of \$30,750; (2) OMB Control Number 0938-1340 will have an estimated burden of 1,500 hours at a cost of \$61,500;

and (3) CROWNWeb reporting requirements for payment years 2023 and 2024 will have an estimated burden of 5,085,050 hours at a cost of \$208 million.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1395d, 1395f, 1395g, 1395i, 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 it will not have substantial direct effects on the rights, roles, and responsibilities of states, local, or tribal governments.