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B-331586

November 25, 2019

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, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements*

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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements” (RIN: 0938-AT70). We received the rule on November 5, 2019. It was published in the *Federal Register* as a final rule

on November 8, 2019. 84 Fed. Reg. 60648. The stated effective date of the rule is January 1, 2020.

The final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2020. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. The rule also updates requirements for the ESRD Quality Incentive Program. In addition, the rule established a methodology for calculating fee schedule payment amounts for new Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items and services, and a methodology for making adjustments to the fee schedule amounts established using supplier or commercial prices if such prices decrease within 5 years of establishing the initial fee schedule amounts. This rule also revises existing regulations relating to the DMEPOS competitive bidding program. This rule also streamlines the requirements for ordering DMEPOS items, and develops a new list of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements. Finally, this rule summarizes responses to requests for information on data collection resulting from the ESRD PPS technical expert panel, changes the basis for the ESRD PPS wage index, and imposes new requirements for the competitive bidding of diabetic testing strips.

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 received by both Houses of Congress on November 5, 2019. 165 Cong. Rec. S6446 (daily ed. Nov. 6, 2019); 165 Cong. Rec. H8782 (daily ed. November 12, 2019). The final rule was published in the *Federal Register* on November 8, 2019. 84 Fed. Reg. 60648. The final rule has a stated effective date of January 1, 2020. 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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
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, END-STAGE RENAL DISEASE QUALITY INCENTIVE PROGRAM, DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES (DMEPOS) FEE SCHEDULE AMOUNTS, DMEPOS COMPETITIVE BIDDING PROGRAM (CBP) AMENDMENTS, STANDARD ELEMENTS FOR A DMEPOS ORDER, AND MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO A FACE-TO-FACE ENCOUNTER AND WRITTEN ORDER PRIOR TO DELIVERY AND/OR PRIOR AUTHORIZATION REQUIREMENTS”
(RIN: 0938-AT70)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) estimated the costs and benefits of this final rule. CMS stated that the finalized revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) will result in an increase of approximately \$210 million in payments to ESRD facilities in CY 2020. These payments represent transfers from the federal government to ESRD providers (\$170 million) and transfers from beneficiaries to ESRD providers (\$40 million). CMS also stated that the ESRD quality incentive program for payment years 2022 and 2023 will result in a decrease of approximately \$18 million for each year in annualized monetized transfers from the federal government to ESRD providers.

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

CMS determined the final rule will not have a significant impact on a substantial number of small entities. CMS also stated the final rule would not have a significant economic impact on 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 that these final rules do not include any mandates that would impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of the threshold amount, which is approximately \$154 million (\$100 million, adjusted for inflation). In the rule CMS stated that HHS interprets the Act as applying only to unfunded mandates, and that CMS does not interpret Medicare payment rules as being unfunded mandates.

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

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

On August 6, 2019, CMS published a proposed rule. 84 Fed. Reg. 38330. In the final rule, CMS summarized the public comments it received, its responses to them, and the policies it is finalizing.

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

According to CMS, all collection of information requirements are already accounted for in Office of Management and Budget-approved information collection requests. CMS stated that, for the purpose of transparency, it was republishing the discussion of the information collection requirements in the final rule.

Statutory authorization for the rule

CMS stated that it promulgated this final rule pursuant to sections 1302; 1395d(d); 1395f(b); 1395g; 1395l(a), (i), and (n); 1395m; 1395x(v); 1395hh; 1395rr; 1395tt; 1395ww; and 1395ddd of title 42, United States Code.

Executive Order No. 12,866 (Regulatory Planning and Review)

CMS found that these final rules were economically significant under the Order. CMS stated that these final rules were reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

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