



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

B-330523

November 28, 2018

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Kevin Brady
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 and 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) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS*

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 and 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) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS” (RIN: 0938-AT28). We received the rule on November 7, 2018. It was published in the *Federal Register* as a final rule on November 14, 2018. 83 Fed. Reg. 56,922. The effective date of the final rule is January 1, 2019, except for amendments to 42 C.F.R. § 413.234, which are effective January 1, 2020.

The final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2019. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, it updates and rebases the ESRD market basket for CY 2019. This rule also updates requirements for the ESRD Quality Incentive Program (QIP), and makes technical amendments to correct existing regulations related to the Competitive Bidding Program (CBP) for certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Finally, this rule finalizes changes to bidding and pricing methodologies under the DMEPOS competitive bidding program; adjustments to DMEPOS fee schedule amounts using information from competitive bidding for items furnished from January 1, 2019, through December 31, 2020; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that new payment classes for oxygen and oxygen equipment are budget neutral; payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment (DME); and revises the payment methodology for mail order items furnished in the Northern Mariana Islands. This rule also includes a summary of the feedback received for the request for information related to establishing fee schedule amounts for new DMEPOS items and services.

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 rule was received by the House of Representatives on November 7, 2018, and received by the Senate on November 13, 2018. It was published in the *Federal Register* on November 14, 2018. 83 Fed. Reg. 56,922. The rule has a stated effective date of January 1, 2019, except the amendments to 42 C.F.R. § 413.234, which are effective January 1, 2020. Therefore, except for the amendments effective January 1, 2020, 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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Julia C. Matta
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas
Regulations Coordinator
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THEDEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND 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) COMPETITIVE BIDDING PROGRAM (CBP) AND FEE SCHEDULE AMOUNTS, AND TECHNICAL AMENDMENTS TO CORRECT EXISTING REGULATIONS RELATED TO THE CBP FOR CERTAIN DMEPOS”

(RIN: 0938-AT28)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and 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 2019. These payments represent transfers from the federal government to ESRD providers (\$160 million) and transfers from beneficiaries to ESRD providers (\$50 million). CMS estimates that approximately \$40 million will be paid to ESRD facilities for dialysis treatments provided to acute kidney injury beneficiaries.

For payment year (PY) 2021, CMS re-estimated the costs associated with information collection requirements under the ESRD Quality Incentive Program (QIP) for this final rule, and also re-estimated the payment reductions under the ESRD QIP. CMS estimates that these updates will result in an overall impact of \$213 million associated with quality reporting burden and payment reductions, which includes a \$12 million incremental reduction in burden in collection of information requirements and \$32 million in estimated payment reductions across all facilities. In addition, PY 2021 ESRD QIP payment reductions represent transfers from the federal government to ESRD providers of -\$32 million, and total ESRD provider costs under the ESRD QIP for PY 2021 total \$181 million. For PY 2022, CMS estimated that the proposed revisions to the ESRD QIP will result in an overall impact of \$234 million, which includes a \$21 million incremental increase associated with the collection of information requirements and \$32 million in estimated payment reductions across all facilities. Also, PY 2022 ESRD QIP payment reductions represent transfers from the federal government to ESRD providers of -\$32 million, and total ESRD provider costs under the ESRD QIP for PY 2022 total \$202 million.

With regard to Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS), CMS stated that impacts are generally considered against the Medicare, Medicaid, and beneficiary cost sharing. CMS estimated that the finalized revisions to base single payment amounts (SPA) on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS Competitive Bidding Program (CBP), will cost about \$10 million in Medicare benefit payments and roughly \$3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019, and ending September 30, 2023. CMS stated that it is finalizing transitional fee schedule adjustments for DMEPOS items and services furnished on or after

January 1, 2019, in areas that are currently competitive bidding areas (CBA) and in areas that are currently not CBAs. The estimated impacts for this part of the rule were calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place as of January 1, 2018. The impacts are expected to cost \$1.05 billion in Medicare benefit payments and \$260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019, and ending December 31, 2020. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be \$45 million and \$30 million, respectively.

CMS states that the rule finalizing new payment classes for oxygen and oxygen equipment is estimated to be budget neutral to the Medicare program. The final rule also establishes payment rules for multi-function ventilators. According to CMS, the impacts for the ventilators are estimated by rounding to the nearest \$5 million and are expected to cost \$15 million in Medicare beneficiary payments and \$3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019, and ending September 30, 2023. With regard to the Northern Mariana Islands in Future National Mail Order CBPs, CMS states this change will not have any fiscal impact.

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

CMS believes that two sections of this final rule will have a significant economic impact on a substantial number of small entities. Those sections are section V, Changes to the DMEPOS CPB, and section VI, Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP. CMS determined that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals. CMS also stated that it received one comment on the RFA analysis provided and responded to it in the final rule.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act (UMRA) 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 \$150 million. As stated in the rule, HHS interprets UMRA as applying only to unfunded mandates, and CMS does not interpret Medicare payment rules as unfunded mandates.

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

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

On July 19, 2018, CMS published a proposed rule. 83 Fed. Reg. 34,304. 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

CMS determined that in accordance with PRA, it solicited public comments in the notice of proposed rulemaking. CMS stated that, for the purpose of transparency, it was republishing the discussion of information collection requirements. According to CMS, all collection of

information requirements are already accounted for in Office of Management and Budget-approved information collection requests.

Statutory authorization for the rule

CMS stated that it promulgated this final rule pursuant to 42 U.S.C. §§ 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; section 124 of Public Law 106–113 , 113 Stat. 1501A–332; section 3201 of Public Law 112–96, 126 Stat. 156; section 3201 of Public Law 112-96, 126 Stat. 156; section 632 of Public Law 112-240, 126 Stat. 2354; section 217 of Public Law 113-93, 129 Stat. 1040; and section 204 of Public Law 113-295, 128 Stat. 4010; and section 808 of Public Law 114-27, 129 Stat. 362.

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 stated that it examined the impacts of this final rule as required by the Order. Specifically, CMS stated that the rules will have substantial direct effects on the rights, roles, and responsibilities of states, local, or tribal governments. CMS estimated that the policies contained in section VI (Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP) of this final rule will add \$30 million dollars of additional expense to state governments because of the added cost sharing expense for Medicare and Medicaid dual eligible beneficiaries.