



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

B-326405

November 21, 2014

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

The Honorable Fred Upton
Chairman
The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander M. Levin
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, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*

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, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (RIN: 0938-AS13). We received the rule on October 31, 2014. It was published in the *Federal Register* as a final rule on November 6, 2014. 79 Fed. Reg. 66,120.

The final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2015. The final rule also finalizes requirements for the ESRD quality incentive program (QIP), including for payment years (PYs) 2017 and 2018.

The final rule has an effective date of January 1, 2015. 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). We received the rule on October 31, 2014, but the rule was not published in the *Federal*

Register until November 6, 2014. 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. Our review of the procedural steps taken indicates that, with the exception of the 60-day delay in effective date, CMS complied with the applicable requirements.

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

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Annie Lamb
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, QUALITY INCENTIVE PROGRAM,
AND DURABLE MEDICAL EQUIPMENT, PROSTHETICS,
ORTHOTICS, AND SUPPLIES"
(RIN: 0938-AS13)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis in conjunction with the final rule. With regard to the End-Stage Renal Disease (ESRD) prospective payment system (PPS), CMS projected the overall impact of the calendar year (CY) 2015 changes to be a 0.3 percent increase in payments, with hospital-based ESRD facilities having an estimated 0.5 percent increase in payments compared with freestanding facilities with an estimated 0.3 percent increase. CMS estimated that the aggregate ESRD PPS expenditures will increase by approximately \$30 million from CY 2014 to CY 2015. This reflects a \$0 change from the payment rate update and a \$30 million increase due to the updates to the outlier threshold amounts. As a result of the projected 0.3 percent overall payment increase, CMS estimates that there will be an increase in beneficiary co-insurance payments of 0.3 percent in CY 2015, which translates to approximately \$10 million.

CMS estimated the overall economic impact of the ESRD quality incentive program (QIP) to be \$12 million in payment year (PY) 2017 and \$11.8 million in PY 2018. In PY 2017, CMS expects the total payment reductions to be approximately \$11.9 million, and the costs associated with the collection of information requirements for the validation of the National Health Safety Network (NHSN) data feasibility study to be approximately \$27,000 for all ESRD facilities. In PY 2018, CMS expects the total payment reductions to be approximately \$11.6 million, and the costs associated with the collection of information requirements for the NHSN Healthcare Personnel Influenza Vaccination reporting measure to be approximately \$248,000 for all ESRD facilities. CMS stated that the ESRD QIP will continue to incentivize facilities to provide high-quality care to beneficiaries.

CMS estimated that adjustments made to the Medicare fee schedule amounts for items subject to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding programs (CBPs) would save over \$4.4 billion in gross payments for the 5-year period beginning January 1, 2016, and ending December 30, 2020. The estimated gross savings are primarily derived from price reductions for items. CMS expects that most of the economic impact would result from reduced payment amounts. CMS does not expect the ability of suppliers to furnish items to be impacted.

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

CMS performed a regulatory flexibility analysis in conjunction with the final rule and determined that the final rule will have a significant economic impact on a substantial number of small

entities. CMS estimated that approximately 16 percent of ESRD dialysis facilities are considered small entities under the Small Business Administration's size standards. In CY 2015, CMS expects that such entities will receive an increase in payments between 0.3 and 0.4 percent. However, in CYs 2017 and 2018 CMS estimates payments to these facilities to decrease by 0.22 and 0.23 percent, respectively.

(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 the final rule does not include any mandates that would impose spending costs on state, local, or tribal governments, in the aggregate, or by the private sector, of \$141 million or more.

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

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

CMS published a notice of proposed rulemaking in the *Federal Register* on July 11, 2014. 79 Fed. Reg. 40,208. CMS received approximately 400 public comments on the proposed rule, including comments from ESRD facilities, national renal groups, nephrologists and patient organizations, patients and care partners, manufacturers, health care systems, and nurses. CMS responded to the comments in the final rule. 79 Fed. Reg. 66,120.

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

The final rule does not include any new information collection requirements as defined in the Paperwork Reduction Act.

Statutory authorization for the rule

The final rule is authorized by sections 1102, 1812(d), 1814(b), 1815, 1833(a),(i), and (n), 1860D-1 through 1860D-42, 1861(v), 1871, 1877, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a),(i) and(n), 1395w-101 through 1395w-152, 1395x(v), 1395hh, 1395nn, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106-113 (113 Stat. 1501A-332), sec. 3201 of Pub. L. 112-96 (126 Stat. 156), sec. 632 of Pub. L. 112-240 (126 Stat. 2354), and sec. 217 of Pub. L. No. 113-93.

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

CMS determined that the final rule is an economically significant rule under the Executive Order. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

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