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November 26, 2012

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. 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 Bad Debt Reductions for All Medicare Providers*

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 Bad Debt Reductions for All Medicare Providers” (RIN: 0938-AR13). We received the rule on November 2, 2012. It was published in the *Federal Register* as a final rule on November 9, 2012. 77 Fed. Reg. 67,450.

The final rule updates and makes revisions to the end-stage renal disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2013. The final rule also sets forth requirements for the ESRD quality incentive program (QIP), including for

payment year (PY) 2015 and beyond. In addition, this rule implements changes to bad debt reimbursement for all Medicare providers, suppliers, and other entities eligible to receive Medicare payment for bad debt and removes the cap on bad debt reimbursement to ESRD facilities.

The regulations setting forth the reductions in Medicare bad debt pursuant to section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96) are applicable for cost reporting periods beginning October 1, 2012.

The final rule is effective January 1, 2013. 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 November 2, 2012; however, it was not published in the *Federal Register* until November 9, 2012. Therefore, the 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 CMS complied with the applicable requirements, with the exception of the 60-day delay in effective date.

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: Ann Stallion
Program Manager
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 BAD DEBT
REDUCTIONS FOR ALL MEDICARE PROVIDERS"
(RIN: 0938-AR13)

(i) Cost-benefit analysis

CMS summarized the cost and benefits for the impacts of the final ESRD PPS, for ESRD QIP, and of bad debt provisions. CMS estimates that the final revisions to the ESRD PPS will result in an increase of approximately \$250 million in payments, from Medicare, to ESRD facilities in CY 2013, which includes the amount associated with the increase in the ESRD market basket reduced by the productivity adjustment, updates to outlier amounts, and the effect of changing the blended payments from 50 percent under the composite rate payment and 50 percent under the ESRD PPS to 25 percent under the composite rate payment and 75 percent under the ESRD PPS. CMS estimates that the requirements related to the ESRD QIP for PY 2015 will cost approximately \$12.4 million and the predicted payment reductions will equal about \$12.1 million to result in a total impact from the proposed ESRD QIP requirements of \$24.6 million. CMS estimates that the self implementing provisions of section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012, dealing with bad debt reimbursement, will result in savings to the Medicare program of \$10.92 billion over the period from 2012 through 2022.

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

CMS states that approximately 19 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than \$34.5 million in any one year. Individuals and states are not included in the definitions of a small entity. CMS does not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis.

For purposes of the RFA, CMS estimates that approximately 19 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small

businesses, nonprofit organizations, and small governmental jurisdictions). Using the definitions in this ownership category, CMS considers the 636 facilities that are independent and the 434 facilities that are shown as hospital based to be small entities. According to CMS, the ESRD facilities that are owned and operated by large dialysis organizations (LDO) and regional chains would have total revenues of more than \$34.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities. For the ESRD PPS updates in this rule, CMS notes that a hospital-based ESRD facility (as defined by ownership type) is estimated to receive a 3.6 percent increase in payments for CY 2013, while an independent facility (as defined by ownership type) is estimated to receive a 3.0 percent increase in payments for 2013. Based on the ESRD QIP payment reduction impacts to ESRD facilities for PY 2015, CMS estimates that of the 1,093 ESRD facilities expected to receive a payment reduction, 278 ESRD small entity facilities will experience a payment reduction (ranging from 0.5 percent up to 2.0 of total payments). CMS anticipates the payment reductions to average approximately \$11,059 per facility among the 1,093 facilities receiving a payment reduction, with an average of \$12,866 per small entity facilities receiving a payment reduction. CMS believes the projected impacts for these small entities are estimates based on current data and the actual impacts may differ. CMS estimates that there are a total of 1,070 small entity facilities. For this entire group of 1,070 ESRD small entity facilities, CMS states that a decrease of 0.30 percent in aggregate ESRD payments is observed.

CMS recognizes that a facility may have additional costs resulting from the ESRD QIP and believes that these costs, however, are necessary in improving care and do not outweigh the utility of the program. CMS will continue to monitor these costs, paying specific attention to their effect upon small facilities. Therefore, CMS states that the Secretary of Health and Human Services has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

CMS states that the final rule does not include any mandates that will impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector, of \$139 million.

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

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

On July 11, 2012, CMS published a proposed rule entitled, Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and

Bad Debt Reductions for All Medicare Providers. 77 Fed. Reg. 40,952. CMS received approximately 40 public comments on the ESRD PPS proposals, including comments from ESRD facilities; national renal, nephrologist and patient organizations; patients; manufacturers; health care systems; and nurses. In the final rule, CMS provides a summary of each proposed provision, a summary of the public comments received and CMS's responses to them, and the policies CMS is finalizing.

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

CMS states that the final rule does not impose any new information collection requirements in the regulation text, but does make reference to several associated information collections that are not discussed in the regulation text contained in the final rule. CMS discusses these information collections in the final rule and is soliciting public comment on each of these issues.

Statutory authorization for the rule

CMS states that the ESRD PPS is authorized by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148). The ESRD QIP program is authorized under section 153(c) of MIPPA, which added section 1881(h) to the Act, and the bad debt reimbursement is authorized by section 3201 of The Middle Class Tax Extension and Job Creation Act of 2012 (Pub. L. 112–96).

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

CMS states that this final rule has been designated economically significant and, accordingly, it has been reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

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