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B-325831

May 16, 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 A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander 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; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral*

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; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral” (RIN: 0938-AR62). We received the rule on May 1, 2014. It was published in the *Federal Register* as a final rule with comment period on May 2, 2014. 79 Fed. Reg. 25,436.

The final rule with comment period implements methodology and payment rates for a prospective payment system for federally qualified health center (FQHC) services under Medicare Part B beginning on October 1, 2014, in compliance with the statutory requirement of the Affordable Care Act. In addition, it establishes a policy which allows rural health clinics (RHCs) to contract with nonphysician practitioners when statutory requirements for employment of nurse practitioners and physician assistants are met, and makes other technical and

conforming changes to the RHC and FQHC regulations. The final rule with comment period also implements changes to the Clinical Laboratory Improvement Amendments (CLIA) regulations regarding enforcement actions for proficiency testing referrals. The provisions of the final rule with comment period are effective on October 1, 2014, except for amendments to sections 491.8(a)(3) (nonphysician practitioners), 493.1, 493.2, 493.1800, and 493.1840 (CLIA regulations), which are effective July 1, 2014.

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.

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
Deputy Director
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; PROSPECTIVE PAYMENT SYSTEM
FOR FEDERALLY QUALIFIED HEALTH CENTERS; CHANGES TO
CONTRACTING POLICIES FOR RURAL HEALTH CLINICS;
AND CHANGES TO CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
OF 1988 ENFORCEMENT ACTIONS FOR PROFICIENCY TESTING REFERRAL"
(RIN: 0938-AR62)

(i) Cost-benefit analysis

As required by section 1834(o)(2)(B)(i) of the Social Security Act, initial payment rates under the FQHC prospective payment system must equal 100 percent of the estimated amount of reasonable costs, as determined without the application of the current system's upper payment limits or productivity standards. CMS's estimate is an overall impact of increasing Medicare payments to FQHCs by approximately 32 percent. The annualized cost to the federal government associated with the final FQHC prospective payment system is estimated to be between \$200 million and \$204 million, based on 5-year discounted flows using 3 percent and 7 percent factors. CMS also estimated that there would be no costs associated with the removal of the contracting restrictions for RHCs or for technical and conforming regulatory changes that would be made in conjunction with the establishment of the FQHC prospective payment system. For the CLIA provisions, CMS projected net average savings per affected certificate holder of \$428,000.

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

All RHCs and FQHCs are considered to be small entities, and for this reason CMS prepared a regulatory flexibility analysis. The provisions in the final rule with comment period result in an increase of approximately 32 percent in the Medicare payment to FQHCs. There is no financial impact on RHCs. CMS also determined that the final rule with comment period would not have a significant 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 the final rule with comment period does not include any mandates that would impose spending costs on state, local, or tribal governments in the aggregate, or by the private section, that would exceed the threshold of \$141 million in the Act.

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

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

On September 23, 2013, CMS published a proposed rule in the *Federal Register*, “Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral.” 78 Fed. Reg. 58,386. CMS received comments on the proposed rule and responded to the comments in the final rule with comment period. CMS determined that it had good cause to waive the notice of proposed rulemaking for certain of the regulatory changes made in response to the comments received. This is because the Social Security Act requires the implementation of the FQHC prospective payment system beginning on October 1, 2014, and it would therefore be impracticable and contrary to the public interest to provide an additional period for public comment before this methodology is implemented. In the final rule, CMS is soliciting an additional round of comments with respect to these regulatory changes. These comments must be received by July 1, 2104. CMS will consider further action if comments received from the public indicate a need to amend or revise these regulatory changes.

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

The data that are used in computing the FQHC prospective payment system rates are derived from the RHC/FQHC cost report. The reporting requirements for FQHCs are in the Medicare regulations. While there are no new information collections in the final rule with comment period, CMS states that there is currently an Office of Management and Budget (OMB) approved information collection request associated with the RHC/FQHC cost report that has an OMB control number of 0938-0107 and an expiration date of August 31, 2014.

Statutory authorization for the rule

CMS stated that the final rule with comment period was authorized by sections 1834(o) and 1861 of the Social Security Act and the Taking Essential Steps for Testing Act of 2012, Pub. L. No. 112-202 (Dec. 4, 2012).

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

CMS determined that the final rule with comment period is an economically significant rule under the Order because the FQHC prospective payment system will increase payments to FQHCs by more than \$100 million in one year. CMS also determined that this final rule with comment period will not have a significant financial impact on RHCs. CMS prepared a regulatory impact analysis of the final rule with comment period. The final rule with comment period was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule with comment period does not have a substantial effect on state and local governments, preempt state law, otherwise have federalism implications.