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November 2, 2015

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

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

The Honorable Sam Johnson
Acting 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 and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017*

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 and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017” (RINs: 0938-AS26, 0938-AS58). We received the rule on October 6, 2015. It was published in the *Federal Register* as final rules with comment period on October 16, 2015. 80 Fed. Reg. 62,762.

The final rule with comment period specifies the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the Medicare EHR Incentive Program. In addition, it changes the Medicare and Medicaid EHR Incentive Programs reporting period in 2015 to a 90-day period aligned with the calendar year. This final rule with comment period also removes reporting requirements on measures that have become redundant, duplicative, or topped out from the Medicare and Medicaid EHR Incentive Programs. In addition, this final rule with comment period establishes the requirements for Stage 3 of the program as optional in 2017 and required for all participants beginning in 2018. The final rule with comment period continues to

encourage the electronic submission of clinical quality measure (CQM) data, establishes requirements to transition the program to a single stage, and aligns reporting for providers in the Medicare and Medicaid EHR Incentive Programs.

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, ODRM
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
ENTITLED
"MEDICARE AND MEDICAID PROGRAMS;
ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM—
STAGE 3 AND MODIFICATIONS TO MEANINGFUL USE
IN 2015 THROUGH 2017"
(RINs: 0938-AS26, 0938-AS58)

(i) Cost-benefit analysis

Based on prior rulemaking, CMS expects spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2015 and 2017 to be \$14.2 billion; however, CMS concluded that the policies in this final rule with comment period do not change estimates over the current period.

CMS's analysis of impacts for the policies in this final rule with comment period relate to the reduction in cost associated with provider reporting burden estimates for 2015 through 2017 as affected by the adopted changes to the current program. The estimates also relate to the transfer payments for incentives for Medicaid providers and reductions in payments for Medicare providers through payment adjustments for 2018 and subsequent years. For 2015 through 2017, CMS estimates the reduction in the reporting burden for providers demonstrating meaningful use in a calendar year as 1.45 hours to 1.9 hours per EP respondent and 2.62 hours per eligible hospital or CAH respondent. CMS estimates the total annual cost savings related to this reduction at \$52,547,132 for a low estimate and \$68,617,864 for a high estimate. CMS expects spending under the EHR Incentive Programs for transfer payments to Medicare and Medicaid providers between 2017 and 2020 to be \$3.7 billion (this estimate includes net payment adjustments in the amount of \$0.8 billion for Medicare providers who do not achieve meaningful use).

In this final rule with comment period, CMS stated that it does not estimate total costs and benefits to the provider industry, but rather provides a possible per EP and per eligible hospital outlay for implementation and maintenance. CMS further stated that it nonetheless believes there are substantial benefits that can be obtained by society (perhaps accruing to eligible hospitals and EPs), including cost reductions related to improvements in patient safety and patient outcomes and cost savings benefits through maximizing efficiencies in clinical and business processes facilitated by certified health information technology.

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

CMS provided a Final Regulatory Flexibility Analysis for this final rule with comment period. This analysis includes (1) a statement of need, (2) a description of the overall impact, (3) a description of anticipated effects, and (4) alternatives considered.

CMS stated that it believes that there are many positive effects of adopting EHR on health care providers and that the net effect on some individual providers may be positive. CMS further stated that it believes the provisions in this EHR Incentive Programs in 2015 through 2017 portion of this final rule with comment period will result in an overall reduction in the reporting burden for providers of all types. Accordingly, CMS concluded that the object of the RFA to minimize burden on small entities is met by this final rule with comment period.

(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 this final rule with comment period imposes no substantial mandates on states. CMS stated that this program is voluntary for states and states offer the incentives at their option and that the state role in the incentive program is essentially to administer the Medicaid EHR Incentive Program. While this entails certain procedural responsibilities, CMS believes that this do not involve substantial state expense. In general, each state Medicaid agency that participates in the incentive program would be required to invest in systems and technology to comply. States would have to identify and educate providers, evaluate their attestations and pay the incentive. However, CMS observed that the federal government would fund 90 percent of the state's related administrative costs, providing controls on the total state outlay. In addition, CMS stated that the changes being made by the modifications portion of this final rule with comment period have very little impact on any state functions.

CMS determined that the investments needed to meet the requirements of the program and obtain incentive funding are voluntary, and hence not “mandates” within the meaning of the statute. However, CMS also observed that the potential reductions in Medicare reimbursement beginning with FY 2015 would have a negative impact on providers that fail to meaningfully use Certified Electronic Health Record Technology for the applicable EHR reporting period. CMS noted that it has no discretion as to the amount of those potential payment reductions. Private sector EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed \$141 million. However, because EPs may choose for various reasons not to participate in the program, CMS stated that it does not have firm data for the percentage of participation within the private sector.

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

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

On March 30, 2015, CMS published a proposed rule entitled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3.” 80 Fed. Reg. 16,731. On April 15, 2015, CMS published a proposed rule entitled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Modifications to Meaningful Use in 2015 through 2017.” 80 Fed. Reg. 20,346. With this final rule, CMS is finalizing both proposed rules. CMS responded to comments in the final rule.

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

CMS determined that this final rule with comment period includes information collection requirements under the Act. CMS estimated the total annual cost burden for all EPs to attest to EHR technology, meaningful use objectives and associated measures, and electronically submit the clinical quality measures would be \$385,834,395 (609,100 EPs times 6 hours 52 minutes

times \$92.25 (mean hourly rate for physicians based on May 2013 Business and Labor Statistics data).

Statutory authorization for the rule

CMS promulgated this final rule with comment period under the authority of sections 1102 and 1871 of the Social Security Act. 42 U.S.C. §§ 1302, 1395hh.

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

CMS determined that this final rule with comment period is economically significant under the Order as it is anticipated to have an annual effect on the economy of \$100 million or more.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule with comment period will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication. CMS noted that state Medicaid agencies are receiving 100 percent match from the federal government for incentives paid and a 90 percent match for expenses associated with administering the program. CMS believes that state administrative costs are minimal. CMS also noted that the Stage 3 portion of this final rule with comment period does add a new business requirement for states, because of the existing systems that would need to be modified to track and report on the new requirements of the program for provider attestations and that it is providing 90 percent Federal Financial Participation (FFP) to states for modifying their existing EHR Incentive Program systems. CMS believes the federal share of the 90 percent match will protect the states from burdensome financial outlays and offering the Medicaid EHR incentive program is optional.