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September 19, 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 Service, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2*

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 2” (RIN: 0938-AQ84). We received the rule on August 27, 2012. It was published in the *Federal Register* as a final rule on September 4, 2012. 77 Fed. Reg. 53,968.

The final rule specifies the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to qualify for Medicare and/or Medicaid electronic health record (EHR) incentive payments. In addition, it specifies payment adjustments under Medicare for covered professional services and hospital services provided by EPs, eligible hospitals, and CAHs failing

to demonstrate meaningful use of certified EHR technology (CEHRT) and other program participation requirements.

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
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 AND MEDICAID PROGRAMS; ELECTRONIC
HEALTH RECORD INCENTIVE PROGRAM—STAGE 2"
(RIN: 0938-AQ84)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis in conjunction with the final rule. In summary, CMS estimated that the total federal cost of the Medicare and Medicaid electronic health record (EHR) Incentive Programs between 2014 and 2019 to be \$15.4 billion, and stated that this estimate includes net payment adjustments for Medicare providers who do not achieve meaningful use in 2015 and subsequent years in the amount of \$2.1 billion. CMS did not quantify the overall benefits to the industry, nor to eligible professionals (EPs), eligible hospitals, or critical access hospitals (CAHs) participating in the Medicare and Medicaid EHR Incentive Programs. Information on the costs and benefits of adopting systems specifically meeting the requirements for the EHR Incentive Programs has not yet been collected and information on costs and benefits overall is limited. Nonetheless, CMS stated that there are substantial benefits that can be obtained by eligible hospitals and EPs, including reductions in medical recordkeeping costs, reductions in repeat tests, decreases in length of stay, increased patient safety, and reduced medical errors. As a result CMS concluded that there is evidence to support the cost-saving benefits anticipated from wider adoption of EHRs.

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

CMS performed a regulatory flexibility analysis in conjunction with the final rule. CMS stated that while the effects of the rule are economically significant, it does not believe that the net effect on individual providers will be negative over time, except in very rare cases.

CMS estimated that there are approximately 624,000 healthcare organizations (EPs, practices, eligible hospitals, or CAHs) that will be affected by the incentive program, including hospitals and physician practices as well as doctors of medicine or osteopathy, dental surgery or dental medicine, podiatric medicine, optometry or a chiropractor. Additionally, CMS determined that as many as 47,000 non-physician practitioners (such as certified nurse-midwives, etc.) will be eligible to receive the

Medicaid incentive payments. Of the 624,000 healthcare organizations estimated to be affected by the incentive program, CMS estimated that 94.71 percent will be EPs, 0.8 percent will be hospitals, and 4.47 percent will be Medicare Advantage organization physicians or hospitals. CMS further estimated that EPs will spend approximately \$54,000 to purchase and implement a certified EHR and \$10,000 annually for ongoing maintenance. CMS determined that for all eligible hospitals, the range is from \$1 million to \$100 million and that the average will be \$5 million to achieve meaningful use. CMS estimated \$1 million for maintenance, upgrades, and training each year.

CMS is also required to prepare a regulatory impact analysis if a rule will have a significant impact on the operations of a substantial number of small rural hospitals. CMS stated that overall any impacts would be positive, but noted that CMS has statutory authority to make case-by-case exceptions for significant hardship, and proposed certain case-by-case applications that may be made when there are barriers to internet connectivity that will impact health information exchange.

(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 imposes no substantial mandates on the states. CMS determined that EPs that voluntarily choose not to participate in the program may anticipate potential costs in the aggregate that may exceed \$139 million; however, CMS stated that it does not have firm data on private sector participation with which to make an estimate of such costs.

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

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

On March 7, 2012, CMS published a proposed rule that specified the potential Stage 2 criteria that EPs, eligible hospitals, and CAHs would have to meet in order to qualify for Medicare and/or Medicaid EHR incentive payments in the *Federal Register* (77 Fed. Reg. 13,698), as well as a proposed rule titled “Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology” (77 Fed. Reg. 13,832). CMS received approximately 6,100 comments on the proposed rule and responded to those comments in the final rule.

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

The final rule contains information collection requirements subject to the Paperwork Reduction Act. These include information collection requirements regarding the demonstration of meaningful use criteria, information collection requirements

regarding qualifying Medicare Advantage organizations, and those relating to state Medicaid agency and Medicaid EP and hospital activities. CMS estimated that these requirements will result in an aggregate burden of 2,034,740.16 hours and a related aggregate cost of \$181,584,656.

Statutory authorization for the rule

The final rule is authorized by titles XVIII and XIX of the Social Security Act, as amended by the American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, as well as sections 1848(a)(7), 1848(o), 1853(l) and (m), 1886(b)(3)(B), 1886(n), 1814(l), 1903(a)(3)(F) and 1903(t) of the Social Security Act.

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

CMS determined that the final rule is “economically significant” under the Order and prepared a regulatory impact analysis for the final rule.

Executive Order No. 13,132 (Federalism)

CMS determined that the final rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have federalism implications.