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November 16, 2005

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program; E-Prescribing and the Prescription Drug Program*

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 and Medicaid Services (CMS), entitled “Medicare Program; E-Prescribing and the Prescription Drug Program” (RIN: 0938-AN49). We received the rule on November 2, 2005. It was published in the Federal Register as a final rule on November 7, 2005. 70 Fed. Reg. 67568.

The final rule adopts standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). These standards will be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in CMS’s incremental approach to adopting final

foundation standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

The final rule has an announced effective date of January 1, 2006. The Congressional Review Act 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. The rule was published in the Federal Register on November 7, 2005, and was received by Congress on November 4, 2005. Therefore, the rule does not have the required 60-day delay.

Enclosed is our assessment of the 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 indicates that, with the exception of the 60-day delay in the rule's effective date, CMS complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; E-PRESCRIBING AND
THE PRESCRIPTION DRUG PROGRAM"
(RIN: 0938-AN49)

(i) Cost-benefit analysis

CMS performed a Regulatory Impact Analysis which noted that it was difficult to precisely predict the monetary impact of the final rule until it becomes clear the degree of participation in e-prescribing by non-mandated providers. However, the analysis discusses the impact on patients, prescribers, and health plans. One benefit cited by CMS is a reduction in the number of adverse drug events (ADEs) with a subsequent reduction in the number of provider visits, hospitalizations, and life-threatening ADEs.

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

The Administrator of CMS has certified that the 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

The final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than \$120 million in any one year. While the final rule will involve expenditures by the private sector, the expenditures will not approach the \$120 million threshold.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On February 4, 2005, CMS published a Notice of Proposed Rulemaking in the Federal Register. 70 Fed. Reg. 6256. In response, CMS received comments from 84 parties which are discussed in the preamble to the final rule.

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

While the final rule contains an information collection, CMS states that since the standards are in use and constitute a usual and customary business practice, the collection is exempt from review by the Office of Management and Budget (OMB) under 5 C.F.R. 1320.3(b)(2).

Statutory authorization for the rule

The final rule is promulgated under the authority found in section 1860D-4(e) of the MMA (Pub. L. 108-173).

Executive Order No. 12866

The final rule was reviewed by OMB and found to be an “economically significant” regulatory action under the order.

Executive Order No. 13132 (Federalism)

The final rule will preempt some state laws and, therefore, CMS has prepared a federalism summary impact statement, which is contained in the preamble to the final rule, and discusses the steps taken to minimize conflicts.