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April 23, 2008

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

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

The Honorable Charles B. Rangel
Chairman
The Honorable Jim McCrery
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; Standards for E-Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)*

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; Standards for E-Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)" (RINs: 0938-AO66 and 0938-AO42). We received the rule on April 9, 2008. It was published in the *Federal Register* as a final rule on April 7, 2008. 73 Fed. Reg. 18,918.

The final rule adopts uniform standards for medication history, formulary and benefits, and fill status notification (RxFill) for the Medicare Part D electronic

prescribing (e-prescribing) drug program as required by section 1860D-4(e)(4)(D) of the Social Security Act. The final rule also adopts the National Provider Identifier (NPI) as a standard for identifying health care providers in e-prescribing transactions. It also finalizes the June 23, 2006, interim final rule that identified the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8.1 as a backward compatible update of the NCPDP SCRIPT 5.0 until April 1, 2009. The final rule is effective on June 6, 2008, but has a compliance date of 1 year from the date the rule was published in the *Federal Register*--April 7, 2009.

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 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 Michael R. Volpe, Assistant General Counsel, at (202) 512-8236.

signed

Robert J. Cramer
Associate General Counsel

Enclosure

cc: Ann Stallion
Program Manager
Department of Health and
Human Services

ENCLOSURE

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 AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; STANDARDS FOR E-PRESCRIBING UNDER MEDICARE PART D AND IDENTIFICATION OF BACKWARD COMPATIBLE VERSION OF ADOPTED STANDARD FOR E-PRESCRIBING AND THE MEDICARE PRESCRIPTION DRUG PROGRAM (VERSION 8.1)"
(RINs: 0938-AO66 AND 0938-AO42)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule. CMS contends that prescribers and dispensers that are now e-prescribing have already largely invested in the hardware, software, and connectivity necessary to e-prescribe. CMS does not anticipate that the retirement of NCPDP SCRIPT 5.0 in favor of NCPDP SCRIPT 8.1 Medication History Standard for the exchange of medication history information, the adoption of the NCPDP Formulary and Benefits 1.0 for formulary and benefits transactions, the adoption of NPI for use in e-prescribing transactions, and the adoption of NCPDP SCRIPT 8.1 (RxFill) for electronic fill status notification purposes will result in significant costs. CMS anticipates that the ability to utilize electronic formulary and benefits inquiries will result in administrative efficiencies and increased prescribing of generic drugs versus brand name drugs, and the access to medication history at the point of care will result in reduced adverse drug events. The benefits accruing from using the adopted standards in these transactions will have an economically significant effect on Medicare Part D program cost and patient safety.

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

CMS concluded that this final rule will not have a significant impact on a substantial number of small entities because, while many prescribing physician practices and independent dispensers would be small entities, e-prescribing is voluntary for prescribers and dispensers. CMS does not anticipate that the requirement to use NPI in e-prescribing would have any effect on Medicare Part D sponsors, prescribers, or dispensers as they likely are already using the NPI in HIPAA-covered transactions.

(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 contain either an intergovernmental or private sector mandate, as defined in Title II, of more than $127 million in any one year.

(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. CMS issued a Notice of Proposed Rulemaking on November 16, 2007, "Medicare Program; Proposed Standards for E-Prescribing Under Medicare Part D." 72 Fed. Reg. 64,900. CMS received various 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 that have been submitted for review by the Office of Management and Budget (OMB) as required by the Act.

Statutory authorization for the rule

The final rule is authorized by section 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act, 42 U.S.C. §§ 1302, 1395W-101 through 1395w-152, and 1395hh.

Executive Order No. 12,866

CMS estimates that the final rule will have an annual benefit on the economy of $100 million or more and will have "economically significant effects." CMS solicited industry and other interested stakeholder comments on the issue of costs and benefits.

Executive Order No. 13,132 (Federalism)

CMS noted that no state categorically bars e-prescribing; in recent years many states have legislated in this area. Should a state law be contrary to the Medicare Part D e-prescribing standards, or should it restrict the ability to carry out the Medicare Part D e-prescribing program, section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established preemption of that state law. CMS also determined that states would not incur any direct costs as a result of this final rule.