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April 30, 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; Policy and Technical Changes to the Medicare Prescription Drug Benefit*

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; Policy and Technical Changes to the Medicare Prescription Drug Benefit" (RIN: 0938-AO74). We received the rule on April 9, 2008. It was published in the *Federal Register* as a final rule on April 15, 2008. 73 Fed. Reg. 20,486.

The final rule codifies clarifications of existing policies associated with the Medicare Prescription Drug Benefit (also known as Medicare Part D), including, for example, guidance that certain supplies associated with the administration of insulin are included in the definition of a Medicare Part D drug. The final rule also codifies clarification of existing policies associated with the Retiree Drug Subsidy (RDS)

program, including, for example, guidance on aggregating plan options for purposes of meeting the net test for actuarial equivalence. In addition, new clarifications and modifications in the final rule include establishing standards with respect to the timely delivery of infusible drugs covered under Medicare Part D and modifications to the retiree drug subsidy regulations.

The final rule is effective on June 9, 2008. 73 Fed. Reg. 20,486. The Congressional Review Act requires major rules to have a 60-day delay in their effective date following publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). The final rule was not published in the *Federal Register* until April 15, 2008, which means that the final rule will not have the required 60-day delay in its effective date.

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, except for the delay in the effective date, 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; POLICY AND TECHNICAL CHANGES
TO THE MEDICARE PRESCRIPTION DRUG BENEFIT
(RIN: 0938-AO74)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule's provision implementing vaccine administration coverage under Medicare Part D. CMS estimates the cost to implement this provision in fiscal year 2008 at $100 million. CMS stated that the impact of the rule's other provisions and policy clarifications were addressed as part of a prior final rule and do not require further analysis. Specifically, CMS performed a full cost-benefit analysis of those provisions in a January 2005 final rule implementing the Medicare Part D provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003. 70 Fed. Reg. 4454.

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

CMS prepared a regulatory flexibility analysis of the final rule. With respect to the provision on vaccine administration, CMS concluded that there would not be any additional costs to physicians in private practice. With respect to the other provisions of the rule, CMS concluded that there would not be any additional burdens placed on small businesses.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

CMS concluded that the final rule will not impose 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 contained in 5 U.S.C. § 553. On May 25, 2007, CMS published a Notice of Proposed Rulemaking in

the *Federal Register*. 72 Fed. Reg. 29,403. CMS received approximately 60 comments in response to the proposed rule and responds to those comments in the final rule.

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

CMS states that the final rule does not impose additional information collection or recordkeeping requirements.

Statutory authorization for the rule

The final rule was promulgated under the authority in sections 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 states that because the estimated net impact of vaccine administration coverage under Medicare Part D for fiscal year 2008 is $100 million (and an estimated $340 million for fiscal years 2008 through 2017), the final rule meets the threshold of being "economically significant" and is consequently a major rule.

Executive Order No. 13,132 (Federalism)

CMS concludes that the final rule will not have a substantial effect on state or local governments. As an example, CMS notes that the clarification in the final rule concerning timing of state reporting for purposes of calculating state phase-down contributions is not expected to affect state governments, since monthly reporting is consistent with the statute.