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October 3, 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; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs*

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; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs" (RIN: 0938-AP52). We received the rule on September 15, 2008. It was published in the *Federal Register* as an "interim final rule with comment period" on September 18, 2008, and has a stated effective date of the same day. 73 Fed. Reg. 54,226.

The interim final rule changes the Medicare Advantage regulations to conform to new statutory requirements regarding special needs plans, private-fee-for-service plans, regional preferred provider organizations plans, and Medicare medical savings accounts plans. It also implements new statutory provisions governing cost-sharing for dual-eligible enrollees in the Medicare Advantage program prescription drug

pricing, coverage, and payment processes in the Part D program. In addition, this interim final rule sets forth new requirements governing the marketing of Part C and D plans.

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. This interim final rule has a stated effective date of September 18, 2008. The Congressional Review Act requires major rules to have a 60-day delay in their effective date following their publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This interim final rule was published on September 18, 2008, and received on September 15, 2008.

However, "any rule which an agency for good cause finds . . . that the notice and public procedure [of section 801] are impractical, unnecessary, or contrary to the public interest" takes effect when the agency determines. 5 U.S.C. § 808(2). In the case of this interim final rule, CMS found good cause to waive the 60-day delay and make this rule effective immediately because a delay would be contrary to the public interest. 73 Fed. Reg. 54,240. Specifically, the Medicare Improvements for Patients and Providers Act of 2008, Public Law 110-275 (July 15, 2008), contained a deadline for promulgating certain marketing provisions of this interim final rule that was less than 150 days from the enactment of the statute. 42 U.S.C. § 1395w-21 note. CMS concluded that, because of this statutory deadline, there is good cause to waive the 60-day delay. 42 USCA § 1395hh. CMS found good cause not to delay the remainder of the rule because, according to CMS, the remaining provisions implement statutory changes and therefore are already set in law. Our review indicates that CMS complied with all the other 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; REVISIONS TO THE MEDICARE ADVANTAGE
AND PRESCRIPTION DRUG BENEFIT PROGRAMS"
(RIN: 0938-AP52)

(i) Cost-benefit analysis

CMS analyzed the costs and benefits of this interim final rule. CMS estimated the prompt payment provisions of the rule to cost the federal government a total of $670 million in calendar years 2010 to 2018. The other provisions will cost Medicare Advantage organizations and prescription drug sponsors $26.7 million in 2010. CMS estimates that the rule will have an incurred savings in total (before the Part B premium offset) of $8.1 billion in calendar years 2011 to 2018. CMS estimates that the rule will result in a net savings in total of $7.43 billion to the federal government from 2010 to 2018.

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

CMS determined that the prompt payment provisions of this interim final rule will have a significant impact on a substantial number of small entities. Specifically, the prompt payment provisions will positively impact retail pharmacies and add costs to Part D sponsors and pharmacy benefit managers. CMS also determined that this interim final rule will not affect small rural hospitals.

(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 interim final rule will not impose costs on state, local, or tribal governments, or on the private sector above the threshold in the Act.

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

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

CMS found good cause to waive the notice-and-comment procedures found in the Administrative Procedure Act. 73 Fed. Reg. 54,240. The Medicare Improvements for Patients and Providers Act contained a deadline for promulgating certain marketing provisions of this interim final rule that was less than 150 days from the enactment of

the statute. 42 U.S.C. § 1395w-21 note. CMS concluded that, because of this statutory deadline, these provisions may be published in final form without notice-and-comment. 42 USCA § 1395hh. CMS found good cause not to delay the remainder of the rule because, according to CMS, the remaining provisions implement statutory changes and therefore are already set in law.

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

Fifteen provisions of this interim final rule contain information collection requirements under the Act. CMS requests public comment on each of these requirements. The aggregate annual burden associated with the collection of information under this interim final rule is approximately 1.2 million hours. CMS lists the Office of Management and Budget (OMB) control numbers for the 15 requirements in the interim final rule. 73 Fed. Reg. 54,244.

Statutory authorization for the rule

CMS promulgated this interim final rule under the authority of sections 1102, 1860D-1 to 1860D-42 and 1871 of the Social Security Act and section 1310 of the Public Health Service Act. 42 U.S.C. 300e, 300e-5, 300e-9, 1302, 1395w-101 to 1395w-152, and 1395hh. CMS also promulgated this interim final rule under the authority of section 9701, title 31, United States Code.

Executive Order No. 12,866

CMS determined that this interim final rule is significant under the Order because it will have an effect on the economy of $100 million or more in any one year. OMB has reviewed this rule.

Executive Order No. 13,132 (Federalism)

CMS determined that this interim final rule will have no federalism implications.