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February 2, 2009

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

The Honorable Henry A. Waxman
Chairman
The Honorable Joe Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable Charles B. Rangel
Chairman
The Honorable Dave Camp
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; Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies*

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; Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies” (RIN: 0938-AP24). We received the rule on January 15, 2009. It was published in the *Federal Register* as an interim final rule with comment period on January 16, 2009. 74 Fed. Reg. 2881.

The interim final rule revises the regulations governing the Medicare prescription drug benefit program (Part D). These provisions change the definition of a covered Part D drug and add new requirements that apply to Part D formularies. This rule

implements provisions of the Medicare Improvements for Patients and Providers Act of 2008. Pub. L. No. 110-275, 122 Stat. 2494 (July 15, 2008).

This interim final rule was received on January 15, 2009, and published on January 16, 2009. This interim final rule has a stated effective date of January 16, 2009. 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).

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. 74 Fed. Reg. 2884. CMS concluded that, because this interim final rule makes conforming changes to the Code of Federal Regulations reflecting statutory changes, it would be unnecessary and contrary to the public interest to seek public comment on this rule or to delay the effective date of such provisions beyond January 16, 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 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
Associate General Counsel

Enclosure

cc: Vivian Stallion
Program Manager, ODRM
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 AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; MEDICARE ADVANTAGE AND
PRESCRIPTION DRUG PROGRAMS MIPPA
DRUG FORMULARY & PROTECTED CLASSES POLICIES"
(RIN: 0938-AP24)

(i) Cost-benefit analysis

The Centers for Medicare and Medicaid Services (CMS) analyzed the costs and benefits of this interim final rule. CMS estimates that the formulary requirements with respect to certain categories or classes of drugs will be \$4.2 billion from 2010 to 2018. With respect to economic benefits, CMS stated that it has no reliable basis for estimating the effects of the proposals contained in this interim final rule. Accordingly, CMS stated that, while there could be economic benefits associated with these proposals, such benefits are difficult to gauge at this time.

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

CMS stated that it is not required to conduct an initial regulatory flexibility analysis for an interim final rule, but that it is CMS's longstanding policy to provide an analysis whenever CMS believes it would aid in the understanding of the effects of the rule. CMS concluded that the only small businesses that will be impacted by this rule are retail pharmacies.

(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 above the Act's current \$130 million threshold (\$100 million adjusted for inflation) on state, local, tribal governments, in the aggregate, or by the private sector.

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

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

CMS did not provide notice of a proposed rule or invite public comments prior to publishing this interim final rule. Notice and comment procedures may be waived when an agency finds good cause that such procedures are impracticable,

unnecessary, or contrary to the public interest. 5 U.S.C. § 553(b). Because this interim final rule makes conforming changes to the Code of Federal Regulations reflecting statutory changes, CMS determined that it would be unnecessary and contrary to the public interest to seek public comment on this rule.

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

This interim final rule does not impose any new information collection and recordkeeping requirements. Existing information collection requirements relevant to this rule have been approved by the Office of Management and Budget (OMB) under OMB Control Number 0938-0763.

Statutory authorization for the rule

CMS promulgated this interim final rule under the authority of sections 1302, 1306, 1395w-101 through 1395w-152, and 1395hh of title 42, United States Code.

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

CMS determined that this interim final rule is economically significant under the Order because it estimates that the rule will have an impact of \$100 million or more in one year. Accordingly, this rule was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS determined that there are no anticipated federalism implications because none of the provisions contained in this interim final rule place any requirements on the states.