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April 29, 2010

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

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

The Honorable Sander M. Levin
Acting Chairman
The Honorable Dave Camp
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare 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 & Medicaid Services (CMS), entitled "Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (RIN: 0938-AP77). We received the rule on April 7, 2010. It was published in the *Federal Register* as a final rule on April 15, 2010, with a stated effective date of June 7, 2010. 75 Fed. Reg. 19,678.

The final rule makes revisions to the regulations governing the Medicare Advantage program (Part C) and prescription drug benefit program (Part D) based on CMS's continued experience in the administration of the Part C and D programs. CMS is making these revisions (1) to strengthen various program participation and exit

requirements, (2) to strengthen beneficiary protections, (3) to ensure that plan offerings to beneficiaries include meaningful differences, (4) to improve plan payment rules and processes, (4) to improve data collection for oversight and quality assessment, (5) to implement new policies, and (6) to clarify existing program policy.

This final rule has a stated effective date of June 7, 2010. However, CMS notes that because health and drug plans under the Part C and D programs operate under contracts that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011, except where otherwise noted in the rule. 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. 5 U.S.C. § 801(a)(3)(A). The rule was received by the House of Representatives on April 7, 2010, and by the Senate on April 8, 2010. 156 Cong. Rec. H2577 (April 14, 2010) (Executive Communications, etc.); 156 Cong. Rec. S2375–S2376 (April 15, 2010) (Executive and Other Communications). However, this rule was not published in the *Federal Register* until April 15, 2010. 75 Fed. Reg. 19,678. Therefore, to the extent that provisions of this rule have a stated effective date of June 7, 2010, this rule does 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 of the procedural steps taken indicates that, with the exception of 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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Annie Lamb
Regulations Coordinator
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 ADVANTAGE AND THE
MEDICARE PRESCRIPTION DRUG BENEFIT PROGRAMS"
(RIN: 0938-AP77)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. CMS estimated the costs and savings of this rule for calendar years 2010 through 2015. CMS estimates that that total cost of this rule in calendar year 2010 will be approximately $260.3 million, and that the rule will have a total net savings over the 6-year period 2010 to 2015 of $341.70 million. CMS also predicts that this rule will improve coordination of care, increase quality of data reporting, increase ability to comply with existing regulations and policies, enhance appeal and grievance procedures, and curtail illegal marketing practices. Additionally, CMS expects this rule to clarify timeframes and notification requirements.

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

CMS determined that this final rule will not have a significant economic impact on a substantial number of small entities. Further, CMS determined that this final rule will not have a significant impact on the operations of a substantial number of 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 final rule is expected to require spending by state, local, or tribal governments, in the aggregate, or by the private sector, of $100 million ($135 million, adjusted for inflation) in any one year. CMS reported that it examined the impacts of the rule as required by the Act.

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

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

On October 22, 2009, CMS published a proposed rule. 74 Fed. Reg. 54,634. CMS received approximately 114 items of timely correspondence containing comments on the proposed rule. Commenters included health and drug plan organizations, insurance industry trade groups, pharmacy associations, pharmaceutical benefit manager (PBM) organizations, provider associations, representatives of hospital and long term care institutions, drug manufacturers, mental health and disease specific advocacy groups, beneficiary advocacy groups, researchers, and others. In this final rule, CMS addressed all timely comments and concerns on the policies included in the proposed rule. CMS noted that there were several comments submitted that were outside the scope of the proposals set forth in the proposed rule and, as such, did not address them within the final rule.

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

CMS determined that this final rule contains 11 information collection requirements under the Act and subject to review by the Office of Management and Budget (OMB). CMS estimates that these requirements will impose a burden on 12,348 respondents and will result in 4,997,523 responses. CMS estimates that the total annual burden for these requirements will be 5,797,650 hours. CMS also estimates that the total annual labor cost will be $290.6 million and the total annual capital/maintenance cost will be $4.9 million, for a total annual cost of $295.5 million.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1102, 1860D-1 through 1860D-42, and 1871 of the Social Security Act (42 U.S.C. §§ 1302, 1395w-101 through 1395w-152, 1395hh), sections 1301, 1306, and 1310 of the Public Health Service Act (42 U.S.C. §§ 300e, 300e-5, 300e-9) and section 9701 of title 31, United States Code.

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

CMS determined that this final rule is economically significant under the Order under the $100 million threshold. OMB has reviewed this rule.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not impose any substantial direct requirement costs on state or local governments, preempt state law, or otherwise have federalism implications.