



G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

B-321856

May 2, 2011

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

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

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes*

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; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes” (RIN: 0938-AQ00). We received the rule on April 6, 2011. It was published in the *Federal Register* as a final rule on April 15, 2011. 76 Fed. Reg. 21,432.

The final rule makes revisions to the Medicare Advantage program (Part C) and Prescription Drug Benefit Program (Part D) to implement provisions specified in the Patient Protection and Affordable Care Act and the Health Care and Education

Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) and makes other changes to the regulations based on CMS's experience in the administration of the Part C and Part D programs. The final rule clarifies various program participation requirements; makes changes to strengthen beneficiary protections; strengthens CMS's ability to identify strong applicants for Part C and Part D program participation and remove consistently poor performers; and makes other clarifications and technical changes

The final rule has an effective date of June 6, 2011. The Congressional Review Act (CRA) 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. sect. 801(a)(3)(A). We received the rule on April 6, 2011, but it was not published in the *Federal Register* until April 15, 2011. Therefore the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of 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 delay in the rule's 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: Ann Stallion
Program Manager
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 & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; CHANGES TO THE MEDICARE
ADVANTAGE AND THE MEDICARE PRESCRIPTION
DRUG BENEFIT PROGRAMS FOR CONTRACT YEAR 2012
AND OTHER CHANGES"
(RIN: 0938-AQ00)

(i) Cost-benefit analysis

CMS prepared a cost-benefit analysis in conjunction with the final rule. CMS estimates that the final rule will result in a net savings of \$76.17 billion over fiscal years (FYs) 2011 through 2016. CMS expects savings to the federal government of approximately \$82.42 billion for FYs 2011 through 2016 as a result of the implementation of the following provisions: payment changes related to Medicare Advantage benchmarks, quality bonus payments, rebates, and application of coding adjustment (\$74.67 billion); increase in Part D premiums due to Income Related Monthly Adjustment Amount (\$4.77 billion); appropriate dispensing of prescription drugs in long-term care facilities under prescription drug plans and Medicare Advantage–Prescription Drug plans and dispensing fees (\$1.00 billion); and elimination of the stabilization fund (\$181 million). CMS estimates total costs to the federal government, states, Part D sponsors, Medicare Advantage organizations, and other private sector entities as a result of the various provisions of the final rule to be approximately \$5.35 billion for FYs 2011 through 2016 as a result of the implementation of the final rule, including the following provisions: changes to Part D coverage gap (\$3.67 billion); determination of Part D low-income benchmark premium (\$770 million); including costs incurred by AIDS Drug Assistance Programs and the Indian Health Service toward the annual Part D out-of-pocket threshold (\$460 million); voluntary de minimis policy for subsidy eligible individuals (\$170 million); and cost-sharing for Medicare covered preventative services (\$148 million).

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

CMS determined that the final rule will not have a significant impact on a substantial number of small entities.

(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 will not impose any mandates requiring spending of more than \$136 million in any one year by state, local, or 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.

On November 22, 2010, CMS published a notice of proposed rulemaking in the *Federal Register*. 75 Fed. Reg. 71,190. CMS received approximately 261 timely comments on the proposed rule. In the final rule, CMS responded to all comments and concerns on the policies included in the proposed rule, and referenced comments that were outside the scope of the proposed rule. 76 Fed. Reg. 21,432.

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

The final rule contains numerous information collection requirements under the Paperwork Reduction Act (PRA). In the final rule, CMS discusses 25 areas of paperwork burden in detail, including whether or not the paperwork burden in any given case meets the definition of an information collection requirement under the PRA. In total, CMS estimates that the total annual labor costs associated with requirements under the PRA will be \$71,352,376.

Statutory authorization for the rule

The final rule is authorized by sections 1851 through 1859 of the Social Security Act, as amended.

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

CMS determined that the final rule is economically significant under Executive Order 12,866, and the final rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

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