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July 20, 2005

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

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
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; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B*

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; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B" (RIN: 0938-AN58). We received the rule on July 7, 2005. It was published in the Federal Register as an "interim final rule with comment period" on July 6, 2005. 70 Fed. Reg. 39022.

The interim final rule implements provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2003 Act) that require the implementation of a competitive acquisition program (CAP) for certain Medicare Part B drugs not paid on a cost or prospective payment system basis. Beginning January 1, 2006, physicians will generally be given a choice between obtaining these drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the average sales price system.

The portion of the final rule dealing with the selection process for approved CAP vendors has an announced effective date of July 6, 2005. 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 published in the Federal Register on July 6, 2005, and received by Congress on July 7, 2005. Therefore, the rule does not have the required 60-day delay.

CMS, in the preamble to the interim final rule, states that it has found "good cause" under 5 U.S.C. 553(d)(3) and 5 U.S.C. 808(2) to make the rule effective on the date of publication because under section 1847B of the 2003 Act, CMS is required to phase in the CAP by the beginning of 2006. To comply with the statutory mandate, CMS states it is necessary to have contracts in place with approved vendors in time for physicians to review and select an approved vendor in their competitive acquisition area.

Section 808(2) provides that where an agency for "good cause" finds that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the delay provisions of section 801 do not apply. Here, CMS did not make such a finding previously but published a Notice of Proposed Rulemaking on March 4, 2005, in accordance with the Administrative Procedure Act. It received and considered comments on the proposed rule. As discussed in our report on a major rule issued by the then Health Care Financing Administration concerning Medicare (B-275549, B-275552, December 9, 1996), the "good cause" exception to the 60-day delay provision found at section 808(2) is not available when notice and comment procedures have been used. Regarding the statutorily directed effective date, the Congressional Review Act is to apply notwithstanding any other provision of law. 5 U.S.C. 806(a).

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 CMS complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO

evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

ENCLOSURE

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; COMPETITIVE ACQUISITION OF
OUTPATIENT DRUGS AND BIOLOGICALS UNDER PART B"
(RIN: 0938-AN58)

(i) Cost-benefit analysis

CMS estimates that more than $100 million will pass through the Competitive Acquisition Program in 2006.

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

The Administrator of CMS has certified that the interim final rule will not have a significant economic 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

The interim final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more than $100 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 interim final rule was promulgated using the notice and comment procedures found at 5 U.S.C. 553. On March 4, 2005, CMS published a Notice of Proposed Rulemaking in the Federal Register. 70 Fed. Reg. 10745. In response, approximately 570 comments were received and the comments are discussed in the preamble to the final rule.

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

The interim final rule contains six information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The preamble to the interim final rule contains a summary of the collections and the annual burden hours, which was submitted to OMB for review.

Statutory authorization for the rule

The interim final rule was promulgated under the authority found in sections 1102, 1871, and 1881(b)(1) of the Social Security Act, 42 U.S.C. 1302, 1395hh, and 1395rr(b)(1).

Executive Order No. 12866

The interim final rule was reviewed by OMB and found to be an "economically significant" regulatory action under the order.

Executive Order No. 13132 (Federalism)

According to CMS, the interim final rule does not have federalism implications under the order.