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Washington, DC 20548

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B-297368

October 21, 2005

The Honorable Chuck 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 and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities*

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 and Medicaid Programs; Condition of Participation: Immunization Standard for Long Term Care Facilities” (RIN: 0938-AN95). We received the rule on October 5, 2005. It was published in the Federal Register as a final rule on October 7, 2005. 70 Fed. Reg. 58834.

The final rule requires long term care (LTC) facilities to offer each resident immunization against influenza annually, as well as lifetime immunization against pneumococcal disease. LTC facilities will be required to ensure that before offering the immunizations, each resident or the resident’s legal representative receives education regarding the benefits and potential side effects of immunizations.

The final rule has an announced effective date of October 7, 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 October 7, 2005, and was received by Congress on October 6, 2005. Therefore, the rule does not have the required 60-day delay.

CMS, in the preamble to the 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 upon publication. CMS also states that to delay the effective date of the final rule would be extremely detrimental to the health of LTC residents as epidemics of influenza occur during the winter months.

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 the proposed rule on August 15, 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.

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, with the exception of the 60-day delay in the rule’s effective date, 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

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 AND MEDICAID PROGRAMS; CONDITION OF PARTICIPATION:  
IMMUNIZATION STANDARD FOR LONG TERM CARE FACILITIES"  
(RIN: 0938-AN95)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the final rule and found that the increased influenza immunizations would have a net federal savings of \$34,777,520. This figure results from a reduction of \$45,288,000 in the cost of inpatient hospital treatment combined with increased federal costs of \$10,510,480. Using an average value of a statistical life of \$5 million and 2,304 lives saved by increased immunizations, CMS estimates the value saved from saving these lives as \$11.5 billion.

Regarding the pneumococcal immunizations, CMS estimates a net federal cost of \$24,058,202 over the first 5 years of the program with 560 lives saved at a valuation of \$2.8 billion.

(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 final rule will not have a significant economic effect 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 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 final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On August 15, 2005, CMS published a Notice of Proposed Rulemaking in the Federal Register. 70 Fed. Reg. 47759. In response, CMS received 61 comments, which are discussed in the preamble to the final rule.

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

The final rule contains an information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. CMS estimates that the first-year burden of the collection will be 161,390 hours.

Statutory authorization for the rule

The final rule is promulgated under the authority found at sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Executive Order No. 12866

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

Executive Order No. 13132 (Federalism)

The final rule does not have sufficient federalism implications to warrant the preparation of a federalism impact statement.