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United States General Accounting Office  
Washington, DC 20548

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B-287288

February 28, 2001

The Honorable Chuck Grassley  
Chairman  
The Honorable Max Baucus  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable W. J. (Billy) Tauzin  
Chairman  
The Honorable John D. Dingell  
Ranking Minority Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Bill Thomas  
Chairman  
The Honorable Charles Rangel  
Ranking Minority Member  
Committee on Ways and Means  
House of Representatives

Subject: Department of Health and Human Services, Health Care Financing Administration: Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

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, Health Care Financing Administration (HCFA), entitled "Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements" (RIN: 0938-AI96). We received the rule on February 13, 2001. It was published in the Federal Register as a final rule on December 29, 2000. 65 Fed. Reg. 83130.

The final rule expands Medicare coverage for outpatient diabetes self-management training and establishes outcome measurements for evaluating the improvement of the health status of Medicare beneficiaries with diabetes.

Enclosed is our assessment of the HCFA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule.

The final rule has an announced effective date of February 27, 2001. Since the rule was not submitted to Congress until February 13, 2001, HCFA has not allowed the required 60-day delay in the effective date of a major rule required by 5 U.S.C. 801(a)(3) for congressional review. The 60-day delay computation starts when Congress receives the rule or it is published in the Federal Register, whichever is later.

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 William Scanlon, Managing Director, Health Care. Mr. Scanlon can be reached at (202) 512-7114.

signed

Kathleen E. Wannisky  
Managing Associate General Counsel

Enclosure

cc: Ms. Catherine P. Beck  
Deputy Executive Secretary to  
the Department  
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,  
HEALTH CARE FINANCING ADMINISTRATION  
ENTITLED  
"MEDICARE PROGRAM; EXPANDED COVERAGE FOR  
OUTPATIENT DIABETES SELF-MANAGEMENT TRAINING  
AND DIABETES OUTCOME MEASUREMENTS"  
(RIN: 0938-AI96)

(i) Cost-benefit analysis

HCFA conducted a cost-benefit analysis of the final rule. The projected budget impact of the final rule is estimated to be \$150 million in fiscal year (FY) 2001, \$200 million in FY 2002, \$270 million in FY 2003, \$270 million in FY 2004, and \$280 million in FY 2005.

The benefits are expected to be substantial because diabetes is the fourth-leading cause of death by disease in the United States. It also causes other medical problems such as heart disease, stroke, kidney disease, and blindness. Proper health care and self-management can circumvent these problems or slow their onset.

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

HCFA prepared a Final Regulatory Flexibility Analysis in connection with the final rule which discusses the steps taken to reduce the impact of the rule on small entities. The major impact will be the completion of the accreditation process, and HCFA has allowed 3 years for implementation of the requirement for a Certified Diabetes Educator and for an exception to the team approach in rural areas.

(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 will not impose 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 contained at 5 U.S.C. 553. On February 11, 1999, HCFA published a Notice of Proposed

Rulemaking in the Federal Register. 64 Fed. Reg. 6827. HCFA received 1,900 comments on the proposed rule and responds to those comments in the preamble to the final rule.

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

The final rule contains several information collections that are subject to review by the Office of Management and Budget (OMB) under the Paper Reduction Act. HCFA has submitted the required information to OMB for approval and summarizes the information, including the estimated annual burden, in the preamble to the final rule.

Statutory authorization for the rule

The final rule is promulgated pursuant to the authority contained in sections 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)) and section 4105 of the Balanced Budget Act of 1997.

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)

HCFA has noted that the final rule does not significantly affect the rights, roles, and responsibilities of the states under the order.