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B-297100

September 9, 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; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles*

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; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles” (RIN: 0938-AM74). We received the rule on August 25, 2005. It was published in the Federal Register as an “interim final rule with comment period” on August 26, 2005. 70 Fed. Reg. 50940.

The interim final rule defines the term power mobility devices (PMDs) as power wheelchairs and power operated vehicles (POVs or scooters). It sets forth revised conditions for Medicare payment of PMDs and defines who may prescribe PMDs. The rule also requires a face-to-face examination of the beneficiary by the physician

or treating practitioner and a PMD prescription and pertinent parts of the medical record that the durable medical equipment supplier maintains in records and makes available to CMS or its agents upon request. Also, the rule discusses CMS's policy on documentation that may be requested by CMS or its agents to support a Medicare claim for payment, as well as the elimination of the Certificate of Medical Necessity for PMDs.

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

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; CONDITIONS FOR PAYMENT OF  
POWER MOBILITY DEVICES, INCLUDING POWER WHEELCHAIRS  
AND POWER-OPERATED VEHICLES"  
(RIN: 0938-AM74)

(i) Cost-benefit analysis

CMS performed a cost-benefit analysis of the interim final rule that shows that the result of the rule should be reduced sales of \$84 million for PMDs and increased sales of \$35 million for POVs.

(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 \$120 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.

CMS has found "good cause" under 5 U.S.C. 553 to waive the normal notice and comment procedure. It believes it would be against the public interest to delay implementing the statutory changes required by section 1834(a)(1)(E)(iv), which requires a face-to-face examination before Medicare will pay for covered items.

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

The interim final rule contains two information collections that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act. The total annual burden of writing the prescriptions and collecting and submitting supporting documentation is 37,000 hours. In addition, CMS is no longer requiring

the submission of a Certificate of Medical Necessity, which had an annual burden of 38,192 hours.

Statutory authorization for the rule

The interim final rule is promulgated pursuant to the authority found in sections 1102, 1834, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395m, and 1395hh).

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)

CMS states that it has reviewed the rule and it does not contain federalism implications.