



United States Government Accountability Office
Washington, DC 20548

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May 11, 2012

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 Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

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

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements*

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 and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements" (RIN: 0938-AQ01). We received the rule on April 25, 2012. It was published in the *Federal Register* as a final rule on April 27, 2012, with a stated effective date of June 26, 2012. 77 Fed. Reg. 25,284.

The final rule requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all applications to enroll in the Medicare and Medicaid programs and on all claims for payment submitted under the Medicare and Medicaid programs. In addition, it requires physicians and other professionals who are permitted to order and certify covered items and services for Medicare beneficiaries to be enrolled in Medicare. Finally, it mandates document retention and provision requirements on providers and suppliers that order and certify items and services for Medicare beneficiaries.

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 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 AND MEDICAID PROGRAMS; CHANGES IN PROVIDER
AND SUPPLIER ENROLLMENT, ORDERING AND REFERRING,
AND DOCUMENTATION REQUIREMENTS; AND CHANGES IN
PROVIDER AGREEMENTS"
(RIN: 0938-AQ01)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid (CMS) estimates that this final rule will save the federal government over \$100 million in each of the next 10 fiscal years, with a total savings of \$1.59 billion. This \$1.59 billion represents a 3 percent reduction in durable medical equipment, prosthetics, orthotics, and supplies; imaging and clinical laboratory services; and Part A and Part B home health costs over the next 10 years attributable to patients who will choose not to seek out an enrolled physician to obtain such services. In addition, some claims without proper documentation will be denied, including some fraudulent claims, although CMS did not have a basis for quantifying the value of such claims.

CMS believes that the rule's other effects will be minimal. With respect to section 424.506, CMS judges practically all providers and suppliers that wish to enroll in Medicare and Medicaid programs have already obtained NPIs and are currently meeting requirements regarding the need to report their NPIs on, as applicable, enrollment applications and claims. Regarding section 424.516(f), CMS believes that most providers and suppliers already retain such documentation as a usual and customary business practice.

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

CMS determined that this final rule will not have a significant impact on a substantial number of small entities. However, CMS prepared a voluntary Regulatory Flexibility Analysis. CMS also determined that this final rule will not have a significant impact on a substantial number of small rural hospitals.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

CMS determined that this final rule does not mandate any expenditure by either state, local, or tribal governments in the aggregate, or on the private sector.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

This final rule finalizes an earlier interim final rule CMS published on May 5, 2010. 75 Fed. Reg. 24,437. CMS received approximately 224 timely comments on the interim final rule, to which it responded to in the final rule.

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

CMS determined that this final rule contains information collection requirements under the Order. The burden associated with section 424.506(b)(1) is accounted for under the Office of Management and Budget (OMB) control number 0938-0999. CMS determined that the burden associated with section 424.507 is exempt from the requirements of the Act because it is a usual and customary business practice. CMS estimates that the information collection requirements under section 431.107(b)(5) will have over 2.5 billion respondents for a total annual burden of over 2 million hours and a cost of over \$30 million.

Statutory authorization for the rule

CMS promulgated this rule under the authority of sections 1102 and 1871 of the Social Security Act. 42 U.S.C. §§ 1302, 1395hh.

Executive Order Nos. 12,866 and 13,563 (Regulatory Planning and Review)

CMS determined that the savings resulting from this final rule will exceed \$100 million in each of the next 10 fiscal years, beginning in fiscal year 2013. Therefore, this is an economically significant rule under the Order.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not impose any significant costs on state or local government, preempt state law, or otherwise have federalism implications.