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October 14, 2005

The Honorable Charles 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; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), entitled “Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care” (RIN: 0938-AO03). We received the rule on September 30, 2005. It was published in the Federal Register as an “interim final rule with comment period” on September 30, 2005. 70 Fed. Reg. 57368.

The interim final rule sets forth the criteria for implementing a loan program for qualifying hospitals engaged in research in the causes, prevention, and treatment of

cancer as specified in section 1016 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173). This rule establishes a loan application process by which qualifying hospitals including specified entities may apply for a loan for the capital costs of health care infrastructure improvement projects.

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; HEALTH CARE INFRASTRUCTURE IMPROVEMENT
PROGRAM; SELECTION CRITERIA OF LOAN PROGRAM FOR QUALIFYING
HOSPITALS ENGAGED IN CANCER-RELATED HEALTH CARE"
(RIN: 0938-AO03)

(i) Cost-benefit analysis

The interim final rule has \$142 million available for the loan program from July 1, 2004, through September 30, 2008. No more than \$2 million may be used for the administration of the program during that time period.

(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 states that it has found "good cause" under 5 U.S.C. 553 to waive the notice and comment procedures because it would delay the improvement of cancer-related health care hospital infrastructure that Congress provided for through the loan program.

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

CMS states that the interim final rule does not contain any information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act because the collection affects less than 10 entities. See 5 C.F.R. 1320.3(c)(4).

Statutory authorization for the rule

The interim final rule is promulgated pursuant to the authority found at section 1016 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173).

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 the final rule does not have federalism implications requiring the preparation of a federalism impact analysis.