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July 15, 2011

The Honorable Tom Harkin  
Chairman  
The Honorable Michael B. Enzi  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services: World Trade Center Health Program Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement*

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 (HHS), entitled "World Trade Center Health Program Requirements for Enrollment, Appeals, Certification of Health Conditions, and Reimbursement" (RIN: 0920-AA44). We received the rule on June 30, 2011. It was published in the *Federal Register* as an interim final rule with request for comments on July 1, 2011. 76 Fed. Reg. 38,914.

The interim final rule implements portions of the World Trade Center (WTC) Health Program under the Public Health Service Act (PHS Act), as amended by the James Zadroga 9/11 Health and Compensation Act of 2010. The WTC Health Program will provide medical monitoring and treatment to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, Shanksville, PA, and at the Pentagon, and to eligible survivors of the New York City attacks. This interim final rule establishes the processes by which eligible responders and survivors may apply for enrollment in the WTC Health Program, obtain health monitoring and treatment for WTC-related health conditions, and appeal enrollment and treatment decisions. This interim final rule also establishes a

process for the certification of health conditions, and reimbursement rates for providers who provide initial health evaluations, treatment, and health monitoring.

The interim final rule is effective on July 1, 2011. The Congressional Review Act (CRA) 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). However, notwithstanding the 60-day delay requirement, any rule that an agency for good cause finds that notice and public comment procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. 5 U.S.C. § 808(2). HHS found that good cause existed under section 808(2) to make this regulatory action effective upon publication because of the need for continued treatment and care for responders and survivors of the 9/11 attacks.

Enclosed is our assessment of HHS'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 HHS 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  
ENTITLED  
"WORLD TRADE CENTER HEALTH PROGRAM REQUIREMENTS  
FOR ENROLLMENT, APPEALS, CERTIFICATION OF  
HEALTH CONDITIONS, AND REIMBURSEMENT"  
(RIN: 0920-AA44)

(i) Cost-benefit analysis

HHS analyzed the costs and benefits of the interim final rule. The benefits would include the improved health of patients treated through the World Trade Center (WTC) Health Program. HHS examined the health and quality of life improvements associated with medical treatment of several of the most common conditions in the covered populations and then compared those expected benefits with those expected if there was no program after June 30, 2011. The available information indicates that the WTC Health Program is likely to provide substantial improvements in health to responders and survivors. The expected gain in undiscounted quality-adjusted life years (QALYs) over a 5-year period for the six health conditions examined ranged from 394 to 824.

The costs associated with the program will include administrative costs and medical monitoring and treatment costs. HHS provided both high and low cost estimates for each of these categories. HHS estimates that administrative costs will range from \$15 million to \$22.5 million per year from FY 2012 – FY 2015. HHS estimates that medical monitoring and treatment costs will range on the low end from \$91.8 million per year in FY 2012 – FY 2015 to highs of \$107.1 million to \$128.8 million per year in FY 2012 – FY 2015.

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

In its submission to the Comptroller General, HHS did not include an analysis of the interim final rule under this Act.

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

HHS states that this interim final rule does not include any federal mandate that may result in increased annual expenditures in excess of \$100 million by state, local, or tribal governments in the aggregate, or by the private sector.

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

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

HHS issued this rule as an interim final rule. Section 553(b) of the APA provides for exceptions to the APA's notice and comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. HHS determined that good cause exists for waiving the notice and comment procedures for this rule because it is not possible to complete the notice and comment procedures in time for the program to become effective on July 1, 2011, and there is a strong public interest in ensuring the continuation of monitoring and treatment benefits for those who were receiving care under the previous treatment program. HHS also determined that under section 553(d)(3) of the APA, good cause exists for this interim final rule to become effective immediately.

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

HHS has determined that this interim final rule contains information collection and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The Centers for Disease Control and Prevention (CDC) will publish periodic summaries of its proposed projects and has invited public comments on its proposed data collection projects. HHS estimates that the total burden for its new information collection request is 19,111 annual burden hours.

Statutory authorization for the rule

HHS promulgated this rule under Title XXXIII of the Public Health Service Act, 42 U.S.C. §§ 300mm to 300mm-61, as amended by the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111-347).

Executive Order No. 12,866 (Regulatory Planning and Review)

HHS determined that this interim final rule is economically significant under Executive Order 12,866.

Executive Order No. 13,132 (Federalism)

HHS has determined that this interim final rule does not have federalism implications.