



441 G St. N.W.
Washington, DC 20548

B-328681

December 27, 2016

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services: World Trade Center Health Program; Amendments to Definitions, Appeals, and Other Requirements*

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; Amendments to Definitions, Appeals, and Other Requirements" (RINs: 0920-AA56, 0920-AA44, 0920-AA48, 0920-AA50). We received the rule on December 15, 2016. It was published in the *Federal Register* as a final rule on December 15, 2016, with an effective date of January 17, 2017. 81 Fed. Reg. 90,926.

The final rule finalizes amendments to a number of existing sections in part 88, including provisions for appeals of certification, decertification, or treatment authorization decisions, and the addition of health conditions to the List of World Trade Center-Related Health Conditions. Additionally, this final rule adds new language on disenrollment, decertification, appeals of reimbursement denials, and coordination of benefits and recoupment to part 88.

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). This final rule was published in the *Federal Register* on December 15, 2016. 81 Fed. Reg. 90,926. It was received on December 15, 2016, and has a stated effective date of January 17, 2017. Therefore, the final rule does not have the required 60-day delay in its effective date.

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. With the exception of the 60-day delay in effective date requirement, 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: Agnes Thomas
Regulations Coordinator
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;
AMENDMENTS TO DEFINITIONS, APPEALS,
AND OTHER REQUIREMENTS”
(RINS: 0920-AA56, 0920-AA44, 0920-AA48, 0920-AA50)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) summarized the costs and benefits of the final rule. HHS stated that the estimated costs of this final rule is approximately \$42,742 in costs to the World Trade Center Health Program associated with updating existing program policies and developing new policies. Additionally cumulative costs associated with the World Trade Center Health Program administration and monitoring and treatment services for all health conditions for fiscal years 2016 through 2025 are projected to range from \$2.9 billion at a 7 percent discount rate to \$3.6 billion at a 3 percent discount rate.

HHS stated that the benefit of the World Trade Center Health Program is that it is likely to provide substantial improvements in health to responders and survivors. HHS summarized the quality-adjusted life year (QALY) estimates for morbidity improvements for aero-digestive conditions, PTSD, and cancer in the final rule to illustrate the benefits.

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

HHS determined that this rule has no significant economic impact upon 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

HHS found that for purposes of the Unfunded Mandates Reform Act of 1995, this 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, 5 U.S.C. §§ 551 et seq.

On August 17, 2016, HHS published a proposed rule. 81 Fed. Reg. 55,086. HHS received comments from three commenters--a labor organization, a joint labor/management trust fund, and the contractor providing care for survivors in the World Trade Center Health Program. HHS responded to comments in the final rule.

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

HHS determined that substantive changes are needed to the information collection already approved by the Office of Management and Budget. HHS stated that it has published a notice of the proposed changes to the existing approved information collection and invites comment from the public during the 60-day period.

Statutory authorization for the rule

HHS stated that it promulgated this rule pursuant to 42 U.S.C. § 300mm – 300mm-61, Pub. L. 111-347, 124 Stat. 3623, as amended by Pub. L. 114-113, and 129 Stat. 2242.

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

HHS determined that this final rule is a significant regulatory action under the Order. HHS provided an analysis of the costs and benefits of the final rule.

Executive Order No. 13,132 (Federalism)

HHS determined that this final rule does not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.