



441 G St. N.W.  
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February 7, 2017

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

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

Subject: *Department of Health and Human Services and Agencies: Federal Policy for the Protection of Human Subjects*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the following agencies: Department of Homeland Security, Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Social Security Administration, Agency for International Development, Department of Housing and Urban Development, Department of Labor, Department of Defense, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, Department of Health and Human Services, National Science Foundation, and Department of Transportation (the agencies) entitled “Federal Policy for the Protection of Human Subjects” (RIN: 0937-AA02). We received the rule from the Department of Health and Human Services on January 24, 2017. It was published in the *Federal Register* as a final rule on January 19, 2017, with an effective date of January 19, 2018. 82 Fed. Reg. 7149.

The final rule announces revisions to modernize, strengthen, and make more effective the federal policy for the protection of human subjects that was originally promulgated as a common rule in 1991. The agencies stated that this final rule is also intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.

Enclosed is our assessment of the agencies' 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 the agencies 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

Aaron Santa Anna  
Assistant General Counsel for Regulations  
Department of Housing and Urban Development

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
AND OTHER AGENCIES  
ENTITLED  
"FEDERAL POLICY FOR THE  
PROTECTION OF HUMAN SUBJECTS"  
(RIN: 0937-AA02)

(i) Cost-benefit analysis

The Department of Homeland Security, Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Social Security Administration, Agency for International Development, Department of Housing and Urban Development, Department of Labor, Department of Defense, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, Department of Health and Human Services, National Science Foundation, and Department of Transportation (the agencies) summarized the costs and benefits of this final rule. The agencies stated that the present value costs of the rule are \$528 million at a discount rate of 3 percent and \$474 million at a discount rate of 7 percent. The annualized costs are \$62 million at a discount rate of 3 percent and \$67 million at a discount rate of 7 percent. These costs include time and money to learn new requirements, update training materials, develop tools, and conduct consultations.

The agencies determined that the present value benefits are \$1,904 million at a 3 percent discount rate and \$1,494 million at a 7 percent discount rate. The annualized benefits are \$223 million at a 3 percent discount rate and \$213 at a 7 percent discount rate. The agencies stated that the non-quantified benefits of this final rule include improved human subjects protections in research, increased uniformity in regulatory requirements among common rule agencies, and increased clarity to the regulated community about how regulations should be interpreted.

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

The agencies found that this 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

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, including an assessment of anticipated costs and benefits, before proposing "any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The agencies stated that the current threshold after adjustment for inflation is \$146 million. The agencies expect this final rule to result in expenditures that will exceed this amount.

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

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

On September 8, 2015, HHS and 15 other federal departments and agencies published a proposed rule. 80 Fed. Reg. 53,933. The agencies responded to comments in the final rule.

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

The agencies stated that this final rule contains collections of information that are subject to review and approval by the Office of Management and Budget under the Act. The agencies provided a description of the provisions and an estimate of the annual reporting and recordkeeping burden in the final rule.

Statutory authorization for the rule

The agencies stated that it promulgated this rule under 5 U.S.C. § 301, Pub. L. 107-296 sec. 102, 306(c), Pub. L. 108-458 sec. 8306, 42 U.S.C. § 300v-1(b), 42 U.S.C. § 3535(d), 42 U.S.C. § 7254, 42 U.S.C. § 289(a), 29 U.S.C. § 551, 20 U.S.C. § 1221e-3, 20 U.S.C. § 3474, 38 U.S.C. §§ 501, 7331, 7334, 7 U.S.C. §§ 136a(a) and 136w(a)(1), 21 U.S.C. § 346a(e)(1)(C), Pub. L. 109-54 sec. 201, and 119 Stat. 531.

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

The agencies determined that this rule will have an annual effect on the economy of \$100 million or more in any one year and therefore is a significant regulatory action under the Order.

Executive Order No. 13,132 (Federalism)

The agencies stated that this final rule does not contain policies that have federalism implications as defined in the Order.