



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

B-331080

June 4, 2019

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

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

Subject: *Department of Health and Human Services, Office of the Secretary, Office for Civil Rights: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*

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, Office of the Secretary (HHS), Office for Civil Rights (OCR) entitled “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority” (RIN: 0945-AA10). We received the rule on May 20, 2019. It was published in the *Federal Register* as a final rule on May 21, 2019. 84 Fed. Reg. 23170. The effective date of the rule is July 22, 2019.

The agency stated the final rule revises existing regulations to ensure vigorous enforcement of federal conscience and anti-discrimination laws applicable to HHS, its programs, and funding recipients, and to delegate enforcement and compliance responsibility to OCR. In addition, the agency states the final rule clarifies OCR’s authority to initiate compliance reviews, conduct investigations, supervise and coordinate compliance by HHS and its components, and use enforcement tools otherwise available in existing regulations to address violations and resolve complaints. The agency further stated the final rule requires certain recipients to maintain records; cooperate with OCR’s investigations, reviews, or other proceedings; and certifications of compliance to HHS. Finally, the agency states the final rule also encourages the recipients of HHS funds to provide notice to individuals and entities about their right to be free from coercion or discrimination on account of religious beliefs or moral convictions.

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. 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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II  
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,  
OFFICE OF THE SECRETARY,  
OFFICE FOR CIVIL RIGHTS  
ENTITLED  
“PROTECTING STATUTORY CONSCIENCE RIGHTS  
IN HEALTH CARE; DELEGATIONS OF AUTHORITY”  
(RIN: 0945-AA10)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) stated the final rule has quantified costs of \$900.7 million over 5 years in present value dollars by a discount rate of 3 percent or \$731.5 million by a discount rate of 7 percent. OCR further stated the final rule has non-quantifiable costs of compliance procedures, such as recordkeeping and compliance reporting and seeking alternative providers of certain objected-to medical services or procedures.

HHS determined the final rule does not have quantifiable benefits, but it does have non-quantified benefits. These benefits include: increased compliance with the law; greater protection of conscience rights; the promotion of the free exercise of religion and moral convictions; more diverse and inclusive providers and health care professionals; improved provider-patient relationships that facilitate improved quality of care; greater equity fairness and nondiscrimination; and increase access to care.

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

HHS certified the final rule will not result in a significant 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

HHS stated the final rule does not trigger the requirements of the Act.

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

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

HHS published a notice of proposed rulemaking in the *Federal Register* on January 26, 2018. 83 Fed. Reg. 3880. The agency stated it received more than 242,000 comments to the proposed rule and responded to them in the final rule.

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

For purposes of the Act, HHS stated the final rule has three collections of information dealing with assurances and certification, voluntary posting of notice of rights, and compliance

requirements. HHS estimated that the assurances and certification collection of information would have a burden labor cost of \$46.9 million in the aggregate for all affected entities. The agency further estimated the voluntary posting of notice of rights would have an aggregate burden labor cost of \$28.7 million in the first year and \$4.6 million in years 2 through 5 for all affected entities. Finally, OCR estimated the compliance requirements collection of information would have a burden labor cost of \$22,655 per year at the firm level at the high end for each recipient or sub-recipient of federal funds found to have violated the rule to include noncompliance information in federal financial assistance or departmental funding applications for 3 years.

#### Statutory authorization for the rule

HHS stated it promulgated the rule under various provisions of titles 22, 26, 29, and 42 of the United States Code and applicable provisions of various public laws, which HHS collectively refers to as “Federal conscience and anti-discrimination laws.”

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

HHS stated it had reviewed the rule pursuant to the Order and found it to be an economically significant rule. HHS included its regulatory impact analysis in the final rule.

#### Executive Order No. 13,132 (Federalism)

OCR determined the final rule comports with the Order.