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

B-335879

January 25, 2024

The Honorable Bernard Sanders
Chairman
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Cathy McMorris Rodgers Chair The Honorable Frank Pallone, Jr. Ranking Member Committee on Energy and Commerce House of Representatives

Subject: Department of Health and Human Services, Office of the Secretary: Safeguarding the Rights of Conscience as Protected by Federal Statutes

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) entitled "Safeguarding the Rights of Conscience as Protected by Federal Statutes" (RIN: 0945-AA18). We received the rule on January 10, 2024. It was published in the *Federal Register* as a final rule on January 11, 2024. 89 Fed. Reg. 2078. The effective date is March 11, 2024.

According to HHS, the final rule partially rescinds the May 21, 2019, final rule entitled, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" ("2019 Final Rule"), while leaving in effect the framework created by the February 23, 2011, final rule entitled, "Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws" which has been in effect continuously since March 25, 2011. HHS stated though the 2019 Final Rule never took effect, HHS also retains, with some modifications, certain provisions of the 2019 Final Rule regarding federal conscience protections, but eliminates others that are redundant or confusing, that undermine the clarity of the statutes Congress enacted to both safeguard conscience rights and protect access to health care, or because significant questions have been raised as to their legality.

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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones

Managing Associate General Counsel

Enclosure

CC: Calvin E. Dukes II

Regulations Coordinator Department of Health and Human Services

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DEPARTMENT OF HEALTH AND HUMAN SERVICES,
OFFICE OF THE SECRETARY
ENTITLED
"SAFEGUARDING THE RIGHTS OF CONSCIENCE
AS PROTECTED BY FEDERAL STATUTES"
(RIN: 0945-AA18)

(i) Cost-benefit analysis

The Department of Health and Human Services, Office of the Secretary (HHS) estimated the final rule would reduce costs at an annualized rate of \$158.4 million at a three percent discount rate and \$128 million at a seven percent discount rate.

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

HHS certified the final rule would 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

HHS determined the final rule would not create an unfunded mandate under the Act because it does not impose any new requirements resulting in unfunded expenditures by state, local, and tribal governments, or by the private sector.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: "the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, Memorandum for the Heads of Executive Departments and Agencies, Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11-12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

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HHS did not discuss the Act in its submission to us.

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

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

On January 5, 2023, HHS published a proposed rule. 88 Fed. Reg. 820. HHS received more than 48,000 comments from private citizens, health care workers and institutions, faith-based organizations, patient advocacy groups, civil rights organizations, professional associations, state and local government and elected officials, and Members of Congress. HHS addressed the comments in the final rule.

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

HHS determined the final rule contained no information collection requirements subject to PRA.

Statutory authorization for the rule

HHS promulgated the final rule pursuant to section 301 of title 5, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that OMB determined the final rule was significant under the Order.

Executive Order No. 13132 (Federalism)

HHS did not discuss the Order in the final rule.

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