



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

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May 21, 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: Nondiscrimination in Health Programs and Activities*

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 “Nondiscrimination in Health Programs and Activities” (RIN: 0945-AA17). We received the rule on April 23, 2024. It was published in the *Federal Register* as a final rule on May 6, 2024. 89 Fed. Reg. 37522. The rule has a stated effective date of July 5, 2024, but provides various applicability dates up to and including one year after the effective date.

According to HHS, this final rule implements the requirements of section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. HHS states the rule also revises its interpretation of whether Medicare Part B constitutes federal financial assistance for civil rights enforcement purposes and amends provisions prohibiting sex discrimination.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Samuel A. Shipley  
Senior Regulatory and Policy 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  
“NONDISCRIMINATION IN HEALTH PROGRAMS AND ACTIVITIES”  
(RIN: 0945-AA17)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) conducted an economic analysis of this final rule. Its summary of costs and benefits included a discussion of baseline conditions, costs of the rule, and total quantified costs. HHS estimated the rule’s total Year 1 costs will be \$1,102.9 million, with ongoing annual costs of \$511.7 million in subsequent years.

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

HHS certified 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

HHS stated this final rule is not subject to the Act because it falls under an exception in the Act for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, or disability.

(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.

HHS did not discuss the Act in this final rule. In its submission to us, HHS stated it did not prepare a statement regarding compliance with the Act.

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

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

On July 25, 2022, HHS published a proposed rule. 87 Fed. Reg. 47824. HHS received 85,280 comments from a wide variety of stakeholders including civil and disability rights groups, health care providers, and academic institutions. HHS stated that, of the total comments, 79,126 were identified as being submitted by individuals, and 70,337, or 80 percent, of the 85,280 comments were form letter copies associated with 30 distinct form letter campaigns. According to HHS, responses are available for public inspection at <https://www.regulations.gov/docket/HHS-OS-2022-0012>. HHS responded to comments in this final rule.

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

HHS determined that this final rule contains information collection requirements under the Act. HHS stated that the collections of information proposed by this final rule relate to rule sections 92.5 (Assurances Required); 92.7 (Designation and Responsibilities of a Section 1557 Coordinator); 92.9 (Training); 92.10 (Notice of Nondiscrimination); and 92.11 (Notice of Availability of Language Assistance Services and Auxiliary Aids and Services). HHS explained that it previously obtained approval under the Act regarding section 92.5 (OMB Control Number 0945-0008) in an update to HHS Form 690, Consolidated Civil Rights Assurance Form. Because HHS provides an online portal for submitting compliance attestations, HHS determined that this requirement imposes no additional reporting or recordkeeping requirements under PRA. In total, for sections 92.7, 92.10, and 92.11, HHS estimated 12.59 burden hours per average response and a burden cost of \$50,563,119.

Statutory authorization for the rule

HHS promulgated this final rule pursuant to various sections of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS determined that this final rule is significant under the Order.

Executive Order No. 13132 (Federalism)

HHS determined that this final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Order.