



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

B-336904

December 12, 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: Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act*

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 “Organ Procurement and Transplantation: Implementation of the HIV Organ Policy Equity (HOPE) Act” (RIN: 0937-AA13). We received the rule on November 21, 2024. It was published in the *Federal Register* on November 27, 2024. 89 Fed. Reg. 93484. The stated effective date of the rule is November 27, 2024.

This rule amends the regulations implementing the National Organ Transplant Act of 1984, as amended (NOTA), to remove clinical research and institutional review board requirements for transplantation of kidney and livers from donors with human immunodeficiency virus (HIV) to recipients with HIV. The rule also serves as publication of the Secretary of HHS’s direction to the Organ Procurement and Transplantation Network (OPTN) to adopt and use standards of quality with respect to kidneys and livers from donors with HIV to ensure that HOPE Act kidney and liver transplants are subject to OPTN policies that are consistent with NOTA, and in a way that ensures the revised requirements for transplantation of such organs will not reduce the safety of organ transplantation.

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). The rule was received by the House of Representatives on November 20, 2024. 170 Cong. Rec. H6200 (daily ed. Nov. 26, 2024). The rule was delivered to the Senate on November 20, 2024. Email from Regulations Coordinator, HHS, to CRA Rules, GAO, *Subject: Official Submission – RIN 0937-AA13* (Nov. 21, 2024). The rule was published in the *Federal Register* on November 27, 2024.

89 Fed. Reg. 93484. The rule has a stated effective date of November 27, 2024. Therefore, the stated effective date is less than 60 days from November 27, 2024.<sup>1</sup>

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: Calvin E. Dukes II  
Regulations Coordinator  
Department of Health and Human Services

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<sup>1</sup> HHS stated in the rule that there was good cause for the rule to be effective upon publication in accordance with 5 U.S.C §§ 553(d)(3) and 808(2). 89 Fed. Reg. 93495. CRA includes two exceptions to its 60-day delayed effective date requirement for major rules. 5 U.S.C. § 808. The rule clearly does not meet the first exception, which applies to rules related to “hunting, fishing, or camping.” *Id.* at § 808(1). The second exception, which HHS cites in its rule, only applies when the agency has found good cause to waive notice and public procedure requirements when promulgating the rule, and incorporates the finding and a brief statement therefor in the rule. 5 U.S.C. § 808(2). Because HHS did not make a finding that notice and public procedure were impracticable, unnecessary, or contrary to the public interest, this exception also does not apply.

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
ENTITLED  
“ORGAN PROCUREMENT AND TRANSPLANTATION:  
IMPLEMENTATION OF THE HIV ORGAN POLICY EQUITY (HOPE) ACT”  
(RIN: 0937-AA13)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) prepared an analysis of the costs and benefits for this rule. See 89 Fed. Reg. 93496–93497 (Nov. 27, 2024). According to HHS, the annualized benefits of the rule range from \$381 million to \$858 million, with a primary estimate of \$612 million; costs range from \$73 million to \$92 million, with a primary estimate of \$83 million; and transfers range from \$24 million to \$37 million, with a primary estimate of \$30 million. *Id.* at 93497. HHS stated that it evaluated monetized, quantified, and unquantified benefits, costs, and transfers in the rule. *Id.* at 93496.

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

HHS has certified that this rule will not have a significant economic impact on a substantial number of small entities. See 89 Fed. Reg. 93496.

(iii) Agency actions relevant to sections 202–205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532–1535

HHS determined that this rule will not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector, of \$100 million in 1995, updated annually for inflation, in any one year. See 89 Fed. Reg. 93496.

(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.

In its submission to us, HHS indicated the Act is not applicable to the rule.

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

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

On September 12, 2024, HHS published a proposed rule. 89 Fed. Reg. 74174. HHS stated that it received comments from various interested parties. See 89 Fed. Reg. 93485. HHS responded to comments in this rule. *Id.* at 93489–93493.

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

HHS determined that this rule contains no information collection requirements under the Act. 89 Fed. Reg. 93496.

Statutory authorization for the rule

HHS promulgated this rule pursuant to sections 215, 371–377, and 377E of the Public Health Service Act (42 U.S.C. §§ 216, 273–374d, 274f–275); sections 1102, 1106, 1138, and 1871 of the Social Security Act (42 U.S.C. §§ 1302, 1306, 1320b–1328, and 1395hh); section 301 of the National Organ Transplant Act, as amended (42 U.S.C. § 274e); and Exec. Order No. 13879, *Advancing American Kidney Health*, 84 Fed. Reg. 33817 (July 10, 2019).

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that this rule is significant under the Order. 89 Fed. Reg. 93496. HHS stated that the rule was submitted to OMB for review. *Id.*

Executive Order No. 13132 (Federalism)

In its submission to us, HHS indicated that this rule does not have federalism implications under the Order.