



February 3, 2025

Anthony Archeval, Acting Director
Office for Civil Rights
U.S. Department of Health and Human Services
Attention: HIPAA Security Rule NPRM
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201
Via regulations.gov

**RE: Comment on Notice of Proposed Rulemaking: HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information, 90 FR 898 (January 6, 2025),
RIN Number: 0945-AA22; Docket No. HHS-OCR-0945-AA22**

Dear Acting Director Archeval,

Alliance Defending Freedom (ADF) encourages the U.S. Department of Health and Human Services (HHS) to promptly withdraw the proposed HIPAA Security Rule, entitled *HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information*, 90 FR 898 (Jan. 6, 2025), and to not reconsider it unless and until HHS's misguided HIPAA Abortion and Gender-Transition Rule from 2024 is eliminated, *HIPAA Privacy Rule To Support Reproductive Health Care Privacy*, 89 FR 32976 (Apr. 26, 2024).

ADF is an alliance-building legal organization that advocates for the right of all people to live and speak the truth. Since its launch in 1994, ADF has handled many legal matters involving federal healthcare laws.

Because the proposed HIPAA Security Rule would help thwart law enforcement investigations into harmful gender transitions on children, if HHS finalizes the rule it would be violating Executive Order 14168, *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*, 90 FR 8615 (Jan. 20, 2025).

Essential Background on the HIPAA Privacy Rule Counsels Withdrawal of the Proposed HIPAA Security Rule

For 24 Years, HHS OCR applied HIPAA without special rules for abortions and gender transitions.

HHS promulgated the HIPAA Privacy Rule in 2000 to enact “standards to protect the privacy of individually identifiable health information.” Standards for Privacy of Individually Identifiable Health Information, 65 FR 82462 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (HIPAA Privacy Rule).

In 2024, HHS OCR imposed its illegal abortion and gender-transition rule.

Late in the Biden administration, HHS amended the HIPAA Privacy Rule through its HIPAA Abortion and Gender-Transition Rule. HHS, *HIPAA Privacy Rule To Support Reproductive Health Care Privacy*, 89 FR 32978 (Apr. 26, 2024) (the HIPAA Abortion and Gender-Transition Rule).

This rule unlawfully restricts healthcare providers from reporting suspected abuse and cooperating with state law enforcement to protect patients from the harms of “gender transitions” and abortions. The rule prohibits or limits disclosure to law enforcement or public health authorities of “reproductive healthcare information,” a vague term that HHS viewed as encompassing medical records about abortion and gender transitions. But under the HIPAA statute, Congress said that “[n]othing in [HIPAA] shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320d-7(b).

A federal court preliminary enjoined the HIPAA Abortion and Gender-Transition Rule for a doctor and her clinic in *Purl, M.D. v. U.S. Dep’t of Health and Human Services*, ECF No. 34, Opinion, *Purl v. HHS*, No. 2:24-cv-00228-Z (N.D. Tex. Dec. 22, 2024). ADF’s client, Dr. Carmen Purl, is a family physician and owner of Dr. Purl’s Fast Care Walk In Clinic in Dumas, Texas. The HIPAA Abortion and Gender-Transition Rule unlawfully prohibits her from reporting suspected abuse of children related to gender-transition procedures and abortions, sometimes even in response to a state investigation, and unlawfully requires her to adopt policies and notices implementing that ban.

While finalizing the abortion and gender-transition rule, HHS OCR simultaneously drafted the proposed HIPAA Security Rule.

The Biden administration also began the current rulemaking—the proposed HIPAA Security Rule—which imposes new cybersecurity standards for the safeguarding of all HIPAA-protected information. The security measures in this proposed rule incorporate the privacy standards as defined by the HIPAA Abortion and Gender-Transition Rule, which fundamentally transformed the HIPAA Privacy Rule. The incorporation of that unlawful mandate will result in increased cybersecurity protections for gender-transition procedures and for abortion.

HHS Should Withdraw the Proposed HIPAA Security Rule Promptly, and Should Not Reconsider It Until the HIPAA Abortion and Gender-Transition Rule Is Eliminated

The proposed HIPAA Security Rule should be promptly withdrawn. It incorporates by reference the HIPAA Abortion and Gender-Transition Rule’s unlawful modifications to the HIPAA Privacy Rule. The proposed HIPAA Security Rule would mandate new IT processes and software to protect the personal health information *as described in and modified by* the HIPAA Abortion and Gender-Transition Rule.

These changes are unacceptable to covered entities. As shown by the injunction in *Purl*, forcing covered entities to engage in policies, practices, processes, and notices that illegally prohibit those entities from protecting children from the harms of gender-transition procedures and abortions imposes unlawful burdens on those entities. The proposed HIPAA Security Rule would require new written policies and cybersecurity protections for gender-transition procedures and for abortion. It is therefore contrary to law, and if it were to be finalized, it should be stayed, held unlawful, and set aside under the Administrative Procedure Act.

The proposed HIPAA Security Rule incorporates special protections for abortions and gender transitions that are not authorized by statute and for which HHS has no authority. Specifically, the proposed HIPAA Security Rule cross-references the HIPAA Privacy Rule (as amended) when it imposes its cybersecurity requirements on all protected information, as defined in subpart E of Part 165 of the Code of Federal Regulations. Subpart E is, of course, the HIPAA Privacy Rule as amended by the 2024 HIPAA Abortion and Gender-Transition Rule.

For example, the proposed HIPAA Security Rule seeks “to require in the standard for information access management and associated implementation specifications that a regulated entity must establish and implement written policies and procedures for authorizing access to ePHI and relevant electronic information

systems that are consistent with the Privacy Rule.” 90 FR at 950. The proposed regulatory text at Section 164.308(a)(10)(i) in turn is entitled “Standard: Information access management” and provides a mandate to “[e]stablish and implement written policies and procedures for authorizing access to electronic protected health information and relevant electronic information systems that are consistent with the applicable requirements of *subpart E of this part*.” *Id.* at 1014 (emphasis added).

As HHS’s press release announcing the proposed Security Rule explained, these cybersecurity changes include new cybersecurity “policies and procedures” that cover all information protected by the HIPAA Privacy Rule, and these new policies and procedures must “be in writing, reviewed, tested, and updated on a regular basis.” HHS, *HIPAA Security Rule NPRM* (Dec. 27, 2024), <https://www.hhs.gov/hipaa/for-professionals/security/hipaa-security-rule-nprm/index.html>. These requirements impose burdens on covered entities that exacerbate the burdens imposed by the 2024 Privacy Rule changes.

Likewise, the proposed HIPAA Security Rule includes Section 164.306(a)(3), entitled “Security standards: General rules.” This section states, “Each covered entity and business associate must do the following with respect to all electronic protected health information it creates, receives, maintains, or transmits.... Protect against any reasonably anticipated uses or disclosures of the electronic protected health information that are not permitted or required under subpart E of this part.” 90 FR at 1012.

These cross-references are inherently flawed because the HIPAA Abortion and Gender-Transition Rule is unlawful. Indeed, prior text in the latest version of the HIPAA Security Rule included the same cross-references to the HIPAA Privacy Rule. Because the proposed HIPAA Security Rule seeks to recodify these cross-references—cross-references which now include the unlawful 2024 HIPAA Abortion and Gender-Transition Rule—the proposed rule is a new reinforcement of the illegal changes HHS OCR made in the 2024 HIPAA Abortion and Gender-Transition Rule.

The new cybersecurity policies and procedures will require covered entities to engage in new and additional steps, and because of the 2024 HIPAA Abortion and Gender-Transition Rule that means implementing new procedures to ensure that medical records about abortion and gender transitions are not released to law enforcement. The proposed HIPAA Security Rule requires encryption of these records, technical controls to ensure they are not released to law enforcement, and contingency plans to avoid any accidental breach or release of this information.

The proposed HIPAA Security Rule is by definition, a midnight rule, issued just days before President Trump took office. The same Biden administration that imposed the illegal HIPAA Abortion and Gender-Transition Rule wrote the

proposed HIPAA Security Rule in the same timeframe. These officials chose to publish this proposed rule just days before the new administration came into office. Publication of this rule then deprived the new administration of the ability to engage in regulatory review.

The proposed HIPAA Security Rule should be withdrawn so the President's appointees can consider its policies and implications. It will be too late in the process for the new appointees to consider those issues when the rule is finalized. Any different approach they may wish to take on these issues will not have logical outgrowth from this proposed rule language, and therefore a different approach cannot be finalized consistent with the Administrative Procedure Act and the public's right to have notice and an opportunity for comment. Withdrawing the proposed HIPAA Security Rule now will expedite the process of eventually finalizing changes if the President and his new appointees find it appropriate to do so, because they will have to republish another proposed rule with their different approach anyway.

Given the timing, the proposed HIPAA Security Rule also necessarily fails to consider President Trump's recent executive orders. Executive Order 14168 says, "Agencies shall remove all statements, policies, regulations, forms, communications, or other internal and external messages that promote or otherwise inculcate gender ideology, and shall cease issuing such statements, policies, regulations, forms, communications or other messages." 90 FR at 8616. It also says, "Federal funds shall not be used to promote gender ideology. Each agency shall assess grant conditions and grantee preferences and ensure grant funds do not promote gender ideology." *Id.* Because the proposed HIPAA Security Rule would impose obligations to maintain security over privacy rules that prohibit protecting children from the harms of gender transitions, HHS would be violating E.O. 14168 if it finalizes this rule, and under the order HHS should "remove" this "polic[y]" from consideration by withdrawing the rule.

Moreover, the recent executive order entitled "Protecting Children from Chemical and Surgical Mutilation," (Jan. 28, 2025), sets forth an unequivocal policy against the mutilation of children through gender transitions. But the HIPAA Abortion and Gender-Transition Rule creates special rules to block doctors, clinics, and states from protecting children from mutilation. And this proposed HIPAA Security Rule codifies security processes to require protection of that information from disclosures that could protect those children. Failing to withdraw the HIPAA Security Rule therefore would also violate this latest executive order.

Finally, the proposed HIPAA Security Rule fails to adequately calculate the costs and burdens of this rule on entities given the HIPAA Abortion and Gender-Transition Rule. The HIPAA Abortion and Gender-Transition Rule created two tiers

of health information privacy: one for health information generally, and special rules blocking covered entities and states from protecting children from the harms of gender transitions and abortions. The proposed HIPAA Security Rule would impose obligations, policies, and procedures on covered entities to maintain security of health information on terms that illegally grant special protection to information about the harms of gender transitions and abortions. But the proposed HIPAA Security Rule proposal does not even mention, much less calculate, the burdens deriving from the HIPAA Abortion and Gender-Transition Rule. Nor does the proposal consider why covered entities would oppose compliance.

Under the Administrative Procedure Act's requirements of reasoned decision-making, HHS cannot finalize the proposed HIPAA Security Rule without considering whether the recodification of these cross-references to subpart E would be appropriate. And given the HIPAA Abortion and Gender-Transition Rule's many legal and policy flaws, HHS could not justify ordering more implementation of the HIPAA Abortion and Gender-Transition Rule—which is exactly what the proposed HIPAA Security Rule seeks to do.

Conclusion

For all these reasons, HHS should promptly withdraw this proposed rule.

Respectfully Submitted,

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Alliance Defending Freedom