ETHICS AND PUBLIC POLICY CENTER

February 7, 2025

Via Federal eRulemaking Portal

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

Re: HHS 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:

I am a scholar at the Ethics and Public Policy Center (EPPC), a member of EPPC's Administrative State Accountability Project (ASAP), and a former attorney in the U.S. Department of Justice's Civil Rights Division. I write to offer public comment regarding the Department of Health and HuHeaman Services' (HHS) notice of proposed rulemaking, "HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information" (proposed HIPAA Security Rule).[1]

I write to draw HHS's attention to one particular aspect of the proposed HIPAA Security Rule. This proposal, which was published in the final days of the Biden Administration, incorporates by reference the Biden Administration's pro-abortion and pro-gender transition HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (HIPAA Reproductive Health Care Privacy Rule). The HIPAA Reproductive Health Care Privacy Rule has been, from the start, clearly illegal. It is the subject of at least two lawsuits and has been enjoined once already. It is also critical that HHS recognize that the HIPAA Reproductive Health Care Privacy Rule is contrary to several of President Trump's early executive orders.

For all these reasons, I urge HHS to promptly withdraw the proposed HIPAA Security Rule and not to reconsider it unless and until HHS's unlawful HIPAA Reproductive Health Care Privacy Rule is eliminated.

[1] 90 Fed. Reg. 898 (January 6, 2025), https://www.govinfo.gov/app/details/FR-2025-01-06/2024-30983.

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A. The proposed HIPAA Security Rule incorporates the problematic HIPAA Reproductive Privacy Rule.

The proposed HIPAA Security Rule suggests revisions to Section 164.306(a)(3), "Security standards: General rules." The proposed new 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 Fed. Reg. at 1012. Subpart E is, of course, the HIPAA Privacy Rule, which now includes the changes introduced to subpart E through the 2024 HIPAA Reproductive Privacy Rule.

The proposed HIPAA Security Rule introduces include new cybersecurity "policies and procedures" that cover all information protected by the HIPAA Privacy Rule.[2] These new cybersecurity policies and procedures would require covered entities to engage in new and additional steps, including encrypting medical 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.

B. The HIPAA Reproductive Health Care Privacy Rule is unlawful.

The proposed HIPAA Security Rule is problematic because the HIPAA Reproductive Health Care Privacy Rule it reinforces is plainly illegal. In July 2023 I submitted a public comment in opposition to the proposed rule that became the HIPAA Reproductive Privacy Rule.[3] That comment identified the following deficiencies in the HHS proposal:

> We offer this public comment to make a record regarding the Proposed Rule's many and serious flaws. First, the Department has failed to establish a need for the Proposed Rule: its self-serving conjectures and its reliance on reaction pieces from last summer do not establish that the current Privacy Rule is causing "confusion." Second, even if the current rule causes "confusion," the Proposed Rule makes the Privacy Rule worse by introducing a number of critical terms that are either poorly defined or not defined at all. Third, the Proposed Rule will also create more confusion by greatly complicating the decision-making process a covered entity must undergo when deciding whether to use or disclose PHI.
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> But the Proposed Rule does not merely make the Privacy Rule more confusing and complicated. Covered entities must navigate this confusion knowing that HHS—the federal agency responsible for writing, finalizing, interpreting, implementing, and enforcing the Privacy Rule—is openly hostile to state efforts to protect unborn human life, protect minors from life-altering "gender transition" procedures, and other related state interests recognized by the Supreme Court in

[2] Press Release, HHS, *HIPAA Security Rule NPRM* (Dec. 27, 2024), https://www.hhs.gov/hipaa/for-professionals/security/hipaa-security-rule-nprm/index.html.
[3] https://eppc.org/wp-content/uploads/2023/07/EPPC-Scholars-Comment-Opposing-the-HIPAA-Privacy-Reproductive-Health-Care-NPRM.pdf.

Dobbs v. Jackson Women's Health Org. Given the political content in the Proposed Rule, given the Department's wide-ranging authority to interpret and enforce these vague rules, and given the considerable civil, criminal, and professional consequences that come with adverse HIPAA determination under the Privacy Rule, we fear that the Privacy Rule would chill health care professionals from cooperating with legal and legitimate state activities that stem from their traditional police powers, which include promoting the public health, morals, or safety, and the general well-being of the community.

Nearly all of the legal problems I identified in the proposed rule remained unaltered in the final rule that HHS published in April 2024.

C. The HIPAA Reproductive Health Care Privacy Rule is subject of ongoing litigation and has already been enjoined.

I am far from the only one that has noted the illegality of HHS's HIPAA Reproductive Privacy Rule. The first lawsuit brought against HHS's final rule is *Purl, M.D. v. U.S. Dep't of Health and Human Services*, No. 2:24-cv-00228-Z (N.D. Tx.). The plaintiff, Dr. Carmen Purl, is a family physician and owner of Dr. Purl's Fast Care Walk-In Clinic in Dumas, Texas. Her complaint alleges that the HIPAA Reproductive Health Care Privacy 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.

On December 22, 2024, the district court granted the plaintiff's motion for a preliminary injunction, finding that Dr. Purl was likely to prevail on her claim that the HIPAA Reproductive Health Rule "is in excess of HIPAA's statutory authority."[4]

A coalition of states led by Tennessee has filed a second lawsuit against the HIPAA Reproductive Health Rule, *State of Tennessee v. U.S. Department of Health and Human Services*, No. 3:25-cv-00025 (E.D. Tn.). This lawsuit stresses the ways HHS's post-*Dobbs* changes to the HIPAA Privacy Rule are unlawfully impeding states' efforts to enforce valid laws that advance important state interests, including those interests recognized by the Supreme Court in *Dobbs* itself. The plaintiffs attached a copy of my public comment in opposition to the HIPAA Reproductive Health Care Privacy Rule as an exhibit[5] to their Motion for Summary Judgment, which is currently pending.

D. The proposed HIPAA Security Rule, by incorporating and reinforcing the HIPAA Reproductive Health Care Privacy Rule, promotes gender ideology in violation of President Trump's executive orders.

As I pointed out in my public comment, while HHS pointed to the Supreme Court's decision in *Dobbs* as justification for changes to the HIPAA Privacy Rule, the rule does not merely frustrate states' efforts to enforce their pro-life laws. A key term in the rule,

[4] https://storage.courtlistener.com/recap/gov.uscourts.txnd.395990/gov.uscourts.txnd.395990.34.0.pdf.
[5] https://storage.courtlistener.com/recap/gov.uscourts.tned.117532/gov.uscourts.tned.117532.26.4.pdf.

"reproductive health care," is defined so broadly that it also impedes states' efforts to protect children from harmful so-called "gender transition" procedures:

> The Proposed Rule also states that "reproductive health care" can be "related to reproductive organs, regardless of whether the health care is related to an individual's pregnancy or whether the individual is of reproductive age." This is a clear indication that the Proposed Rule would also cover drugs and surgeries related to "gender transition," as puberty blockers, cross-sex hormones, and the removal of reproductive organs are all "health care related to reproductive organs." Pro "gender transition" advocacy groups are already celebrating that the Proposed Rule would cover not just "abortion and reproductive health care" but also "gender affirmation."

As such, were HHS to finalize the proposed HIPAA Security Rule, it would be further thwarting law enforcement investigations into harmful gender transitions on children.

For this reason, the proposed HIPAA Security Rule is out of step with President Trump's early executive orders condemning and seeking to protect children from gender ideology.

Executive Order 14168, "Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government," 90 Fed. Reg. 8615 (Jan. 20, 2025), requires federal agencies like HHS to "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 Fed. Reg. 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.

President Trump has also issued Executive Order 14187, "Protecting Children from Chemical and Surgical Mutilation," 90 Fed. Reg. 8771 (Jan. 28, 2025), which clearly states that it is the policy of this Administration to protect children from being mutilated through so-called "gender transitions." This is directly contrary to HHS's HIPAA Reproductive Privacy Rule, which creates special rules designed to block doctors, clinics, and states from protecting children from mutilation. As described above, the proposed HIPAA Security Rule codifies security processes to require protection of that information from disclosures that could protect those children. As such, I suggest that this Executive Order likewise compels HHS to withdraw the HIPAA Security Rule.

Conclusion

For the reasons stated above, I urge HHS to promptly withdraw the proposed HIPAA Security Rule and not to reconsider it unless and until HHS's unlawful HIPAA Reproductive Health Care Privacy Rule is eliminated. I hope this public comment helps you better carry out your important responsibilities and ensure that the Departments regulations are consistent with federal law and reflect the President's priorities and directives.

Sincerely,

Eric Kniffin, J.D.
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