ALLIANCE DEFENDING FREEDOM
FOR FAITH. FOR JUSTICE.

June 16, 2023

VIA Federal eRulemaking Portal

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments on Notice of Proposed Rulemaking: HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 FR 23506 (April 17, 2023), RIN: 0945-AA20, Docket No. 2023-07517

Dear Secretary Becerra:

Alliance Defending Freedom (ADF) opposes the Notice of Proposed Rulemaking (NPRM) entitled, "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," issued by the U.S. Department of Health and Human Services. The proposed HIPAA rule impermissibly hampers the enforcement of state laws regulating abortion and thwarts state laws protecting children from dangerous medical procedures such as puberty blockers, cross-sex hormones, and genital surgeries.

ADF is an alliance-building legal organization that advocates for the right of all people to freely live out and speak the truth. ADF pursues its mission through litigation, training, strategy, and funding. Since its launch in 1994, ADF has handled many legal matters involving federal healthcare laws, constitutional rights, and other legal principles addressed by the proposed rule. ADF strongly opposes the revision of existing HIPAA regulations and asks that the proposed rule be withdrawn.

I. Summary of Alliance Defending Freedom's Comments.

This proposed rule is a thinly-veiled effort to undermine state laws that protect pregnant women and their unborn children from the harms of abortion—in direct response to and contravention of the U.S. Supreme Court's holding in *Dobbs v.*

Jackson Women's Health Organization[1] that abortion is to be regulated by the states—and to shoehorn a *de facto* federal right to abortion into privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act ("HITECH Act").

In addition, the proposed rule attempts to make it impossible for states to protect children and families from a variety of sterilizing procedures—such as puberty blockers, cross-sex hormones, and genital surgeries—that are sought by persons who identify as a member of the opposite sex, even though state laws restrict these drugs and procedures because of their irreversible damage, especially for minors.

As described more fully herein, ADF submits the following comments in response to the proposed rulemaking:

- The proposed rule is inconsistent with the U.S. Supreme Court's decision in *Dobbs* that the regulation of abortion is a subject returned to our elected representatives, and federal bureaucracies lack authority to interfere with federal or state law enforcement efforts through the proposed rule.

- The proposed rule's prohibition on the disclosure of abortion-related information lacks statutory authority, conflicts with other federal laws, and fails to satisfy the requirements for a major regulation of this kind.

- By prohibiting the disclosure of abortion-related information to state administrative agencies, the proposed rule deprives the states of data that is relevant to the regulation of abortion in their jurisdictions as well as other legitimate state public health interests.

- By prohibiting the disclosure of abortion-related information to state law enforcement agencies, the proposed rule deprives the states of critical evidence relevant to the investigation and successful prosecution of sex crimes.

- By prohibiting the disclosure of abortion-related information to state law enforcement agencies, the proposed rule facilitates the exploitation of common exceptions to state statutes regulating abortion for pregnancies resulting from sex crimes.

- The proposed rule wrongly diminishes the value of unborn life and undermines legal protections afforded to the unborn by unlawfully, arbitrarily, and

[1] 142 S. Ct. 2228 (2022).

capriciously excluding the unborn from the definition of "person" and "child" as that term is defined by 1 U.S.C. § 8.

- The proposed rule defines "reproductive health care" too broadly and improperly restricts public health information about sterilizing interventions sought by persons identifying as members of the opposite sex, such as puberty blockers, cross-sex hormones, and genital surgeries.

II. Discussion.

A. The proposed rulemaking exhibits a decidedly hostile view of, and adversarial demeanor toward, state regulation of abortion, in violation of *Dobbs v. Jackson Women's Health Organization*.

For half a century, the authority of the people's elected representatives to regulate the practice of abortion to protect maternal health and prenatal life, to preserve and promote the integrity of the medical profession, to prevent discrimination, and to promote other legitimate interests was usurped by *Roe v. Wade*[2] and *Planned Parenthood of Southeastern Pennsylvania v. Casey*.[3] Last year in *Dobbs*, the U.S. Supreme Court overturned both *Roe* and *Casey*, holding that "the Constitution does not confer a right to abortion. . . . and the authority to regulate abortion must be returned to the people and their elected representatives."[4]

With their legislative powers thus restored, individual states have revived or enacted statutes and regulations related to abortion that conform to the unique policy preferences of their residents as expressed through their elected representatives. The *Dobbs* decision does not prescribe that states must use their inherent authority to increase or decrease their regulation of abortion;[5] some of these policies place

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[2] 410 U.S. 113 (1973).

[3] 505 U.S. 833 (1992).

[4] 142 S. Ct. at 2279.

[5] Recognizing that "[a]bortion presents a profound moral issue on which Americans hold sharply conflicting views," 142 S. Ct. at 2240, Justice Alito, writing for the majority in *Dobbs*, said:

> It is time to heed the Constitution and return the issue of abortion to the people's elected representatives. "The permissibility of abortion, and the limitations, upon it, are to be resolved like most important questions in our democracy: by citizens trying to persuade one another and then voting." *Casey*, 505 U.S. at 979, 112 S.Ct. 2791 (Scalia, J., concurring in judgment in part and dissenting in part). That is what the Constitution and the rule of law demand.

Id. at 2243.

constraints on the practice of abortion, while others enshrine abortion to a greater extent than *Roe* and *Casey*.[6]

State laws "regulating abortion, like other health and welfare laws, [are] entitled to a 'strong presumption of validity,'" and "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests."[7] *Dobbs* further held:

> These legitimate interests include respect for and preservation of prenatal life at all stages of development; the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability.[8]

As will be explored more fully below, however, the proposed rule interferes with states' pursuit of these legitimate interests by improperly preempting state statutes that regulate abortion.

Rather than respecting *Dobbs* as the clear and binding precedent of the U.S. Supreme Court, the Department of Health and Human Services ("the Department" or "HHS") regards the high court's opinion as a mere "[d]evelopment[] in the [l]egal [e]nvironment" that has "created new concerns about the privacy of PHI [protected health information] and is "[e]roding [i]ndividuals' [t]rust in the Health Care System."[9] Relatedly, the Department makes no pretense of its contempt for state interests in this information:

> This modification would prohibit a regulated entity from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or proceeding against the individual, a health care provider, or other person in connection with seeking, obtaining, providing, or facilitating reproductive health care that: (1) is provided outside of the state where the investigation or proceeding is authorized and such health care is lawful in the state in which it is provided; (2) is protected, required, or authorized by Federal

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[6] *See*, *e.g.*, Wyo. Stat. Ann. § 35-6-120 *et seq.* (2023) (Wyoming's "Life is a Human Right Act"); and Colo. Rev. Stat. Ann. §§ 6-1-734 and 12-30-120 (2023) (SB 190, "Concerning policies to make punishable deceptive actions regarding pregnancy-related services," outlawing certain methods of aid to a woman who has changed her mind after beginning a chemical abortion and desires to continue her pregnancy).

[7] 142 S. Ct. at 2284 (internal citations omitted).

[8] *Id.*

[9] 88 Fed. Reg. 23519.

> law, regardless of the state in which such health care is provided; or (3) is provided in the state in which the investigation or proceeding is authorized and that is permitted by the law of that state. *In these three circumstances, the state lacks any substantial interest in seeking the disclosure.*[10]

It is not difficult to conceive of scenarios in which a state statutory or regulatory scheme that permits abortion under some circumstances may nevertheless need to conduct an abortion-related criminal, civil, or administrative investigation or proceeding in furtherance of legitimate state interests.[11] The proposed rule is an impermissible hindrance to such lawful state actions and should not be adopted.

B. The proposed rule's prohibition on the disclosure of abortion-related information lacks statutory authority, conflicts with other federal laws, and fails to satisfy the requirements for a major regulation of this kind.

There is no congressional or constitutional authority for the Department to arrogate to itself this important question about the proper regulation of abortion. The Biden administration reacted to *Dobbs* by issuing a raft of abortion mandates—even though the statutes that the agencies cite contain no such authorizations.[12] Agencies launched new programs forcing states and private citizens to perform abortions and spend taxpayer money to perform and pay for abortions.[13] In each case, agency officials used their positions to brush aside the absence of federal authority and to claim primacy over state laws to which the Supreme Court deferred in *Dobbs* as a matter of federalism. These agency actions, of which the proposed rule is one example,

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[10] 88 Fed. Reg. 23522 (emphasis added).

[11] The proposed rule improperly allows one state's investigation to be thwarted so long as some part of the abortion has a nexus to a state in which abortion is legal. This proposed rule will effectively prohibit law enforcement agencies from enforcing abortion laws in instances where the abortion or the importation of abortion drugs into that state requires crossing state lines.

[12] *See, e.g.*, Exec. Order No. 14076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42,053 (July 8, 2022); Exec. Order No. 14079, Securing Access to Reproductive and Other Healthcare Services, 87 Fed. Reg. 49,505 (Aug. 3, 2022).

[13] For instance, even though Congress explicitly stated that no funds in the Title X family planning program can "be used in programs where abortion is a method of family planning," HHS is giving those funds to abortion clinics that engage in no physical or financial separation of their abortions and their federally funded family planning. 42 C.F.R. 59.5(a)(5)(i) & (ii) (entities must provide "referral upon request" for "[p]regnancy termination"). Other examples include HHS's EMTALA mandate and the VA's abortion IFR (described below).

epitomize the kind of "whole-of-government" and "nationwide" effort that the Supreme Court warned is an inadequate substitute for clear statutory authority.[14]

An agency may not rely on ancillary provisions of long-extant statutes to create a transformative expansion of its regulatory authority, and without a clear statement on such a major question, there is no reason to believe that Congress ever gave the Department this unprecedented authority.[15] The Supreme Court recently reiterated that it "requires Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power."[16] Even in interpreting "expansive language," a court may "insist on a clear" statement before intruding on the state's traditional police powers.[17] Health and medicine fall squarely within the state's historic "police power."[18] And thwarting state law enforcement in their investigation of criminal and civil violations of abortion laws is undoubtedly a question of vast political significance. The Supreme Court thus will demand a clear statement for "[a]n overly broad interpretation" of federal privacy laws that impinges on these traditional areas of state regulation.[19]

The Department points to no statute in which Congress has clearly delegated to it the power to interfere with and shield from investigators, prosecutors, and courts any information concerning reproductive healthcare—whether related to abortion or to sterilizing procedures, such as puberty blockers, cross-sex hormones, and genital surgeries. Under the major questions doctrine and the federalism clear-notice canon, the agency must point to an unmistakably clear source of congressional authority before displacing state regulation on a subject of such great political importance. But not only does the Department lack such authority, the authority that it cites in support is so vague and general that it raises independent questions about whether it complies with Article I's vesting clause and the non-delegation doctrine.[20]

For support for its assertion that federal law may "protect[], require[], or authorize[]" an abortion, the Department refers to the 1986 Emergency Medical

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[14] *Cf. West Virginia v. EPA*, 142 S. Ct. 2587, 2604 (White House described Clean Power Plan as "aggressive transformation in the domestic energy industry"); *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 142 S. Ct. 661, 663 (2022) (per curiam) (White House stated multi-agency goal to impose vaccine requirements on about 100 million Americans).

[15] 142 S. Ct. at 2616 (2022) ("A decision of such magnitude and consequence rests with Congress itself, or an agency acting pursuant to a clear delegation from that representative body.").

[16] *Sackett v. EPA*, 598 U.S. ----, 2023 WL 3632751, at *14 (May 25, 2023) (cleaned up).

[17] *Bond v. United States*, 572 U.S. 844, 860 (2014).

[18] *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905).

[19] *Sackett*, 2023 WL 3632751, at *14.

[20] U.S. Const. art. I, Section 1.

Treatment and Labor Act (EMTALA) and a Department of Veterans Affairs ("VA") interim final rule promulgated in direct contravention of the Veterans Health Care Act of 1992, PL 102–585, November 4, 1992, 106 Stat 4943 ("[T]he Secretary of Veterans Affairs may provide . . . general reproductive health care . . . not including . . . abortions."). 88 FR 23531. These authorities are not bases for a federally protected, required, or authorized elective abortion.

First, HHS has no authority for its efforts to turn practically all hospitals into on-demand abortion clinics. As part of its anti-*Dobbs* campaign, HHS told all hospitals receiving Medicare funds that have emergency rooms, that regardless of state laws protecting the unborn they must perform abortions under HHS's novel interpretation of EMTALA, 42 U.S.C. 1395dd.[21] This was a brazen bureaucratic imposition on several levels. As a federal district court held when it preliminary enjoined the mandate in Texas, and for members of certain pro-life medical organizations represented by undersigned counsel, the mandate lacked statutory authority for several reasons: (1) EMTALA says nothing about abortions or mandating them; (2) four times, EMTALA explicitly requires stabilizing the "unborn child"; (3) EMTALA and the Social Security Act disavow any preemption of state laws unless there is a direct conflict with the language of EMTALA; and (4) lower courts have widely held that EMTALA imposes no medical standard of care, but instead is a statute designed to stop the dumping of patients unable to pay.[22] President Reagan signed EMTALA in 1986, and not once until HHS's post-*Dobbs* memorandum did a federal agency declare that EMTALA mandates abortions. Yet the agency officials not only concluded that the statute authorized them to impose that mandate, they imposed it without giving notice or an opportunity to the public to comment, in violation of the Medicare Act and the Administrative Procedures Act.[23]

Second, the VA likewise has no authority for its claimed new power to promote abortion—a power it had "never before adopted" or even noticed.[24] In response to *Dobbs*, the VA began performing abortions in veterans' hospitals—on demand through all nine months of pregnancy—without regard to contrary state laws. [25] Just as with HHS, the VA seized on the flimsiest of statutory reeds to support its new assertion of power. In the VA's underlying statute, Congress explicitly banned the

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[21] Memorandum from Ctrs. for Medicare & Medicaid Servs. on Reinforcement of EMTALA Obligations Specific to Patients Who Are Pregnant or Are Experiencing Pregnancy Loss (July 11, 2022) (revised Aug. 25, 2022), https://perma.cc/ND68-86SK.

[22] *See Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525, at *19–26 (N.D. Tex. Aug. 23, 2022).

[23] *Id*. at *27–28.

[24] *Nat'l Fed'n of Indep. Bus. v. Occupational Safety & Health Admin.*, 142 S. Ct. 661, 666 (2022).

[25] Dep't of Veterans Affairs, Interim Final Rule, Reproductive Health Services, 87 Fed. Reg. 55,287 (Sept. 9, 2022).

performance of abortions in the VA system.[26] But in the summer of 2022, for the first time, the VA (in conjunction with the Department of Justice's Office of Legal Counsel) claimed that Congress had silently negated the effect of Section 106 by implication of its 1996 amendments to the Act.[27] That 1996 amendment did not actually repeal Section 106, and it said nothing about abortion. 38 U.S.C. § 1710 merely states that the VA can give eligible veterans "medical services which the Secretary determines to be needed." And in the Assimilative Crimes Act, Congress declared that in a federal government building, such as a VA hospital, state criminal law will apply—meaning state laws regulating elective abortion will apply, along with other state laws regulating the practice of medicine. But in another post-*Dobbs* memorandum, DOJ brushed aside those concerns as well.[28]

Both the HHS EMTALA mandate and the VA abortion IFR are invalid under the major questions doctrine. Both are increasingly common attempts to "discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy.'"[29]

Nor is there any other source of authority for a federal abortion program of this kind. HHS officials certainly have no such authority under Section 1557 of the Affordable Care Act, 42 U.S.C. 18116, and Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794, which merely prohibit sex and disability discrimination and do not mention abortion. The Affordable Care Act states that nothing in it negates federal laws regarding "refusal to provide abortion" or state laws prohibiting abortion.[30] And Section 1557 only bans sex discrimination by incorporation of that ban under Title IX of the Education Amendments of 1972, which includes Congress' explicit statement in Title IX that it does not require any entity to provide any service related to an abortion.[31]

What is more, the Department's regulations create a conflict with federal criminal and civil law enforcement governing these issues, impeding federal regulators and prosecutors in important areas within their jurisdiction and creating conflicts with federal criminal laws. Federal law regulates abortion in many

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[26] *See* Section 106 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585, 106 Stat. 4943.

[27] *Id.*; Dep't of Justice, Intergovernmental Immunity for the Department of Veterans Affairs and Its Employees When Providing Certain Abortion Services, 46 Op. O.L.C. ___, 7–8 (Sept. 21, 2022).

[28] Dep't of Justice, Application of the Assimilative Crimes Act to Conduct of Federal Employees Authorized by Federal Law, 46 Op. O.L.C. ___ (Aug. 12, 2022).

[29] *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (citation omitted).

[30] 42 U.S.C. 18023(c).

[31] 20 U.S.C. 1688.

important ways.[32] The Department has no authority to ignore these laws, let alone to create carve-outs to their application by authorizing the obstruction of lawful investigations under these statutes. But, by defining "reproductive health care" broadly as "care, services, or supplies related to the reproductive health of the individual," and shielding them from any use in enforcement proceedings, the Department seeks to immunize from prosecution or regulation any mailing, transportation, or provision of chemical abortion drugs and other items used for abortion—essentially creating a right to do what federal law expressly forbids. The proposed rule also impedes the investigation of civil violation of conscience laws designed to protect those who object to participation in abortions, sterilizations, or other related procedures.[33] All of this Departmental overreach will result in the disregard of the health and safety of women, girls, and other Americans across the country.

C. The proposed rule's prohibition of disclosure of abortion-related information to state administrative agencies deprives states of data relevant to legitimate state public health and regulatory interests.

Far from respecting the validity of state and federal abortion laws, the Department makes a blanket invocation HIPAA's state law preemption authority without any reference to the numerous ways in which HIPAA also *defers* to state law.[34] After HIPAA's assertion of a general rule that contrary state laws are preempted, it nevertheless provides numerous exceptions in which HIPAA "shall not supersede a contrary provision of state law."[35] These exceptions include state

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[32] 10 U.S.C. § 919a; 18 U.S.C §§ 1841, 1461, 1462, 1531; 19 U.S.C § 1305; *see also* 18 U.S.C. §1961(1)(b), as added by the Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, 98 Stat. 2143; 18 U.S.C. §§ 1852, 1956, 1957.

[33] *See, e.g.*, the Church Amendments, 42 U.S.C. § 300a-7 et seq.; Public Health Service Act § 245; Weldon Amendment, Consolidated Appropriations Act, 2009, Pub. L. No. 111-117, 123 Stat 3034; Hyde Amendment, Pub. L. No. 117-103, Div. H, §§ 506–507, 136 Stat. 49. Claims that the Hyde Amendment permits the government to fund and facilitate abortions, Dep't of Justice, Application of the Hyde Amendment to the Provision of Transportation for Women Seeking Abortions, 46 Op. O.L.C. ___ (Sept. 27, 2022), are simply contrary to this statutory text. Congress has restricted spending military money for abortion. *See* 10 U.S.C. § 1093 (P.L. 117-103. Div. H, §§ 506–507).

[34] 88 Fed. Reg. 23530 (citing 42 U.S.C. § 1320d-7(a)(1), which expresses the "[g]eneral rule" that HIPAA provisions and regulations "supersede any contrary provision of State law," such as a "State law that requires medical or health plan records . . . be maintained or transmitted in written rather than electronic form.").

[35] 42 U.S.C. § 1320d-7(a)(2).

authorities that enable them to regulate insurance and health plans or report on health care delivery or costs.[36]

Two additional areas in which HIPAA explicitly does *not* preempt state laws are those of public health and regulatory reporting:

> (b) Public health
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> Nothing in this part 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.
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> (c) State regulatory reporting
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> Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.[37]

States' legitimate interests include the health of their residents and assessing and reporting the costs and effectiveness of their regulatory efforts. The abortion-related information sought to be withheld from states by the proposed rule is rationally related to these legitimate state interests. Moreover, the federal administrative state has no greater interest in protecting the privacy of individuals' sensitive health information than state governments. The proposed rule's prohibition of disclosure of abortion-related information to federal officials deprives federal officials of data relevant to legitimate federal public health and regulatory interests. It asserts an authority to preempt state law in excess of its statutory warrant and should be withdrawn.

And, of course, the federal government has its own programs protecting unborn life, regulating abortion, and implicating other aspects of "reproductive health care" covered under the proposed rule. Congress has recognized important federal interests in regulating certain forms of abortion that are contrary to public policy, as well as in

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[36] *Id*.

[37] 42 U.S.C. § 1320d-7.

protecting unborn life from criminal activity—interests that the Department is required to respect.[38] But the proposed rule disregards these federal interests, too.

D. Prohibiting the disclosure of abortion-related information to state law enforcement agencies deprives states of critical evidence relevant to the investigation and successful prosecution of sex crimes.

States have an obvious and legitimate interest in the investigation and prosecution of sex crimes. States require medical professionals who deliver a baby or perform an abortion under circumstances indicating that the mother has been the victim of a sex crime or child abuse to report to an appropriate law enforcement authority.[39] As described above, HIPAA explicitly exempts state laws requiring the reporting of child abuse from its preemption provisions.

Criminals who victimize women or girls who may become pregnant as a result of a sex crime have an obvious and nefarious interest in obtaining abortions: the abortion destroys evidence of the crime and, in the case of sex trafficking or serial sexual abuse, preserves the ability of the criminal to continue to victimize the mother of an aborted child.

Incredibly, the proposed rule prohibits the disclosure of information "[w]here the use of disclosure is for a criminal . . . investigation into or proceeding against *any person* in connection with seeking, obtaining, providing, or facilitating" an abortion.[40] The proposed rule would even prohibit the disclosure of information where the person criminally responsible for a pregnant woman's plight sought, obtained, provided, or facilitated an abortion by "expressing interest in, inducing, using, performing, furnishing, paying for, . . . arranging, insuring, assisting or otherwise taking action"[41] to procure an abortion to get rid of an unborn child. By prohibiting the disclosure of abortion-related information to law enforcement authorities, the proposed rule protects sex criminals while leaving their victims exposed to repeat victimization.

All of this is even more shocking because the proposed rule cuts out parental consent and parental rights for a minor's reproductive health information while

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[38] *E.g.*, 10 U.S.C. § 919a; 18 U.S.C §§ 1461, 1462, 1531, and 1841; 19 U.S.C § 1305; *see also* 18 U.S.C. §1961(1)(b), as added by the Comprehensive Crime Control Act of 1984, Pub. L. No. 98-473, 98 Stat. 2143; 18 U.S.C. §§ 1852, 1956, 1957.

[39] *See*, *e.g.*, Mo. Ann. Stat. § 188.023 (2023) ("Any licensed health care professional who delivers a baby or performs an abortion, who has prima facie evidence that a patient has been the victim of statutory rape . . . or if the patient is under the age of eighteen, that he or she has been a victim of sexual abuse, including rape in the first or second degree, or incest, shall be required to report such offenses.")

[40] Proposed 45 CFR § 164.502(a)(5)(iii)(A)(1) (emphasis added).

[41] Proposed 45 CFR § 164.502(a)(5)(iii)(B).

allowing abusers to access that information. HHS's disregard of a parent's right to access and control a minor's health information on all subjects conflicts with the constitutional right of parents to control and direct the upbringing of their children.

Moreover, the proposed rule requires a covered individual and entity to decide whether a particular demand for abortion-related information satisfies the proposed rule's criteria for disclosure, under penalty of federal law, or whether the covered person or entity must defy the instructions of a state law enforcement agency or court:

> [T]he Privacy Rule, if modified as proposed, would prohibit the disclosure of PHI to law enforcement in furtherance of a law enforcement investigation of an individual for obtaining reproductive health care that is lawful under the circumstances in which it is provided. It would also prohibit the disclosure of PHI for a law enforcement investigation of a health clinic for providing reproductive health care that is lawful under the circumstances in which it is provided, *even in response to a court order, such as a search warrant*.[42]

Such an unworkable rule places covered entities in an impossible position of deciding whether to comply with a rule buried within the Code of Federal Regulations or the state law enforcement officer presenting them with a valid search warrant issued by a state court of competent jurisdiction.

More absurd, however, is the notion that under the terms of the proposed rule, a state law enforcement authority investigating abortion-related criminal activity must depend on the determination of an abortion *provider*—which may be the very target of the investigation—that the state's investigation complies with the proposed rule.

The proposed rule withholds vital information and prevents state law enforcement officers from effectively investigating and prosecuting some of the most heinous crimes and criminals, and facilitates the ongoing victimization of women and girls subjected to sex trafficking or sexual abuse while protecting sex criminals.

And, again, all of these concerns equally apply to federal and state criminal and civil laws regulating abortion and other aspects of "reproductive health care" covered under the proposed rule. The Department's attempt to hamper and impede state law enforcement will equally improperly impede federal law enforcement—a set of reliance interests and legal restrictions that the Department fails to reasonably consider. Such a rule should not be the policy of the United States.

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[42] 88 Fed. Reg. 23530.

E. The proposed rule undermines state abortion laws by making it difficult to verify allegations of rape or incest where such allegations trigger exceptions to state laws limiting abortions except in such circumstances.

States that place limits on elective abortions often provide exceptions to permit abortions in the case of pregnancies caused by rape, incest, or other sex crime.[43] Such exceptions, however, usually require that a report of the sex crime be reported to a law enforcement agency.[44]

By prohibiting the disclosure of abortion-related information to state law enforcement agencies for the purposes of criminal investigation, the proposed rule makes possible the unscrupulous exploitation of states' rape and incest exceptions. This circumstance could enable an exception designed to accommodate the most tragic of circumstances to swallow the rule.

F. The proposed rule misstates a federal statute defining "person" and "child," and unlawfully, arbitrarily, and capriciously excludes the unborn from these definitions.

The proposed rule purports to be concerned with the protection of PHI in the context of reproductive health services, and yet it entirely removes that protection from a class of human beings who have been protected in the past by HHS under HIPAA in enforcement proceedings. Although HHS has enforced HIPAA in the past to protect unborn life, HHS now seeks to define the term "person" in the Privacy Rule to exclude unborn life. There is little reason to suspect that the Department is concerned with protecting the PHI of unborn children being subjected to an elective abortion. Accordingly, it is not readily apparent why the proposed rule undertakes to redefine the terms "person" and "child" to explicitly exclude the unborn, except to seize an opportunity to undermine the status and legal protections afforded to the unborn.

To arrive at this definition, the proposed rule attempts to selectively anchor its preferred definition in a federal statute defining these terms. The NPRM cites 1 U.S.C. § 8, which states, in paragraph (a):

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[43] *See*, *e.g.*, Wyo. Stat. Ann. § 35-6-124 (2023) ("It shall not be a violation of W.S. 35-6-123 for a licensed physician to . . . [p]erform an abortion on a woman when the pregnancy is the result of incest . . . or sexual assault.")

[44] *See*, *e.g.*, *id*. ("Prior to the performance of any abortion under this paragraph the woman, or the woman's parent or guardian if the woman is a minor or subject to a guardianship, shall report the act of incest or sexual assault to a law enforcement agency and a copy of the report shall be provided to the physician.").

> In determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States, the words "person", "human being", "child", and "individual", shall include every infant member of the species homo sapiens who is born alive at any stage of development.

This definition in Section 8 merely imparts a rule of construction in which a certain class of persons (those born alive) cannot be excluded from federal legal protections. But this definition does not exclude other classes of persons from the protections of federal law. Yet the NPRM takes this definition one step further to assert that the "definition of 'person' and 'child' . . . does not include a fertilized egg, embryo, or fetus."[45]

In its zeal to restore a federal right to abortion, however, the NPRM goes too far and conflicts with Section 8 itself. Section 8 goes on to say, at paragraph (c), "Nothing in this section shall be construed to affirm, *deny*, expand, *or contract* any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being 'born alive' as defined in this section." (Emphases added.). The status of the unborn as a "person" or "child" is not relevant to the purpose of this proposed rule, and as such, any effort to exclude it as such is arbitrary and capricious and should be rejected. What is more, it is arbitrary and capricious to deny unborn life legal protections for the period of time in which the child was alive in utero.

And, of course, the proposed rule conflicts with state and federal laws that protect unborn life. For instance, under the Unborn Victims of Violence Act,[46] any person who injures or kills a "child in utero" commits an offense in certain circumstances. The term "child in utero" means "a member of the species homo sapiens, at any stage of development, who is carried in the womb."[47] This federal statute recognizes that the unborn child is a human person, and it grants the child federal protection.

Other health statutes directly protect the unborn as persons, too. *First and foremost*, the Genetic Information Nondiscrimination Act of 2008 ("GINA"), Pub. L. 110–233, 122 Stat. 881, defines an individual to include an unborn child. GINA's many protections for genetic information extends to information of any "individual or family member of an individual," which GINA defines to include information of "any fetus carried by such pregnant woman" and "any embryo." GINA amended the HIPAA Privacy rule, and so GINA's statutory context powerfully suggests that HHS has no

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[45] 88 Fed. Reg. 23523.

[46] *See* Pub. L. No. 108-212, §§ 2, 3, 118 Stat. 568 (2004).

[47] 18 U.S.C. § 1841(d); *see also* 10 U.S.C. § 919a(d).

authority (let alone any clear authority) to exclude the unborn from the definition of a person protected by HIPAA's Privacy Rule. *Second*, the National Childhood Vaccine Injury Act covers the unborn child independently for vaccine injuries due to maternal vaccination: "both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine."[48] *Third*, again, EMTALA specifically protects the "unborn child."[49] And, in addition, HHS regulations concerning human testing and research provide additional protections for the unborn.[50]

The Department's attempt to exclude unborn children from the definition of "person" thus conflicts with the congressional recognition of personhood in other laws. All these laws protecting unborn life suggest that the better reading of HIPAA is *not* to give HHS the authority to affirmatively define unborn life as non-persons. And all these laws highlight that, under the major questions doctrine and the clear-notice canon, HHS lacks any clear statutory authority for this redefinition and constriction of the term "person."

Indeed, agency practice has shown that HHS has long understood the term "person" to include unborn life. In 2019, HHS enforced HIPAA against a Florida medical center for failing to provide a mother timely access to prenatal health records for her unborn child.[51] HHS thus appears to be changing its position on the legal status of children in the womb without demonstrating awareness of the change and without considering the reliance interests of mothers, fathers, and children in the status quo.

HHS has also failed to consider reasonable alternatives to this policy—such as no action, such as incorporating the full definitional provisions in GINA, EMTALA, and the other federal statutes cited in this comment, or such as more flexible policies in which unborn life is protected in at least some circumstances. The Department

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[48] 42 U.S. Code § 300aa–11.

[49] *See Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525, at *19–26 (N.D. Tex. Aug. 23, 2022).

[50] *E.g.*, 45 C.F.R. Subpart B.

[51] *See* HHS OCR, *OCR Settles First Case in HIPAA Right of Access Initiative* (Sept. 9, 2019), https://public3.pagefreezer.com/browse/HHS.gov/31-12-2020T08:51/https:/www.hhs.gov/about/news/2019/09/09/ocr-settles-first-case-hipaa-right-access-initiative.html ("Bayfront Health St. Petersburg (Bayfront) has paid $85,000 to OCR and has adopted a corrective action plan to settle a potential violation of the right of access provision of the Health Insurance Portability and Accountability Act (HIPAA) Rules after Bayfront failed to provide a mother timely access to records about her unborn child. . . . This right to patient records extends to parents who seek medical information about their minor children, and in this case, a mother who sought prenatal health records about her child.").

should at least consider allowing states to investigate abortion crimes when any part of that crime occurred in the state.

HHS's lack of reasoned decision making violates the Administrative Procedure Act, which requires the Department to consider these issues in its notice of proposed rulemaking and then allow the public to comment on its reasoning and rationales. A truly pro-woman and pro-healthcare rule would respect and care for both the mother and the child, as well as for all families.

G. The proposed rule improperly restricts information about sterilizing interventions sought by persons identifying as members of the opposite sex, such as puberty blockers, cross-sex hormones, and genital surgeries.

The proposed rule goes far beyond abortion: it defines "reproductive health care" so broadly that it sweeps in information about sterilizing interventions sought by persons identifying as members of the opposite sex, such as puberty blockers, cross-sex hormones, and genital surgeries. All of the problems in the proposed rule identified in the abortion context are thus extended and multiplied to this context as well, given that an increasing number of states regulate and prohibit these procedures, especially for minors.

Denying the truth that we are either male or female hurts real people, especially vulnerable children. Science and common sense tell us that children are not mature enough to properly evaluate the serious, lifelong ramifications when making important medical decisions. And the decision to undergo dangerous, experimental, and likely sterilizing gender-transition procedures is no exception.

Children who experience discomfort with their biological sex deserve to be treated with dignity and respect and need compassionate, effective mental health care. But radical activists have sought out these vulnerable minors to push them toward "gender clinics" that deceive them into believing that unnatural, life-altering and even permanently sterilizing puberty blockers, hormones, and surgeries are the solution to their struggle.

State lawmakers can and do protect children and parents from being pressured into agreeing to these harmful, experimental "gender transition" procedures by enacting laws that prohibit the administration of puberty blockers, cross-sex hormones, and surgeries on minors. These laws are needed because the experimental gender-transition procedures foisted on our children are often irreversible. They prevent healthy puberty, radically alter the child's hormonal balance, and may even remove healthy external or internal organs and body parts. And not only are such drugs and procedures dangerous, but they are also experimental and unproven. In fact, multiple long-term studies show that when young children who experience

gender dysphoria are allowed to mature naturally, most of them—over 90 percent according to some sources—grow out of their dysphoria.[52]

A growing number of nations, including some that pioneered these medical transitions, are reversing course. Health authorities and medical associations in England, Sweden, Finland, France, Australia, and New Zealand are warning against and even curtailing the use of puberty blockers, hormones, and surgeries on children with gender dysphoria. Instead, they are putting psychological treatment and counseling at the forefront of caring for these minors, who frequently suffer from other psychiatric conditions. Children suffering discomfort with their sex are best served by compassionate mental health care that gives them time and support to grow into comfort with their bodies and with their true identities as male and female.

We are also hearing from a growing movement of "detransitioners" who have come to realize—after undergoing hormone treatments or surgeries—that they were lied to, that their medical gender transition was a devastating mistake, and that their true "gender identity" is aligned with their biological sex. Many of them are now bravely speaking out about the damage caused by being rushed into these drugs and procedures without understanding the consequences. Sadly, proponents of these procedures aren't relying on common sense or biological reality. And our children are bearing the brunt of the harm.

Irreversible, potentially sterilizing pharmaceutical interventions and surgical procedures are never the answer for children who are experiencing discomfort with their sex. Drugs like cross-sex hormones and surgeries that permanently alter children's bodies have lifelong irreversible consequences, including sterility. They destroy health, turn children into lifelong patients, and irreparably deprive them of the fulfillment and basic human right of becoming parents later in their lives, all with no proven long-term benefits. HHS should not define any of these interventions as "reproductive health care" and effectively immunize them from all federal or state regulation.

Nothing in the proposed rule indicates that HHS has fulfilled the requirements of reasoned decision making as to the proposed rule's effects on state laws protecting children and families from these dangerous and life-altering procedures. HHS fails to adequately consider the science of the harms of these procedures (including the growing international consensus), and HHS fails to adequately consider the reliance interests of elected representatives and state law enforcement in protecting families from the damage of these irreversible procedures.

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[52] Leor Spir, *'Trust the Experts' Is Not Enough: U.S. Medical Groups Get the Science Wrong on Pediatric 'Gender Affirming' Care*, https://media4.manhattan-institute.org/sites/default/files/how-to-respond-to-medical-authorities_claiming_gender_affirming_care_safe.pdf.

III. Conclusion.

This proposed rule would undermine state statutes enacted in furtherance of legitimate state interests relating to the subject of abortion. The regulation of the practice of abortion is the province of elected representatives, not federal administrative bureaucracies. The proposed rule exceeds the authority given to HHS by HIPAA and the HITECH Act, and barely attempts to hide its purpose of preserving a federal right to abortion after *Dobbs* definitively declared that no such right exists. The proposed rule would have a deleterious effect on states' abilities to protect the lives and health of pregnant women and their unborn children, to protect children and families from dangerous medical procedures, to collect and analyze data regarding the effectiveness of public health regulations, and to investigate and prosecute sex traffickers and other criminals.

The Department should immediately withdraw this proposed rule.

Respectfully submitted,

s/Timothy A. Garrison
Timothy A. Garrison
MO Bar No. 51033
ALLIANCE DEFENDING FREEDOM
440 First Street NW, Suite 600
Washington, DC 20001
(202) 393-8690
tgarrison@adflegal.org

s/Julie Marie Blake
Julie Marie Blake
VA Bar No. 97891
ALLIANCE DEFENDING FREEDOM
44180 Riverside Parkway
Leesburg, VA 20176
(571) 707-4655
jblake@adflegal.org