THE NATIONAL CATHOLIC BIOETHICS CENTER

June 16, 2023

U.S. Department of Health & Human Services
Office for Civil Rights
Attention: HIPAA and Reproductive Health Care Privacy NPRM
Hubert H. Humphrey Building
Room 509F
200 Independence Ave., SW
Washington, DC 20201

Subj: HIPAA Privacy Rule to Support Reproductive Health Care Privacy
RIN 0945-AA20

Dear Sir or Madam:

On behalf of the National Catholic Bioethics Center (Center), the National Association of Catholic Nurses, USA, and the Catholic Medical Association (the latter two referred to as the Associations), we respectfully submit the following comments on the proposed rule, published by the Department of Health and Human Services (HHS) at 88 Fed. Reg. 23506 (Apr. 17, 2023), in the above-captioned matter.

The proposed regulations would forbid health care entities and providers, health care clearinghouses, and health plans to disclose requested health care information whenever it is sought in connection with a criminal, civil or administrative investigation or proceeding and concerns a "reproductive health service," (preferring the broader term "Reproductive Health Care") including an abortion, that was itself lawful.

The Center is a non-profit research and educational institute which for over fifty years has been committed to providing education, guidance, and resources to individuals, institutions, and the larger society, promoting the dignity of the human person in health care and biomedical research. The Center provides educational programming and consultations to

individuals and institutions, including health care institutions and health care providers, seeking its guidance in the domain of bioethics. The Center has been at the forefront of the effort to navigate the difficult waters of bioethical dilemmas in medicine, law, and culture. Not only have we taught thousands of students and completed tens of thousands of free consultations, but we also have assisted health care institutions and providers in addressing the most challenging bioethical questions which society has confronted, especially the escalating threats to the provider's ability to address the best interest of the patients served, while respecting Protected Health Information.

The National Association of Catholic Nurses, U.S.A. is the national non-profit professional organization for Catholic nurses in the United States, representing a membership of hundreds of nurses. Nursing plays an integral role in patient advocacy, and in securing the privacy of Protected Health Information. In that role, nurses advocate for patients, protect the vulnerable, and promote human dignity and, thus, have a great interest in this policy. Nurses are essential health care partners in the delivery of Reproductive Health Care.

The Catholic Medical Association is a non-profit national organization comprised of over 2,000 members representing physicians and other health care providers in over 75 medical specialties. CMA helps to educate the medical profession and society at large concerning issues in medical ethics, assisting providers in addressing the most challenging bioethical questions which society has confronted, especially the escalating threats to the provider's ability to address the best interest of the patients served, while respecting Protected Health Information. CMA accomplishes this through its annual conferences, local Guilds, its quarterly award-winning bioethics journal, *The Linacre Quarterly*, and its other programs, publications, and web communications. It educates thousands of health care professionals through these media, a number of whom are involved in the delivery of Reproductive Health Care.

Increasingly the Center and both Associations are approached by providers being subject to demands placed upon them as individuals, agencies, institutions, and corporations. Such demands violate a deep-seated commitment to protect patients from practices that violate the Hippocratic tradition. These health care entities and providers take seriously their obligations to respect patient confidentiality and respect all the provisions of HIPAA. At the same time, they honor their obligations to always act in the best interest of those they serve, especially if such persons are the victims of criminal activity or violations of a standard of care. The proposed regulations seriously impede the health care entities' and providers' abilities to meet these obligations. Thus, the Center and the Associations oppose the proposed regulations and urge HHS not to adopt them.

I. <u>The Proposed Regulations Will Impede or Prevent the Enforcement of State, Local and Federal Laws</u>

If adopted, the regulations would circumvent the Constitutionally protected states' rights by thwarting the enforcement of state, local, and even federal laws, in cases involving Reproductive Health Care and abortion, including criminal cases, if the procedure, including abortion itself, was lawful where performed, *regardless of what other laws may have been*

violated. The Proposal states that the proposed regulations would protect from disclosure information that could otherwise be used to enforce state laws on abortion now that such laws have been held to be constitutionally permissible. However, the U.S. Supreme Court recognized the authority of the People themselves, through their elected representatives, to regulate and prohibit abortion. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228 (2022). The current proposed rule would undermine their ability to do so. This is a manifest injustice without any legitimate interest, violative of the state's substantial interest in protecting human life, as well as protecting patients from criminal or negligent activity.

To justify the proposed regulations, HHS compares information about abortion to a psychotherapist's sessions with a patient. The analogy is inapt. Psychotherapy is a form of health care that, to be effective and bring about an eventual cure, must occur in a confidential setting that is protected from disclosure subject to well-recognized exceptions involving threat to life or limb. Those exemptions include evidence of criminal activity such as abuse, which will not be reported if the Reproductive Health Care or abortion are legal. States will lose not only their right, but their obligation to protect their residents from such unlawful actions. And health care entities and providers will be thwarted in meeting their obligations to protect patients from criminal or substandard care, just because a procedure was performed legally.

In one of many surprising statements, HHS claims the need for special protection for abortion is "now more acute than it was before, given the actions taken by states to regulate, and even criminalize" abortion (*id*. at 23510) in the wake of *Dobbs*. But the states have a settled and substantial interest in regulating, and even criminalizing the performance of, abortion and in seeing that their laws in this area are enforced, an interest that the U.S. Supreme Court vindicated in *Dobbs*. HHS is clearly indicating an intention to violate Constitutionally protected states' rights through a mechanism to circumvent the decision of the U.S. Supreme Court. Pressed to its logical extreme, this could form a basis for a future rule preventing the states from enforcing their own laws on *any* issue relating to the health professions and health care. Such a rule would impede or render impossible the enforcement of state law in an area of law in which *states* (not the federal government) have a general police power. The federal government has no police power in this area, but only such powers as the Constitution delegates to it. Any proposal that would blunt the enforcement of state or local law whenever the enforcement proceeding pertains to an abortion is, at its very foundation, arbitrary and capricious.

HHS repeatedly cites the need to foster trust between patient and health care provider as a basis for its proposed rule, but the need to foster trust does not vitiate the interest of states and localities in enforcing their own laws. Oddly, in support of its proposed rule, HHS cites the interest in "enhanc[ing] support for victims of rape, incest, and sex trafficking." Yet to the contrary, the proposed rule would *impede* the investigation and prosecution of persons who commit rape, incest, and sex trafficking, all for the purported purpose of maintaining trust between patient and provider For that matter, it may be the assailant himself who procures the abortion of a child whom he has fathered and, if state lines were crossed, there may be an underlying *federal* violation even if the abortion itself was lawful. That is not a situation that calls for shielding information from the federal, state, or local authorities.

The proposed rule would likewise make it difficult to enforce countless state laws that are designed to protect the lives and health of women, such as requirements pertaining to informed consent and parental notification, including when the procedure itself is legal. Because "reproductive health service," is defined broadly (88 Fed. Reg. at 23552) to mean "care, services, or supplies related to the reproductive health of the individual," all of the problems we have noted with respect to abortion would also impact state, local, and federal laws regulating contraceptives, sterilization, and laws protecting the unborn child, while recognizing the child's humanity: the *Unborn Victims of Violence Act*, Pub. L. No. 108-212 (Apr. 1, 2004), which recognizes the humanity of the child in utero, and the *Emergency Medical Treatment and Active Labor Act* (*EMTALA*), which protects both the pregnant woman and her "unborn child" in an emergency. However, HHS claims that *EMTALA* "protects access" to abortion "in particular circumstances." 88 Fed. Reg. at 23519. We believe that is demonstrably incorrect. *EMTALA* says nothing about abortion but, by its express terms, protects *both* the pregnant woman and her "unborn child" (a term that *EMTALA* uses no less than four times). Health care entities and providers who recognize that they are caring for two patients in such situations, will be impeded from addressing the best interest of both mother and child, violative of the Hippocratic tradition. Additionally, were the Department to require a hospital to provide an abortion, it would violate the Weldon amendment. In our view, there is no conflict between *EMTALA* and the Weldon amendment because *EMTALA* does not require the performance of any abortion. But if there were a conflict, the Weldon amendment would govern because it is the more recent enactment and more specific to abortion. See *Texas v. Becerra*, No. 5:22-CV-185-H, 2022 WL 3639525 (N.D. Tex. Aug. 23, 2022).

The exclusion of unborn children from the definition of "person" appears to create absurd results. On the one hand, if unborn children are not persons, then medical information about them would seem to have no privacy protection under HIPAA even in instances where the unborn child should enjoy such protection. On the other hand, if such information is not subject to disclosure under HIPAA, perhaps on the theory that it is medical information pertaining to the pregnant woman, then the ability to disclose information about unborn children may be chilled in cases where it *should* be disclosable, as, for example, when there is a threat to the health and safety of unborn children, as in the case of contagion to which unborn children are uniquely or especially susceptible.

The adverse impact on the enforceability of federal, state, and local laws is sweeping enough to raise significant questions whether the Department has exceeded its authority under the major questions doctrine. Under that doctrine, agency regulations that have breathtaking scope or great political significance are permissible only if Congress clearly conferred that authority on the agency.[1] While HIPAA has a preemption clause, there is no evidence that Congress intended HIPAA enforcement to have the sort of broad, disruptive, and unprecedented sweep that HHS is now giving the statute.

[1] *See, e.g., West Virginia v. EPA*, 142 S. Ct. 2587 (2022) (EPA lacked the statutory authority to devise emissions standards under the Clean Power Act); *Nat'l Fed. of Indep. Bus. v. Dep't of Labor*, 142 S. Ct. 661 (2022) (OSHA lacked the statutory authority to impose a COVID vaccine mandate in the workplace); *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485 (2021) (CDC likely had no statutory authority to impose a nationwide moratorium on tenant evictions).

Not only are there legal questions, as the above examples illustrate, there may be (and indeed, there often will be) a factual dispute over whether any particular abortion is lawful or not. For example, the lawfulness or unlawfulness of an abortion will often depend on the age of the aborted child and/or the reason for the abortion. Indeed, information may be sought precisely to determine whether, under the particular facts presented, a given abortion is lawful.

Our point is this: it is unreasonable to expect that stakeholders, both officials and providers, will necessarily know with certainty when an abortion is lawful and when it is not. Information may be sought in criminal, civil, and administrative proceedings for the very purpose of *making* that determination. The proposed regulations therefore create a "Catch 22" by requiring stakeholders to know in advance whether an abortion was lawful, essentially requiring a legal opinion and a factual investigation that is hampered at the outset by the inability to obtain the very information needed to form such an opinion and complete such an investigation.

II. Specific Problematic Sections of the Proposed Regulations

The Center and the Associations wish to cite some specific areas that are particularly inconsistent with sound public policy:

A. Section 160.103—Definitions

1. There is a need to Clarify the Definition of "Person" - cf. Pg. **23523:** Define "person" in Section 160.103, not just as "born alive." See 1 U.S.C. § 8: "[T]he 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." [Emphasis added]. In the Proposal "born alive…does not include a fertilized egg, embryo, or fetus." Regardless of the stage of embryonic and fetal development, these human beings are members of the species homo sapiens and should not be victims of discrimination based on stage of development. Whether existing inside the womb, or outside the womb, even the fertilized eggs (which can be alive outside the womb through assisted reproductive technologies) are separate and unique organisms and members of the species homo sapiens.
2. There is a problematic Interpretation of Terms Used in Section 1178(b) of the Social Security Act – cf. Pg. **23523–23527**
    a. Scope of public health: "[L]aws 'providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention." Thus, in the Proposal criminal, civil, or administrative investigations or proceedings are not seen as having public health purposes. This is a significant error. States have a greater interest in imposing their own penalties for actions performed by their citizens, for which there could be criminal or civil liability, than the federal government has in enforcing strict privacy of Public Health Information (PHI). The collection of such health information would be crucial in enforcement of the validly promulgated laws limiting or prohibiting abortion, and this Proposal runs afoul of those interests.

b. Public Health Surveillance, Investigation, or Intervention are defined as "activities aimed at improving the health of a population." Such a definition excludes information relevant to civil and criminal law violations. Thus, it creates a false dichotomy between public laws and laws mandating privacy of health information, without a legal basis and with the intent of making it more difficult for states to enforce their abortion laws.

i. Child Abuse Reporting: While regulated entities are permitted to report suspected child abuse to proper authorities under the Privacy Rule, this "[D]oes not include permission for the covered entity to disclose PHI . . . for a criminal, civil, or administrative investigation into or proceeding against a person based on suspected child abuse." It should not matter if law enforcement approaches the regulated entities or if the regulated entities approach the authorities when there is a suspicion of child abuse.

ii. The Proposal explicitly notes that seeking, obtaining, providing, or facilitating Reproductive Health Care is not child abuse. This creates a problem when the significant evidentiary basis for suspicions of child abuse is that a minor is seeking Reproductive Health Care, etc.

c. There is a problematic Definition of "Reproductive Health Care" - cf. **23527-23258,** which is defined as a broad subcategory of health care applying to a wide range of services and procedures:

i. "[C]are, services, or supplies related to the reproductive health of the individual."

ii. [H]ealth care 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."

a) This could create an absolute privacy right of minors to access whatever procedures they choose, without parental consent including abortion, Hormone Replacement Therapy, contraception, etc., even donation of gametes for invitro fertilization.

B. Section 164.502—Uses and Disclosures of Protected Health Information (PHI): General Rules

1. There is a provision of a "gag order" against the disclosure of PHI by regulated entities – cf. Pg. **23528:** The Proposal would prohibit regulated entities from disclosure when there is investigation into a person for seeking, obtaining, providing, or facilitating lawful Reproductive Health Care.

a. Application of the prohibition – cf. Pg. **23528-23533:** The regulated entity is in a better position to question whether the Reproductive Health Care was provided under circumstances which were lawful or unlawful. It is imprudent to leave such legal determinations solely to medical professionals whose legal expertise has limitations and may be a party to the illegal activity.

2. Clarifying Personal Representative Status in the Context of Reproductive Health Care – cf. Pg. **23533-23534:** The Proposal states that a "regulated entity could not

deny personal representative status to a person, where such status would otherwise be consistent with state and other applicable law, *primarily because that person facilitates or facilitated or provided Reproductive Health Care for an individual*." (Emphasis added).

a. This could lead to situations in which someone pretending to be a personal representative, of the person requiring a representative, consents to an abortion, etc., for the person, discouraging entities from asking any questions whatsoever in order to comply with federal regulations.

C. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity to Agree or Object Is Not Required

1. Attestation to access PHI from the individual for whom the information applies is required but only is specified for information about Reproductive Health Care: "For example, a regulated entity may continue to disclose PHI without an authorization to a state medical board, a prosecutor, or a coroner, in accordance with the Privacy Rule, when the request is for PHI that is not potentially related to Reproductive Health Care or accompanied by the required attestation." [Pg. **23538]** This requirement for an attestation only for information about Reproductive Health Care could lead to denials of such consent and will enable illegal and negligent behavior to be unreported, especially if the consenting party for a minor is an abuser.

a. Providing or Facilitating Reproductive Health Care cannot be considered evidence of abuse, neglect, etc. - cf. Pg. **23538**

i. If a medical professional cannot make such an inference merely from the fact that a young child is coming in to get an abortion, or to get contraception, etc., then on what basis can they make such an inference?

ii. In comparison, when a child presents with a broken nose and a black eye, one would be negligent for not suspecting child abuse, since such injuries are suspicious for children? Why can you not presume that the need for abortion, contraception, etc., is suspicious in a particular circumstance?

b. "PHI may be disclosed pursuant to an administrative request 'for which a response is required by law.'" - cf. Pg. **23538-23539:** Once again, this puts medical professionals into a position where they must make a legal determination that they often are not able to make.

D. Section 164.520—Notice of Privacy Practices for Protected Health Information

1. The regulated entity must notify individuals how their PHI may or may not be used – cf. Pg. **23539:** This may be the most effective way to handle this situation—rather than draft new regulations which could have disastrous effects, the federal government could simply enjoin regulated entities to inform their patients how their PHI may be used.

Conclusion

Clearly there will be more confusion created if these proposed regulations are promulgated, despite the U.S. Department of Health and Human Services' claim that they are needed to reduce confusion. (cf. Pg. **23548**) The claim that the mechanism of valid authorization for information release can be coercive to patients is inconsistent with the Proposal's provision for attestations. Clearly advanced notice of how information may be shared for valid reasons pertaining to criminal and civil complaints could occur.

Furthermore, the claim that the provisions in the Proposal will "strengthen the stability of the family and marital commitment" (cf. Pg. **23551)** is erroneous. The secrecy, with the inability of regulatory and criminal enforcement agencies to have legitimate access to specifically demarcated Protected Health Information sought in connection with a criminal, civil or administrative investigation or proceeding will only breed suspicion and distrust of health care entities, providers, consumers, and their families. This is particularly true since this restriction would only apply to Reproductive Health Care.

For the reasons stated here, the proposed regulations are arbitrary, capricious, an abuse of discretion, and contrary to law. They also present a danger to the very persons they are purported to protect. The regulations, if adopted, are likely to be challenged and, if challenged, are likely to be struck down either on their face or, at a minimum, as applied to situations where they would impede or prevent the enforcement of state, local, or federal law.

We urge the U.S. Department of Health and Human Services to reject this Proposal.

Sincerely yours,

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