AMERICAN ACADEMY OF FAMILY PHYSICIANS

May 31, 2023

The Honorable Xavier Becerra
United States Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Becerra:

On behalf of the American Academy of Family Physicians (AAFP), representing 129,600 family physicians and medical students across the country, I write in response to the notice of proposed rulemaking, "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," as published in the April 17, 2023 Federal Register.

This proposed rule seeks to increase protections for protected health information (PHI) in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care. Specifically, it would prohibit sharing reproductive health-related PHI for criminal, civil, or administrative investigations against any person in connection with said reproductive health services. This proposed rule would require an attestation affirming any such requests are not for prohibited purposes prior to sharing PHI with entities who may be conducting or connected to criminal, civil, or administrative investigations.

The AAFP applauds HHS for undertaking rulemaking to uphold privacy standards for sensitive health information like reproductive health care. **This proposed rule is aligned with AAFP policy and advocacy efforts to protect the patient-physician relationship. To minimize the onus on clinicians and sufficiently disincentivize inappropriate patient information requests and use by law enforcement and other state agencies, the AAFP recommends HHS**:

- **Finalize the proposal to prohibit sharing reproductive health-related PHI for criminal, civil, or administrative investigations against any person in connection with lawfully provided reproductive health services, as well as to require an attestation affirming any such requests are not for prohibited purposes prior to sharing PHI with entities who may be conducting or connected to criminal, civil, or administrative investigations,**
- **Expand this proposal to other types of "highly sensitive PHI," specifically sexual health and gender-affirming care or other health services supporting gender diverse individuals**,
- **Work with electronic health record (EHR) vendors to modernize the functionality of healthcare data management platforms to comply with this proposed rule without cost to the physician or their practice**,
- **Include examples of reproductive health care in the regulatory text to ensure clear and consistent understanding of the applicability of this rule,**
- **Make resources available with publication of the final rule to assist physicians and other clinicians in understanding their rights and how to respond to contradictions between state laws and this proposed rule, and**
- **Make information widely available about a patient's rights regarding requesting and sharing their PHI with other entities and how to report inappropriate attempts of coercion to use or access their PHI.**

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The Health Insurance Portability and Accountability Act (HIPAA), and specifically the Privacy of Individually Identifiable Health Information ("Privacy Rule") within HIPAA, is designed to protect the privacy and security of individuals' PHI. HHS already recognizes certain types of PHI as being "particularly sensitive," like psychotherapy notes, and has afforded additional protections to ensure patients do not forego lawful health care out of fear that their sensitive information would be revealed to other entities outside of the patient-clinician relationship. HHS correctly notes that privacy protections are critical to building trust within a patient-physician relationship. Data shows that trust between a patient and physician leads to better health outcomes and is essential to an individual's well-being, especially within historically marginalized populations.[1, 2, 3, 4] Without appropriate protections for health data, patients may withhold aspects of their health history or physicians may be unable to appropriately record a patient's health history or make medical recommendations out of fear of retaliation or legal threats.[5]

Following the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization,* which struck down longstanding protections afforded by *Roe v. Wade* and *Planned Parenthood v. Casey,* some states have imposed criminal, civil, and/or administrative liability against individuals in connection with obtaining, providing, or facilitating certain reproductive healthcare services, including an abortion. HHS, in accordance with the Federal Trade Commission (FTC) and the Department of Defense (DOD), has determined that reproductive health information is particularly sensitive and requires heightened protections. **The AAFP strongly agrees with this determination and supports heightened protections for reproductive health information. Reproductive care is highly personal and private for many patients. Without appropriate protections, patients may refrain from sharing their full health history with their primary care physician, including in emergency situations, out of fear of inappropriate use or disclosure of their PHI**. This could result in an incomplete health assessment and inappropriate diagnoses, which could lead to worsening of health outcomes and exacerbation of health disparities.

HHS requests comment on whether this proposal should apply broadly to any health care, rather than limiting it to reproductive health care, or whether the proposal should apply to other types of "highly sensitive PHI."

The AAFP supports expanding this proposal to other types of "highly sensitive PHI," specifically sexual health and gender-affirming care or other health services supporting gender diverse individuals. The AAFP recognizes gender-affirming care as medically necessary for transgender, non-binary, and other gender diverse individuals. The AAFP asserts the full spectrum of gender-affirming care should be legal and should remain a treatment decision between a physician and their patient, yet many states are criminalizing the provision of health care for gender diverse individuals just as they are for reproductive health care. Moreover, transgender and nonbinary people often experience a variety of barriers to healthcare, including overt discrimination, inadequate health insurance coverage, and legislative interference in the physician-patient relationship. **Without appropriate protections for gender-affirming care and other types of care for transgender, nonbinary, and gender diverse individuals, the AAFP is extremely concerned that PHI will be used to target patients, their families, and their physicians**.

The AAFP recommends defining "highly sensitive PHI" in a way that protects patients from inappropriate use of their health information by law enforcement. It must include abortion and reproductive health care, gender-affirmation, substance use disorder, and other types of care that may become criminalized.

The AAFP does not support expanding this proposal to all types of health care. While the purpose-based prohibition, discussed in further detail below, will lessen the negative impact on care

coordination, implementation of this proposal will require some additional administrative work. The benefit of preserving a trusting patient-physician relationship in a legal environment where certain types of care are criminalized significantly outweighs the administrivia associated with this proposed rule. However, not all types of health care are criminalized or can be used against a patient or care provider in a court of law or in administrative proceedings, thus the threat to the patient-physician relationship for other types of health care is minimal. As a result, expanding the administrivia to any type of health care would no longer outweigh the benefit of preserving a trusting patient-physician relationship.

HHS further asks whether regulated entities have the technical ability to differentiate between types of PHI in their electronic records and apply special protections if there is a new category considered "highly sensitive PHI."

Currently, not all electronic systems offer this ability to distinguish between "types" of PHI and implementation of this proposal would require an update to EHR systems. The AAFP remains concerned about the feasibility and functionality of EHRs and other platforms to improve data sharing while protecting patient privacy. Modernization of current widely available technology is needed to ensure physicians and their practices can segment appropriate data elements, ensure timely and effective deidentification of data when needed, and uphold patient consent and privacy requirements. Physicians generally lack the ability to segment out certain parts of a patient's record while maintaining the ability to meaningfully share treatment data across the patient's care team for the purposes of care coordination and management. This is a particular challenge for primary care physicians who may provide multiple types of "highly sensitive" care in addition to several other primary care services. This lack of granular data segmentation functionality increases administrative burden and creates challenges for clinicians who are complying with requests not to disclose PHI while still complying with HIPAA and information blocking requirements. **As such, the AAFP urges HHS to work with EHR vendors to modernize the functionality of healthcare data management platforms to comply with this proposed rule without cost to the physician or their practice**.

Purpose-Based Prohibition

This proposed rule would prohibit the use or disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care, or identifying any person for the purpose of initiating such an investigation or proceeding. HHS further proposes that "seeking, obtaining, providing, or facilitating" would include, but not be limited to, expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care, as well as attempting to engage in any of the same.

HHS acknowledges that this purpose-based restriction of PHI use and disclosure is intentional to avoid a disruption in data sharing for care and treatment purposes between clinicians and between a clinician and their patient. **The AAFP agrees with HHS that a purpose-based approach to restrict inappropriate use of reproductive health information will minimize the impact on care coordination and appropriate data sharing between clinicians as compared to a blanket prohibition on reproductive health information sharing.**

HHS requests comment on whether use and disclosure for the prohibited purpose described in this section should be allowed with a valid authorization from the patient. **The AAFP strongly opposes allowing use and disclosure for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating**

lawful reproductive health care or other highly sensitive care, or identifying any person for the purpose of initiating such an investigation or proceeding, even with a valid authorization from the patient. Medical information may have legitimate purposes outside of the physician-patient relationship, such as billing, quality improvement, quality assurance, population-based care, patient safety. However, these purposes do not unduly restrict, criminalize, or penalize the provision of safe, confidential, evidence-based medical care. The AAFP believes that allowing patient authorization to share PHI with an entity with the express purpose of a criminal, civil, or administrative investigation into a patient or physician related to legally provided health care will create a threat to patient safety and physician wellbeing. The AAFP is concerned that the burden of counseling patients on whether or not to permit the use and disclosure of information for these purposes will fall to their physician, who are not equipped to provide legal advice or related counseling. Further, the AAFP shares HHS' concerns that law enforcement and other entities may coerce patients to sharing their medical information to pursue criminal, civil, or administrative investigations against physicians who provide legal health care services, and we believe allowing patient authorization for such use will further promote coercion.

Implementation

When requesting reproductive health PHI for a permitted purpose, HHS proposes to require that the requestor provide an attestation to the regulated entity, such as a physician practice, certifying that the PHI would not be used or disclosed for a prohibited purpose, as described above. The proposed rule does not inhibit regulated entities from using or disclosing reproductive health PHI to defend against a professional misconduct or negligence investigation or proceeding where reproductive health care is involved.

The AAFP supports this method of implementation and encourages HHS to provide a template attestation and best-practices alongside the final rule. The AAFP recognizes that some practices may choose to implement standards of care requiring attestations in situations beyond the prohibited purposes of this proposed rule, such as for any PHI request that includes sensitive health data. We believe clear templates and guidelines for best-practices are necessary to limit excessive use of attestations and to ensure compliance with this rule.

Effect of Concerns About Potential Use and Disclosure of PHI

Throughout the proposed rule, HHS asserts that patients may be unwilling to share their health information and background with their physician out of fear that the information may be shared with law enforcement or otherwise used against them.

The AAFP fully agrees with HHS' reasoning and applauds HHS for the agency's commitment to upholding the patient-physician relationship. AAFP policy asserts that the confidential relationship between physician and patient is essential for the free flow of information necessary for sound medical care. A trusting patient-physician relationship is necessary for a patient to share a complete personal history that enables the physician to comprehend fully, to diagnose logically, and to treat properly.[6] The AAFP supports full access by physicians to all electronic health information within the context of the medical home and with the patient's consent. However, we recognize that the current legal environment requires certain restrictions to the flow of a patient's health information.

The AAFP acknowledges that, despite the limited scope established by the purpose-based prohibition, the proposed required attestation may result in some additional administrative work and/or slight delays in the appropriate exchange of PHI between physicians and other healthcare clinicians. The AAFP also acknowledges that standards of care may be adjusted to require an

attestation for reproductive PHI in more circumstances than required by this proposed rule. **However, this additional administrative work and potential delay in care coordination is a minimal and calculated risk that will preserve the trusting, and in many cases lifesaving, patient-physician relationships.** Patients must be able to depend on their physicians to help them make critical decisions about their personal health. Further, physicians must be able to practice medicine that is informed by their years of medical education, training, experience and the available evidence, freely and without threat of punishment, harassment or retribution.

Rule of Applicability

The proposed prohibition of use or disclosure of reproductive-related PHI would preempt any contradicting state laws and apply in all cases where the reproductive health care (1) is provided outside of the state where the investigation or proceeding is authorized and that is lawful in the state in which such health care is provided; (2) is protected, required, or authorized by Federal 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.

As proposed, this rule would apply in situations where reproductive care is provided under the Emergency Medical Treatment and Labor Act (EMTALA), even when the care is otherwise prohibited in the state. It would also provide protections for physicians providing reproductive care for patients who have traveled across state lines, regardless of whether such care is allowed under the patient's state laws or any other states' laws so long as it is lawful in the location where the patient receives care.

The AAFP strongly urges HHS to finalize this rule of applicability as proposed. As physicians who provide longitudinal primary care services to patients across the lifespan, family physicians are deeply concerned with the impact of state and local laws will have on their patients' health, and that of new patients who may travel across state lines to see them. The AAFP agrees that the protections proposed in this rule and the examples of applicability are needed to ensure physicians can provide and patients can obtain lawful, necessary, and sometimes life-saving health care.

Definitions

HHS proposes to define "reproductive health care" for the purpose of the Privacy Rule as "care, services, or supplies related to the reproductive health of the individual." HHS notes that this is intended to be broadly and inclusive of all types of health care related to an individual's reproductive system. **The AAFP agrees with this broad definition, which includes both prescription and over-the-counter medication and supplies, as well as services provided regardless of the location.** HHS has not proposed a definition of "reproductive health." **The AAFP strongly encourages HHS to define reproductive health in the final rule as "the condition of the reproductive systems during all life stages, including organs, hormones, and mental well-being."**

Further, the AAFP supports HHS including examples of reproductive care in the regulatory text to ensure clear and consistent understanding of the applicability of this rule. These examples should include: contraception, including emergency contraception; pregnancy-related health care, including miscarriage management, molar or ectopic pregnancy treatment, and pregnancy termination; fertility and infertility-related health care; hormone replacement therapy, regardless of diagnosis or purpose; hysterectomy or vasectomy; and other types of services, care, or supplies used for the diagnosis and treatment of conditions related to the reproductive system. The intent of this proposed rule is to protect the patient-physician relationship by establishing additional

protections for the use and disclosure of particularly sensitive PHI given the current regulatory and legal environment. As such, the AAFP urges HHS to clearly establish these examples of reproductive health care in the regulatory text. The AAFP encourages HHS to also provide examples of gender-affirming care in the regulatory text when expanding this proposed rule to other types of "highly sensitive PHI."

HHS proposes to clarify that the definition of "natural person" under HIPAA is consistent with existing statute and does not include a fertilized egg, embryo, or fetus. HHS further clarifies that this definition is specific to HIPAA and is still applicable in states where the definition of a "person" includes a fetus. **The AAFP agrees with this clarification and finds it necessary to include in the final rule.** This clarifies that the fetus's PHI is included with a mother's PHI until after a live birth, in alignment with standard practice in obstetrics and gynecology.[7] Moreover, the PHI protections under this proposed rule apply only to the mother until after a live birth.

State Reporting

The Privacy Rule allows for the use and disclosure of PHI without authorization for public health reporting, typically on "disease or injury," "birth," or "death." This reporting is typically for cases or conditions of certain diseases, like COVID-19 or foodborne illness, certain types of injuries, like those caused by gunshots, knives, or burns, or conditions or incidents that may be linked to child abuse. The majority of states adhere to the Model State Vital Statistics Act which includes distinct categories for "live births," "fetal deaths," and "termination of pregnancy," where an abortion may not be considered a "fetal death." HIPAA includes an exception for these types of public health reporting but does not include an exception for criminal or other laws outside of public health concerns. HHS thus asserts that any state reporting requirements on seeking, obtaining, providing, or facilitating reproductive health care would be inconsistent with and not permissible under the Privacy Rule.

HHS further clarifies that this rule still allows for reporting known or suspected child abuse and neglect to relevant authorities, so long as the relevant authority is authorized to receive such a report and only the minimum necessary information is shared. HHS further clarifies that the definitions of "person" and "child" must be met for PHI to be lawfully shared for a report of child abuse or neglect. As discussed above, a fetus does not constitute a "person" under HIPAA and this provision preempts state law.

The AAFP strongly agrees with this interpretation and clarification. Public health reporting is a critical tool for state officials, communities, and physicians to understand and respond to public health threats and inequities in health care access and treatment. The AAFP agrees that this rule does not prevent state reporting requirements that are necessary for the health and wellbeing of individuals and their communities. However, HHS is correct in asserting that certain reporting requirements may be used inappropriately to target patients and physicians for seeking, providing, or facilitating lawful healthcare.

Preemption of State Law

As proposed, the changes discussed above would preempt any contrary state laws. HHS clarifies that if a regulated entity is issued a court order or subject to other legal action consistent with state law but inconsistent with the currently proposed Privacy Rule and complies with the court order or other legal action, the regulated entity would be in violation of the Privacy Rule and subject to an OCR investigation and civil monetary penalties.

The AAFP agrees with HHS that preemption of state law is necessary to sufficiently protect patients and their physicians from having PHI disclosed to law enforcement and used against them when a state law would require such disclosure. However, we remain concerned that this places physicians in an impossible position by either requiring that they violate state or local laws or face possible penalties for violating federal privacy regulations. **The AAFP strongly encourages HHS to make resources available with publication of the final rule to assist physicians, particularly those in small and solo practices, in understanding their rights and how to respond to contradictions between state laws and this proposed rule. The AAFP urges HHS to exercise enforcement discretion in such cases and avoid further penalizing physicians and other clinicians who may be forced to comply with court orders or other legal action in violation of the privacy rule.**

Right of Access

In this proposed rule, HHS reaffirms an individual's right to request their own PHI and that this right of access may not be denied under the proposed protections. **The AAFP agrees that a patient's right to their PHI is necessary to promote shared decision making between a patient and physician and that this right is paramount to the proposed protections**. The AAFP appreciates that, in current HIPAA rules and this proposed rule, there are no instances that prohibit patient's ability to request and obtain their personal PHI (except when it may be harmful to the patient in the case of psychotherapy notes). It is of the utmost importance for patients to maintain access to their PHI and ensure it can be shared with members of the patient's care team.

The AAFP also shares HHS' concerns that a patient may be coerced into requesting and then sharing their PHI as means for law enforcement or other entities to take legal action against a physician or other individual involved in seeking, obtaining, or providing lawful health care. **As such, the AAFP strongly urges HHS to make information widely available about a patient's rights regarding requesting and sharing their PHI with other entities and the right to decline to do so. These resources should include where patients can report such attempts of coercion to OCR, the Department of Justice, or other entities**.

Thank you for the opportunity to provide these comments. The AAFP is committed to upholding patient privacy and protecting the patient-physician relationship, and we look forward to working with your agency to do so. For additional questions, please contact Morgan Bailie, Senior Regulatory Specialist, at mbailie@aafp.org.

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