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June 16, 2023

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

Re: Proposed Rules Regarding Reproductive Health Care Privacy

Dear Mr. Coffey:

The County of Santa Clara appreciates the opportunity to submit comments on the U.S. Department of Health and Human Services' (HHS) proposed rules related to reproductive health care privacy (Proposed Rules).

The County of Santa Clara Health System provides local healthcare safety net services as well as comprehensive care and services including reproductive health care services to the residents of Santa Clara County. It is one of the largest public health and hospital systems in the United States. The County of Santa Clara Health System operates three major hospitals; more than a dozen primary and specialty care clinics; the Behavioral Health Services Department; the Public Health Department; the Custody Health Services Department; and a health plan, among other components. The Health System's goal is to provide integrated, person-centered, evidence-based care across all types of health care programs and services and to protect and uphold the privacy of patients' protected health information. The requirements of the Health Insurance Portability and Accountability Act of 1996's (HIPAA) Privacy Rule and proposed changes to its provisions have a significant impact on the County of Santa Clara Health System's ability to efficiently respond to requests for medical records and to meaningfully protect patients' privacy rights.

Now, more than ever, robust privacy protections for reproductive health care records are a critical prerequisite to ensure patients seek the reproductive health care they need. With many individuals facing significant barriers to accessing reproductive health care as well as the threat of civil and criminal liability under certain state or local laws for receiving reproductive health care services, strong and functional privacy protections will determine whether a patient seeks medically necessary care.

While the County is in agreement with the intent of the Proposed Rules, the proposed privacy structure as outlined would not achieve the desired goal of ensuring strong privacy protections for reproductive health care records, but would instead place ineffective administrative burdens on medical records department staff to function as a court instead of shifting the burden and liability to the requestor seeking such information for non-treatment, payment, or operations (TPO) purposes. The Proposed Rules accurately identify that disclosures for judicial and administrative proceedings pose a significant risk to patient who seek reproductive health care. A framework where requestors face additional process requirements and are subject to redisclosure prohibition as well as penalties for non-compliance offers an effective solution that is narrowly tailored to protect patient privacy. Courts, not medical records staff, are experts in deciding when information should be released pursuant to a search warrant, subpoena, or under a protective order.

The County supports the Proposed Rules recognition of the need for public health authorities to continue to access protected health information, including reproductive health care records. The continued commitment to allowing covered entities to use and disclose protected health information for public health surveillance, investigation, or interventions acknowledges the vital function of public health departments.

In light of the sensitive patient privacy rights at issue, the County proposes that HHS consider amending the HIPAA Privacy Rule to align with the schema of protections already in place for certain types of particularly sensitive medical records, such as substance use treatment records.

Accordingly, the County offers the following comments:

- 1. The proposed new section 45 C.F.R. § 164.509 requiring an attestation does not adequately address the patient privacy concerns raised in the Proposed Rules.**

The Privacy Rule generally requires HIPAA covered entities to provide to patients, upon request, with access to the protected health information (PHI) about them maintained by or for the covered entity. This includes the right to inspect or obtain a copy of the PHI, as well as to direct the covered entity to transmit a copy to a designated person or entity of the individual's choice. Considering this general right of access, the purpose of the authorization is not to serve as a barrier to accessing records and is usually meant to memorialize the individual's consent and

request to access or disclose their records. In authorizations, an individual may write that the purpose of the release of the records is “at the request of the individual.” 45 C.F.R. § 164.508(c)(1)(iv). Under the current schema, a regulated entity would not need to probe this stated purpose.

The proposed new section 164.509 would create a class of uses and disclosures for which an attestation is required to ascertain purpose of use for certain disclosures. This proposed condition would require a regulated entity to obtain assurances from the person requesting the PHI, in the form of a signed and dated written statement attesting that the use or disclosure would not be for a purpose prohibited under 45 C.F.R. § 164.502(a)(5)(iii) where the request is made under the Privacy Rule permissions at 45 C.F.R. § 164.512 and the request is for PHI that is potentially related to reproductive health care. Unfortunately, the attestation requirement creates an additional burden on regulated entities without providing any benefit for patient privacy. Generally, requests for medical records specify a date range for all care provided, not the specific type of medical records sought. To verify whether an attestation is even necessary for certain requests, medical records staff would be required to sift through medical records to determine the specific content of the records, which will significantly delay access to records, even when a patient has not accessed reproductive health care.

While a signed attestation may be sufficient to protect the regulated entity from liability, it is not a meaningful mechanism to vindicate the patient’s privacy interest in their reproductive health care information. Additionally, it is not clear what the consequences will be to a requestor should they fail to provide the attestation when seeking protected health information that may include reproductive health care records or misuse the documents contrary to their statement in the attestation because the current framework imposes penalties on the covered entity for a breach, not the requestor. It would be more effective to impose a limited redisclosure obligation on requestors that receive reproductive health care records for purposes other than TPO, similar to the redisclosure prohibition for substance use treatment records in 42 C.F.R. § 2.32 or for medical records under California Civil Code section 56.13. A redisclosure prohibition with penalties for violations on the requestor would effectively limit use reproductive health care records with a privacy mechanism that is tailored to address the risk of harm to the patient while placing the consequences on the proper party, the requestor.

**2. HIPAA’s current framework for the release of PHI in disclosures for judicial and administrative proceedings is inadequate to protect reproductive health information.**

As the Proposed Rules note, disclosures for judicial and administrative proceedings that include reproductive health care records pose a significant risk to patients seeking medically necessary health care. Under HIPAA’s current framework, so long as a patient has notice of the subpoena, a covered entity may release the patient’s protected health information. The County agrees this framework is inadequate, but respectfully offers an approach that would better protect

the patients' privacy interests while keeping reproductive health care records within the protection of the covered entity and placing the burden to prove that a request for reproductive health care records for non-TPO purposes is lawful on the requestor.

The procedure already in place to protect 42 C.F.R. Part 2 records could be adopted and modified to create additional privacy protections for reproductive health care records. Under 42 C.F.R. § 2.61 *et seq.*, substance use treatment records may not be released pursuant to a subpoena, or a standard court order; rather, "a unique kind of court order is required to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290dd-2." The regulatory framework outlines the narrow circumstances in which a court would be allowed to authorize the disclosure of Part 2 records as well as the procedural process that must be followed, which includes notice to the patient as well as a review of the evidence and criteria for determining that good cause exists to issue an order authorizing the disclosure of sensitive records. 42 C.F.R. §§ 2.63-2.66. These same procedures should also be used to protect the patient privacy interests in their reproductive health care records and to ensure that the records being sought are not being requested for a criminal, civil, or administrative investigation into or proceeding against, any person for seeking, obtaining, providing, or facilitating reproductive health care or to identify any person for the purpose of initiating such an investigation or proceeding.

The requestor of the records should bear the responsibility of establishing their request is lawful, instead of the covered entity, by being required to articulate to a court their rationale for the records requested and demonstrate that other ways of obtaining the information are not available or would not be effective. Courts, not medical records staff, are uniquely trained and capable of serving this factfinding purpose of a evaluating a request for reproductive health care records and to adjudicate whether the reproductive health care records are being sought for a permissible purpose.

**3. The County supports the continued commitment that covered entities may use or disclose PHI to conduct public health surveillance, investigation, or interventions under 45 C.F.R. 164.512(b)(1)(i).**

The Privacy Rule currently permits a covered entity to use or disclose PHI to conduct "public health" surveillance, investigation, or intervention. 45 C.F.R. § 164.512(b)(1)(i). Section 1178(b) of the Social Security Act exempts state laws providing for "public health" surveillance, investigations, or intervention from HIPAA's general preemption rule. The proposed rule defines public health surveillance, investigation, or intervention as population-based activities to prevent disease and promote health of populations. The rule goes on to specify that such public health activities do not include uses and disclosures for the criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, or to identify any person for the purpose of initiating such an investigation or proceeding.

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The County supports the clear delineation between public health work and civil, criminal, or administrative investigations against individuals for seeking, obtaining, providing or facilitating reproductive health care that is lawful in the state where the care is provided or is protected, required, or authorized under federal law. Maintaining patient privacy and community trust is vital for public health departments to effectively conduct their mission of protecting and promoting public health and reaching some of the most vulnerable community members. The County's Public Health Department has a long-standing commitment to protect the public against communicable diseases, prevent chronic disease and injury, provide targeted maternal, child, adolescent, and family health services, and utilize data to inform public health interventions. To further these goals, the County's Public Health Department has prioritized high-impact strategies to address the root causes of disparate health outcomes, to shape policy to support positive health outcomes, and to improve access to data to assess health status in the county and increase the efficacy of public health interventions.

Public health work focuses on improving the health of members across the community and encouraging residents to seek necessary health care. Current law authorizes public health authorities to access PHI to perform their infectious disease and response functions. Similarly, public health authorities should have access to reproductive health care information to order to be able to fulfill their role. The handling of sensitive information is not new to public health departments and, accordingly, they are well-positioned to handle sensitive information. Given the importance of the work of public health departments, the ability to apply other protections if necessary to address the risk of redisclosure, and the proven ability to appropriately handle sensitive information, the County supports the continued authority for public health departments to access reproductive health care records to promote and protect public health.

Thank you for the opportunity to comment on this critical issue.

Very truly yours,

JAMES R. WILLIAMS  
County Counsel



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Deputy County Counsel