June 14, 2023

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

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: HIPAA Privacy Rule to Support Reproductive Health Care Privacy (RIN 0945-AA20)

Dear Secretary Becerra:

The American Society of Hematology (ASH) appreciates the opportunity to comment on the Department of Health and Human Services’ (HHS) proposed rule entitled, HIPAA Privacy Rule to Support Reproductive Health Care Privacy.

ASH represents more than 18,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the field of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy.

ASH thanks HHS and the Office of Civil Rights (OCR) for issuing this proposed rule. We are pleased to see these efforts to strengthen reproductive health care privacy to better protect sensitive information related to reproductive health care and bolster patient-provider confidentiality. The policies outlined in this proposed rule are very forward-thinking and well suited to protect the rights of those seeking care related to reproductive health. ASH supports this proposed rule and offers the following comments for your consideration.

Strengthening Patient-Provider Confidentiality

According to HHS OCR, this proposed rule is intended to strengthen patient-provider confidentiality and facilitate full and honest exchange of health care information between patients and providers. ASH agrees that provider-patient confidentiality as it relates to reproductive health care information must be strengthened. ASH agrees with HHS OCR that information about a patient’s reproductive health care is particularly sensitive and requires heightened protections, like e.g., psychotherapy notes that are protected connected to the nature and treatment of mental health conditions.

Specifically, it is important for health care providers to be able to openly discuss the full range...
of health care needs and options without the threat of legal penalties. This unrestricted communication significantly improves patients’ reproductive autonomy and is crucial for fostering a trusting and collaborative provider-patient relationship, allowing for more accurate diagnoses, effective treatment plans, and improved health outcomes. It also ensures that patients feel comfortable openly expressing their concerns and preferences, enabling them to make informed decisions with their providers, ultimately enhancing the overall quality of healthcare delivery.

Definitions

The proposed rule adds and defines a new term, “reproductive health care,” as a subcategory of the existing term “health care.” HHS OCR proposes to define “reproductive health care” as “care, services, or supplies related to the reproductive health of the individual,” and is interpreting “reproductive health care” to include, but not be limited to:

1. Contraception, including emergency contraception;
2. Pregnancy-related health care, including but not limited to miscarriage management, molar or ectopic pregnancy treatment, pregnancy termination, pregnancy screening, products related to pregnancy, prenatal care and similar or related care;
3. Fertility- or infertility-related health care;
4. Other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system.

ASH would like to acknowledge that there are unique barriers and disparities related to reproductive health care for individuals with sickle cell disease, blood cancers, and other hematologic conditions. ASH agrees with HHS OCR’s proposed definition of reproductive health care; however, we recommend the addition of “preconception counseling” and “management of mental health disorders relating to reproductive health, such as postpartum depression,” to this list. Additionally, ASH would like to clarify that this definition also includes contraception in association with pre-existing and new medical conditions, such as patients with conditions such as factor V Leiden +/− thromboembolic episodes. Regarding “fertility- or infertility-related health care,” ASH would like to ensure that this will include fertility preservation in advance of treatment for cancer, sickle cell disease, or other hematologic conditions. This will provide individuals with the opportunity to protect their reproductive potential and preserve their ability to have children after completing treatment. With these additions and clarifications, we believe this will be a comprehensive definition and will cover the relevant care delivered to patients with hematologic diseases and disorders.

Uses and Disclosures of Protected Health Information (PHI)

Under this proposal, HHS OCR would prohibit the disclosure of PHI when reproductive health information is sought as part of a criminal, civil, or administrative investigation against patients, health care providers, or others involved with the facilitation of reproductive health care. The proposed rule would amend the uses and disclosures of PHI to add a purpose-based prohibition to ban a covered entity or business associate from using or disclosing PHI for certain non-health care purposes.

ASH supports this proposal; however, we have concerns that these policies may not effectively safeguard patients and their providers who provide medically essential practices that are legal. For example, with the integration across state lines of electronic medical charts through systems like EPIC, medical notes about a procedure conducted in one state where it is legal may be readily accessible to healthcare providers in states where it is not legal. This lack of automatic separation of records poses a risk to both the patient and their physician.

ASH strongly opposes the misuse of medical information for criminal purposes and firmly supports upholding HIPAA in all cases, including the sharing of reproductive health care information. Additionally, the variability of state regulations raises concerns about inconsistencies when it comes to crossing state lines. ASH respectfully recommends that HHS OCR consider these comments as the HIPAA privacy rule is finalized to better protect patients’ health information.
ASH recognizes that the prohibition against disclosure applies even if a patient has executed an authorization. HHS OCR reasoned that the authorization could be used improperly. In addition, HHS OCR proposes an attestation requirement for disclosures that are "required by law" or similar when not prohibited. The proposed rule will require covered entities, in certain circumstances, to obtain an attestation from the person requesting the use or disclosure that the use or disclosure is not for a prohibited purpose. ASH supports the proposed attestation requirement and does not think this will create an additional administrative burden. We believe preserving HIPAA and prioritizing the well-being of our patients take precedence over the administrative burden.

ASH thanks HHS for the opportunity to share these comments. Should you have any questions or require further information, please contact Suzanne Leous, ASH’s Chief Policy Officer, at sleous@hematology.org.

Sincerely,

Robert A. Brodsky, MD
President