



June 16, 2023

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

Submitted electronically via regulations.gov

Re: HIPAA Privacy Rule to Support Reproductive Health Care Privacy
[RIN Number 0945-AA20]

Dear Secretary Becerra:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services (HHS) for the opportunity to provide comments in response to the proposed rule titled "HIPAA Privacy Rule to Support Reproductive Health Care Privacy" published in the Federal Register on April 17, 2023 (Proposed Rule).

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

In this comment, AMCP expresses its support for finalizing HHS' proposal to prohibit sharing reproductive health-related protected health information (PHI) for criminal, civil, or administrative investigations in connection with lawful reproductive health services.

Definitions

AMCP generally supports defining terms to prevent potential confusion due to conflicting interpretations. AMCP concurs with HHS' proposed definitions, including the clarification that the definition of "person" and related terms is statutorily limited to the definition at 1 U.S.C. 8.

Defining "reproductive health" in the Final Rule could help to avoid potential misinterpretations and further advance public health policy. In developing such a definition, AMCP suggests starting with the definition articulated by the International Conference on Population and Development in 1994, which is widely espoused by the global health and human rights communities. This definition focuses on reproductive well-being and personal autonomy: "Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and

to its functions and processes. Reproductive health implies that people ... have the capability to reproduce and the freedom to decide if, when and how often to do so.”¹

Uses and Disclosures of Protected Health Information

AMCP supports HHS’ proposal to prohibit regulated entities from using or disclosing an individual’s PHI for use against any individual, regulated entity, or other person for the purpose of a criminal, civil, or administrative investigation or proceeding in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. AMCP agrees with HHS that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) should preempt state or local laws requiring the disclosure of highly sensitive PHI for non-public health purposes – such as criminal, civil, or administrative investigations or proceedings that are based on whether the patient sought, obtained, provided, or facilitated reproductive health care.

As a professional organization dedicated to ensuring access to needed medications,² AMCP supports the Proposed Rule’s overarching goal of safeguarding highly sensitive PHI. Privacy and confidentiality have long been recognized as essential elements of the relationship between patients, pharmacists, physicians and other health care professionals. When patients are confident that their sensitive PHI will remain private and not be used against them, they can establish a level of trust with their health care providers. This trust encourages the patient to obtain medically necessary care and to provide their health care provider with all relevant health information. The compilation of a complete, accurate medical record is essential to optimal patient care and leads to better health outcomes. Patients need assurance that those privileged to access their confidential PHI will protect such information from inappropriate disclosure and that the responsible, judicious use of such information will enhance their medical care.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP’s comments or would like further information, please contact AMCP’s Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,



Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer

¹ For the complete definition set forth by the International Conference on Population and Development, see:

https://www.un.org/development/desa/pd/sites/www.un.org.development.desa.pd/files/files/documents/2020/Jan/un_1995_programme_of_action_adopted_at_the_international_conference_on_population_and_development_cairo_5-13_sept._1994.pdf, at page 30, section 7.2.

² <https://www.amcp.org/about/about-amcp/amcp-strategic-priorities>