

March 3, 2021

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: NPRM, RIN 0945-AA00
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically to www.regulations.gov

Re: HHS–OCR–0945–AA00 for the Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement

Dear Acting Secretary Cochran:

The American Nurses Association (ANA) appreciates the efforts of the Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS) to modify privacy regulations to support and facilitate better coordinated care and patient access to information. While care coordination and individual engagement are important aspects of the nation's health care delivery system, so is ensuring patient privacy and upholding the protections under the Health Insurance Portability and Accountability Act (HIPAA). ANA supports the OCR's review of HIPAA privacy and security regulations that may impede the transformation to value-based health care or that limit coordinated care among individuals and covered entities without meaningfully contributing to the protection of the privacy and security of an individual's personal health information (PHI). However, the balance between privacy and disclosure of PHI requires special consideration. ANA remains concerned that certain proposed provisions in the above-captioned rule may jeopardize patient privacy without further clarification of evidence-based standards. Through this comment opportunity, we urge HHS to:

- Finalize the proposed provisions related to defining an Electronic Health Record (EHR) and allowing patient greater access and control of their PHI.
- Refrain from finalizing the proposed elimination of the requirement for written acknowledgment of a provider's Notice of Privacy Practices (NPP).
- Carefully consider expanding disclosure standards to ensure that patient privacy is balanced appropriately with care facilitation or response to health or safety threats. The agency should monitor that disclosures are made appropriately and provide continued guidance and education to covered entities.

ANA Principles on HIPAA, Privacy, and Confidentiality

HIPAA was enacted to not only protect PHI but also to provide insurance continuity, increase the federal government's authority over fraud and abuse in the health care arena, and to further develop the electronic health record. HIPAA has also ensured that information transferred from one covered entity to another is protected, while also giving individuals rights with respect to their PHI.

ANA fully supports the underlying principles of HIPAA and believes that protection of privacy and confidentiality is essential to maintaining the trusting relationship between health care providers and patients and integral to professional practice.¹ The lack of privacy can undermine patients' relationships with providers and may adversely affect the quality of care, if patients are reluctant to share personal health information.² Recognized as the most honest and ethical profession and most trusted health professionals, nurses must be at the table to determine how information is used to not only keep trust but ensure positive health outcomes for all patients.³

The Code of Ethics for Nurses (the Code) Provision 3.1, guides the nurses role in protecting the rights of privacy and confidentiality.⁴ Moreover, nurses are also subject to Provision 2 of the Code which states "the nurse's primary commitment is to the patient, whether an individual, family, group, community or population."⁵ Nurses are instructed to collaborate with all health professions in order to provide high-quality, patient centered care which requires transparency, shared decision-making, and open communication among all who share concern and responsibility for health outcomes.⁶

HHS Must Support Increased Use of EHR and Ensure Patient Access to PHI to Further Care Coordination

The proposed rule would add a definition for the term "electronic health record" that appropriately defines clinicians and identifies the nurse's role in patient care delivery. Further, the proposed rule includes several modifications allowing for patient access to PHI in EHRs and more transparency with respect to disclosures within the EHR. As the proliferation and increased use of EHRs become commonplace in the health care delivery system, HHS is right in proposing provisions that capitalize on EHR capabilities to support care coordination and case management.

Care coordination has long been a core professional standard and competency for nurses. Through evidence-based practices, care-planning, educating patients and their families, and facilitating continuity of care for patients across providers, nurses need to be recognized for their role in improving care across all healthcare settings. ANA encourages rules and regulations to allow for a patient-centered approach to care and engaging the patient and family at all encounters across the care trajectory. As such, the association encourages HHS to finalize the proposed provisions related to defining an EHR and allowing patient greater access and control of their PHI.

Patients Must be Provided Complete Information About Their Privacy Rights

In the proposed rule, HHS would eliminate the requirement for written acknowledgement of a provider's NPP and modify the requirements for what NPPs must contain. It is critical that patients fully

¹ American Nurses Association (June 2015). "Position Statement on Privacy and Confidentiality." Retrieved from: <https://www.nursingworld.org/~4ad4a8/globalassets/docs/ana/position-statement-privacy-and-confidentiality.pdf>

² Ibid.

³ Gallup Poll, December 2020, "U.S. Ethics Ratings Rise for Medical Workers and Teachers," retrieved from <https://news.gallup.com/poll/328136/ethics-ratings-rise-medical-workers-teachers.aspx>

⁴ American Nurses Association (2015, Jan.). Code of Ethics for Nurses with Interpretive Statements. Provision 3.1. Retrieved from <https://www.nursingworld.org/coe-view-only>

⁵ American Nurses Association (2015, Jan.). Code of Ethics for Nurses with Interpretive Statements. Provision 2. Retrieved from <https://www.nursingworld.org/coe-view-only>

⁶ American Nurses Association (2015, Jan.). Code of Ethics for Nurses with Interpretive Statements. Provision 2.3. Retrieved from <https://www.nursingworld.org/coe-view-only>

understand their privacy rights and how a provider ensures compliance with all requirements to keep PHI private. ANA is concerned that eliminating the written acknowledgement requirement will remove an important care component of educating patients on their rights. While the association understands that some providers may find this requirement burdensome, we believe that making patients aware of their rights under HIPAA outweighs any perceived burden. As part of their critical role in care delivery, nurses educate and advise patients and their family members as they navigate the health care system—including education about privacy rights. The conversation between a patient and provider about how HIPAA protects their information is critical. As such, ANA urges HHS not to finalize the proposed elimination of the requirement for written acknowledgment of a provider’s NPP.

HHS Must Carefully Consider Expanding Privacy Standards

Covered entities can use and disclose PHI without consent utilizing a “professional judgment” standard. The proposed rule would modify that standard to allow an entity to use “good faith” to determine use and disclosure that is in the best interest of the patient. While both standards are subjective, ANA is concerned that the proposed change could result in broad interpretations of when disclosure is appropriate. Broad interpretations could lead to disclosure that undermines the privacy of patients. HHS must carefully consider this proposed change and monitor for disclosures that could violate patient privacy.

Additionally, the agency is proposing to change the privacy standard for disclosure when there is a threat to health or public safety. Currently, covered entities are permitted to disclose PHI in instances where disclosure serves to avert a threat to health or safety—if that threat is “serious and imminent.” The rule proposes to lessen that strict standard to a “serious and reasonably foreseeable” standard. As noted above, these standards are subjective and could lead to broad interpretation. The association understands the agency’s reasoning for the proposed change to allow covered entities to better determine whether threat of harm may be imminent in light of recent mass violence events. The proposed change intends to prevent situations where a covered entity does not disclose information out of concern that they do not have the authority because they are unable to determine if the threat is truly imminent. However, expansion to “reasonably foreseeable” may result in covered entities more likely to disclose patient information out of an abundance of caution and to prevent potential liability issues.

ANA urges HHS to carefully consider expanding disclosure standards to ensure that patient privacy is balanced properly with care facilitation or response to health or safety threats. The agency should monitor that disclosures are made appropriately and provide continued guidance and education to covered entities.

ANA is the premier organization representing the interests of the nation’s 4.2 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA members also include the four advanced practice registered nurse roles (APRNs): nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs). ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. RNs serve in multiple

direct care, care coordination, and administration leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions including essential self-care, and provide advice and emotional support to patients and their family members.

ANA appreciates the opportunity to submit these comments and looks forward to continued engagement with HHS on this important issue. Please contact Ingrida Lusi, Vice President, Policy and Government Affairs, at (301) 628-5081 or Ingrid.Lusis@ana.org with any questions.

Sincerely,


Debbie Hatmaker, PhD, RN, FAAN
Chief Nursing Officer/EVP

cc: Ernest Grant, PhD, RN, FAAN, ANA President
Loressa Cole, DNP, MBA, RN, NEA-BC, FACHE, FAAN, ANA Chief Executive Officer