

February 8, 2019

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

Submitted electronically to <https://www.regulations.gov>

Re: HHS-OCR-09454-AA00 for the “Request for Information (RFI) to assist OCR in identifying provisions of the Health Insurance Portability and Accountability Act privacy and security regulations that may impede the transformation to value-based health care or that limit or discourage coordinated care among individuals and covered entities (including hospitals, physicians, and other providers, payors, and insurers), without meaningfully contributing to the protraction of the privacy or security of individuals’ protected health information”

Dear Secretary Azar,

The American Nurses Association (ANA) is pleased to provide written comment to the Centers for Disease Control and Prevention (CDC), regarding Docket No. FDA-2018-N-2727 for “Request for Information (RFI) to assist OCR in identifying provisions of the Health Insurance Portability and Accountability Act privacy and security regulations that may impede the transformation to value-based health care or that limit or discourage coordinated care among individuals and covered entities (including hospitals, physicians, and other providers, payors, and insurers), without meaningfully contributing to the protraction of the privacy or security of individuals’ protected health information”. ANA is the premier organization representing the interests of the nation’s 4 million registered nurses (RNs) through its constituent and state nurses associations, organizational affiliates, and individual members. RNs serve in multiple direct care, care coordination, and administrative 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, and provide advice and emotional support to patients and their family members. ANA members also include those practicing in the four advanced practice registered nurse (APRN) roles: nurse practitioners, clinical nurse specialists, certified nurse-midwives and certified registered nurse anesthetists.¹ ANA is dedicated to partnering with

¹ The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model

health care consumers to improve practices, policies, delivery models, outcomes, and access across the health care continuum.

ANA's Principles on HIPAA, Privacy, and Confidentiality

The Health Insurance Portability and Accountability Act (HIPAA) was enacted to not only protect Personal Health Information (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.² 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.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 Recognized as the most honest and ethical profession and most trusted health professionals⁷, 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.

describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.

² 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>

³ *Ibid*

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>

⁷ Gallop Poll, December 2018, "Nurses Again Outpace Other professions for Honesty, Ethics", retrieved from: <https://news.gallup.com/poll/245597/nurses-again-outpace-professions-honesty-ethics.aspx>

The balance between privacy and timely coordination of care can require special consideration. ANA supports the Office of Civil Rights 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 individual's PHI. ANA also encourages OCR to provide more education to all providers, patients, and covered entities on HIPAA regulations to ensure that unintended barriers are not occurring to delay or prevent information from being shared during the care of individuals.

ANA Supports Coordinated Care Through the Increased Use of Electronic Health Records for Improved Interoperability

ANA continues to support the achievement of the 21st Century Cure's Act establishment of an interoperable health system that fully empowers individuals to use their Electronic Health Information (EHI); enables providers and communities to deliver smarter, safer and more efficient care; and promotes innovation at all levels throughout the ecosystem. However, we encourage OCR to support ensuring parity of resources and incentives as a path to promote interoperability to allow for increased coordinated care. Ensuring parity of available resources and infrastructure, including incentives, across all settings and providers in which patients receive care is paramount to the mission of interoperability and vision for patient-centered care.⁸ To ensure parity we recommend policies for how eligible providers are defined and identified and encourage inclusive language for all types of providers that provide patient care, including the definition of care delivery should be expanded to include concepts of "patient-centered care" and "interdisciplinary teams". Increasing the number of providers using EHR's to the fullest extent ensures timely transfer of pertinent information to individuals and their care team.

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. Studies evaluating Health Information Exchanges (HIE) in the community setting were more likely to find benefits from interoperability efforts than

⁸ American Nurses Association (June 2018). American Nurses Association and Alliance for Nursing Informatics. "ANA and Alliance for Nursing Informatics Comments on Promoting Interoperability and Electronic Healthcare Information Exchanges through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers". Retrieved from: <https://www.nursingworld.org/~49f420/globalassets/docs/ana/anianacmsinteroperability-final.pdf>

studies that evaluated health system HIEs, highlighting the importance of interoperability efforts across the entire care trajectory.⁹ Again, ANA encourages inclusion of all relevant providers in any incentive program.

Promoting Information Sharing in Addressing the Opioid Crisis and Serious Mental Health Conditions

The Privacy Rule currently allows covered entities to disclose PHI to caregivers in certain circumstances, including certain emergency circumstances, and this permission has relevance in relation to the opioid crisis and efforts to address serious mental health conditions. ANA, and its nurse members, have been on the front lines of fighting this crisis. Coordinated care and access to treatment, including complimentary and alternative medicines and social supports, are vital to addressing opioid addiction, other substance use disorders, and serious mental health conditions.

ANA fully supports taking steps to increase the interoperability of state Prescription Drug Monitoring Programs (PDMPs) in order to better monitor the prescription of opioids and other prescribed substances. As noted in ANA's August 2018 issue brief, "The Opioid Epidemic: The Evolving Role of Nursing"¹⁰, as of August 2017, all 50 states, the District of Columbia and the territory of Guam have a PDMP program.¹¹ However, there is no standard related to drugs monitored, or data collected or shared between states. Provider use of the PDMPs varies according to state mandate and ease of system access. Emerging research on the efficacy of PDMPs has shown mixed results, in part due to the lack of standardization across programs. ANA and the Alliance for Nursing Informatics jointly noted in a February 2018 letter to the Office of the National Coordinator for Health Information Technology¹² that "there is currently not complete interoperability among the states on data sharing. In addition, current epidemiological data are not collected as part of PDMPs. A single on-ramp to such data could not only bolster prescription drug monitoring but open avenues to more comprehensive data mining to support population health and evidence-based practice development." ANA

⁹ Menachemi, N., Rahurkar, S., Harle, CA., Vest, JR. The benefits of health information exchange: an updated systematic review. *JAMIA*, 28 April 2018, <https://doi.org/10.1093/jamia/ocy035>

¹⁰ American Nurses Association (August 2018). "The Opioid Epidemic: The Evolving Role of Nursing". Retrieved from: <https://www.nursingworld.org/~4a4da5/globalassets/practiceandpolicy/work-environment/health--safety/opioid-epidemic/2018-ana-opioid-issue-brief-vfinal-pdf-2018-08-29.pdf>

¹¹ Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC). (2017) Status of prescription drug monitoring programs (PDMPs). Retrieved from: http://www.pdmpassist.org/pdf/PDMP_Program_Status_20170824.pdf

¹² American Nurses Association and Alliance for Nursing Informatics (February 2018). "ANA and Alliance for Nursing Informatics Comments to The Office of the National Coordinator for Health Information Technology Regarding Draft US Core Data for Interoperability (USCDI) and Proposed Expansion". Retrieved from: <https://www.nursingworld.org/~49b0b1/globalassets/docs/ana/aniandanaresponsetooncuscdi02-15-2018.pdf>

continues to support such efforts to improve interoperability between PDMPs in order to combat the opioid crisis.

The PDMP will equip providers with accurate information and this information can be used to address potential compounding problems with patients, their families and/or caregivers. Nurses are overwhelmingly the health care providers who educate patients and their families on prescription use, potential reactions, storage, and disposal. Through the use of interoperable technology, the entire care team can have access to vital information without compromising privacy and the security of information.

We look forward to the opportunity to further engage with OCR with respect to the information above. If you have any questions, please contact Ingrida Lusi, Vice President, ANA Policy and Government Affairs, at 301.628.5081 or Ingrid.Lusi@ana.org.

Sincerely,



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

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