



February 11, 2019

Roger Severino
Director, Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Re: RIN 0945-AA00; Request for Information on Modifying HIPAA Rules to Improve Coordinated Care; submitted electronically via <http://www.regulations.gov>

Dear Director Severino,

Trinity Health appreciates the opportunity to identify recommendations to promote care coordination and remove barriers to value-based health care associated with the Health Insurance Portability and Accountability Act (HIPAA). We recognize the importance of balanced regulations that respect the privacy of patients and promote improved quality of care through data sharing focused on the continuum of care.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns \$1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 23 Clinically Integrated Networks (CINs) that are accountable for approximately 1.4 million lives across the country through alternative payment models (APMs).

If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,

Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy

Promoting Information Sharing for Treatment and Care Coordination

I. Align HIPAA and 42 CFR part 2 to improve the quality and safety of clinical care

We have previously commented on the confidentiality of substance use disorder patient records regulations in June 2017 (CMS-1677-P, Requests for Information: CMS Flexibilities and Efficiencies) and provided input to the Substance Abuse and Mental Health Services Administration (SAMHSA) via the 2018 public listening session comments concerning the effect of 42 CFR Part 2 on patient care, health outcomes, and patient privacy. Our recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all, while maintaining the privacy and dignity of the individuals we serve.

Trinity Health recommends that Part 2 be aligned with HIPAA with regard to permitting the disclosure of protected health information for treatment, payment, and health care operations purposes (TPO) including care coordination. In addition, care providers would benefit from focused education on the appropriate criteria needed for sharing information with family members. Medical professionals recognize the interdependence of physical and behavioral health and the role care coordination has on both quality of care and cost; aligning HIPAA and Part 2 is necessary to treat the whole patient. As OCR works to ensure regulations are revised to address these concerns, proper parameters must be included to prevent misuse of patient information.

Further, we recommend eliminating the prohibition of re-disclosure and the requirement to provide notice to lawful recipients of identifiable substance use disorder information that the information cannot be re-disclosed. Aligning the confidentiality of substance use records with HIPAA requirements – thereby granting health care providers access to information to diagnose and effectively treat patients who use opioids and other controlled substances – will better ensure integrated care across providers and settings. While this recommendation will require a federal regulatory change, it is necessary to provide quality care to this population. As a result of antiquated regulations, opioid and substance use disorder diagnosis and treatment information gets locked away from other providers and care managers, fueling bifurcation, limiting care coordination, and creating safety risks for beneficiaries. In addition, we recommend HHS explore if there is an opportunity to combine Part 2 funding with patient safety and data sharing language requirements to improve data sharing.

II. Update Patient Education to promote and support data sharing across the continuum of care

Current HHS/OCR Patient Education offerings explain the patients' rights under HIPAA for access and confidentiality. However, the education does not discuss data sharing as a means for improved quality of care. Our patients frequently express that their understanding of HIPAA is that "no one" is allowed to see their records; it would be beneficial to discuss the importance of all care providers having a complete summary of their health status with compliant data sharing.

We recommend HHS OCR explore whether offering providers incentives to offset the costs of electronic transfers needed to help facilitate care coordination would promote more robust data sharing (e.g. conduct studies and share results of patient safety advantages and cost savings obtained through better coordination of care).

III. Pre-emption of more restrictive State Laws

HIPAA does not pre-empt more restrictive state laws, which creates additional barriers and administrative burden to coordinated care of patients who seek care in multiple states. State laws requiring patient consent for sharing information needed for treatment not only create barriers and burdens, but also present a potential for patient harm. Many of these laws are historic and inconsistent with current patient care standards and interoperable electronic health systems. We recommend implementing a single standard of Privacy regulations at the Federal level to provide much needed relief from navigating multiple and conflicting regulations. This recommendation will require a federal regulatory change and ONC should consider using federal funding for regulatory relief as an interim alternative to prevent an unfunded mandate.

IV. Clarify guidance for third party request vs. patient directed to a third party

Health Systems are concerned about non-clinical requests for access to medical records for purposes that are not fully supportive to the patients' right to privacy. The current authorization for disclosure regulation does provide needed protections from "over reaching" requests for information. Health Systems continue to be challenged with the discernment of third party vs. patient requests for transmittal to a third party. The third party requestors demand the patient pricing and the documentation does not always provide assurances that the requestor is the patient or that the patient is aware of the request. Health Systems are entrusted to protect patient privacy. Requests that do not meet the OCR criteria for a patient directed request for delivery for a third party could be fulfilled promptly if the price due from a third party was not in dispute.

Trinity Health supports the promulgation of a rule to support seamless and secure access by patients to electronic health information. Assuring that patients have electronic access may form the basis for providing health care providers with the ability to recover their actual costs of providing access/copies to third parties.

V. Express requirement for Covered Entities to timely respond to requests for protected health information (PHI) from other Covered Entities

Trinity Health fully supports data sharing for integrated care purposes in the recommendations listed in the previous comments. HIPAA does provide important protections for the patients that should remain intact. We are concerned that any changes to HIPAA which create a "mandate" to share data could create new administrative burdens and potentially compromise privacy. Health Information Exchanges (HIE's) and Accountable Care Organizations (ACO's) act as intermediaries between care providers and offer another level of privacy protection. The HIPAA regulations should acknowledge the sophisticated analytics available to provide detailed summaries and risk ratios associated with patient care. We are concerned that mandated open sharing may be utilized to ultimately deny care to patients. Support for streamlined data sharing between care providers should be implemented without compromising the privacy protections in place for non-clinical disclosures.

Notice of Privacy Practices

I. Establishing a safe harbor for Covered Entities that use OCR's Model Notice of Privacy Practices (NPP) and eliminate or modify the obligation for covered health care providers with direct treatment relationships with individuals to make a good faith effort to obtain a written acknowledgment of an individual's receipt of the provider's Notice of Privacy Practices (NPP).

Trinity Health is supportive of eliminating undue administrative burden associated with obtaining written acknowledgement of the NPP. This regulation may have been appropriate in the early years of HIPAA and should be revisited now that HIPAA is widely known to our patients. Trinity Health also recommends eliminating the requirement for covered entities to physically distribute the NPP's to patients. This requirement creates administrative burden and requires significant resources (e.g. printing and individual distribution). Covered entities would continue to post the NPP on their websites, and make physical copies available on request.

II. Expand HIPAA accounting of disclosures requirement to include disclosures through an Electronic Health Record (EHR) for treatment, payment and health care operations (TPO).

Trinity Health is not supportive of expanding the accounting of disclosures requirement to include treatment, payment and healthcare operations. While regulations can move vendors toward development, the purchasers of the technology have the obligation to comply and the technology market is currently not ready for this measure. The low volume of requests for accounting of disclosures over the years indicates that this information is not an area of concern for our patients. An accounting of disclosure that includes TPO disclosures will not provide clarity for our patients and would create an undue administrative burden.

Conclusion

Trinity Health appreciates the opportunity to comment on the Request for Information on Modifying HIPAA Rules to Improve Coordinated Care and we look forward the opportunity to continue to partner with the Administration.