October 25, 2019

Elinore McCance-Katz, MD, PhD
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20852

Re: SAMHSA 4162-20: Confidentiality of Substance Use Disorder Patient Records

Submitted electronically via http://www.regulations.gov

Dear Assistant Secretary McCance-Katz,

Trinity Health appreciates the opportunity to comment of the Substance Abuse and Mental Health Administration's (SAMHSA) proposed rule amending federal regulations for confidentiality of substance use disorder (SUD) patient records. We applaud the Administration for taking steps to provide clarity and some additional flexibility for 42 CFR Part 2 and recognize the importance of balanced regulations that respect the privacy of patients and promote improved quality of care. We urge the Department of Health and Human Services (HHS) to work with Congress to align 42 CFR Part 2 and the Health Insurance Portability and Accountability Act (HIPAA)—this is critical to providing more effective care coordination for individuals in treatment for substance use disorders. Our comments and 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.

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. Our People-Centered Health System puts 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 providers committed to 16 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs).

Congressional Action is Necessary

Alignment with HIPAA

The Confidentiality of Substance Use Disorder Patient Records regulations were implemented in the 1970s to protect information and records for patients who were treated for SUD at a time in which HIPAA and associated protections did not yet exist. Existing regulations prohibit Part 2 providers—federally funded alcohol and drug treatment programs providing SUD treatment—from disclosing identities and records of individuals seeking or receiving treatment for SUD without written patient consent.

While the proposed rule makes improvements to sharing this data, the proposed rule does not change the fundamental structure of confidentiality requirements under Part 2, many of which are prescribed by statute, and continues to exclude care coordination from the definition of healthcare operations. **Trinity Health urges the Administration to work with Congress to change the basic framework for information sharing to more closely align 42 CFR Part 2 with HIPAA.**

HIPAA regulations codified after the Part 2 regulations were finalized permit disclosures of non-SUD-related patient record information without patient consent with few exceptions. **It is imperative for providers to have complete medical histories for patients in order to coordinate care and prescribe the most effective treatment; Part 2 restricts information sharing between health providers and endangers the safety of patients.** Absent this information, patients who suffer from a SUD could receive opioids or other drugs that can have a negative effect on their health and place them at risk of relapse or overdose.

In addition to patient safety concerns, Part 2 restrictions also result in great administrative burden for providers who have to go to extraordinary lengths to comply with the requirements.

Necessity of information sharing in value-based care arrangements

Participants in value-based care arrangements, such as accountable care organizations (ACOs), rely on sharing medical records and information to coordinate and integrate patient care. In the preamble of SAMHSA's final 2018 rule (83 FR 246), the agency states ACOs or similar CMS-regulated health care models may wish to evaluate the impact of integrated care by participating providers or how individuals receive substance use disorder treatment through audits and evaluations provided by §2.53. Additionally, SAMHSA finalized regulations allowing disclosures to contractors, subcontractors, or legal representatives on behalf of third-party payers or quality improvement organizations under §2.53. This would allow ACOs and others access to a full, unredacted claims set the ability to self-evaluate themselves and see how they are treating addiction, identify hotspots in communities, and overall manage population health. **HHS has yet to leverage its authority to provide this information—we strongly recommend HHS provide this information and work with SAMHSA to educate the provider communities on this flexibility.**

Further, absent alignment with 42 CFR Part 2 and HIPAA, SAMHSA and HHS should work with Congress to provide participants in risk-based CMMI models access to full Part 2 information for robust use, including for care coordination, without a beneficiary having to explicitly opt-in to data sharing with the ACO. This would serve as a test for how participants use Part 2 information and if access to this information leads to improved outcomes.

Providers aim to improve patient care, which is a shared goal of the Administration's. CMS-regulated models, including ACOs, have the required leadership and governance structure needed to safeguard patient protections, as required under regulations.

Applicability and Re-disclosure

The proposed rule clarifies the distinction between medical record information collected or documented by non-Part 2 providers and those disclosed from Part 2 providers. SAMHSA clarifies records created by a non-Part 2 provider that mention information about SUD status and treatment are not automatically subject to Part 2 privacy restrictions. However, providers who receive SUD records from a Part 2 provider with patient consent must continue to segregate these records and information from other records, such as treatment notes, based on separate clinical encounters.

Trinity Health agrees this language clears up some confusion for providers on how to capture and treat information in medical records, particularly when a patient voluntarily offers this information. As a result, providers may more freely document SUD information disclosed by a patient without concern these records may become subject to Part 2.

However, even after finalizing changes proposed in this rule, providers must continue to keep information received from Part 2 providers separate from the rest of a patient's record, decreasing effective care coordination and creating administrative burden**. This separation is not conducive to a fully interoperable environment and creates barriers to developing a single platform medical record. It is also not conducive to creating a patient-centered plan of care that considers a patients full set of clinical conditions and helps organize and integrate care around the patient and his/her goals.**

In addition, there remains confusion on what constitutes a Part 2 record, Trinity Health recommends SAMHSA engage with stakeholders to inform future guidance that clarifies ambiguity.

Opioid Treatment Program (OTP) Enrollment in Prescription Monitoring Programs (PDMPs) and Non-OTP Querying of Central Registries

SAMHSA's proposal would permit OTPs to report patient identifying information (PII) *with the patient's written consent* into a PDMP and would allow non-OTP providers to query central registries to determine whether specific patients are receiving opioid use disorder (OUD) treatment.

Trinity Health supports allowing OTPs to report methadone, buprenorphine, and other treatments to a PDMP and allowing non-OTP providers to access central registries. This will help prevent individuals from receiving duplicate or contraindicated prescriptions, as well as prevent individuals from enrolling in and receiving medication from multiple treatment programs. **However, this does not go far enough and still requires an additional step for providers to obtain important information about a patient. It is critical for providers to have access to complete medical information to ensure safe and effective treatment and care coordination for individuals with substance use disorders.**

Disclosures

Patients must identify specific individuals when disclosing protected information to entities that do not have a treatment/provider relationship with the patient. This requirement presents challenges and delays in accessing services when an individual wants to apply for assistance from programs. SAMHSA proposes to no longer require a specific name within an organization in order to disclose records.

Trinity Health supports removing this requirement and agrees this change will make it easier for patients seeking a disability determination, participating in a deferred prosecution program, such as a drug court, or seeking to participate in case management programs offered by third-party payers to obtain necessary services or meet requirements integral for their recovery.

Natural Disasters as Medical Emergencies

Under current regulations, disclosures of records are permitted without patient consent when a patient requires immediate clinical care to treat a life-threatening condition. The proposed rule would permit disclosure of patient records without consent when a state or the federal government declares a state of emergency as a result of a disaster and the Part 2 programs is unable to provide services or obtain patient consent.

Trinity Health recommends SAMHSA ensure this additional flexibility during natural disasters is as closely aligned with HIPAA as possible. In addition, current regulations allow for providers to access Part 2 information during a medical emergency without patient consent; this flexibility should remain regardless of whether necessity arises during a national disaster or some other emergency.

Examples of Activities Requiring Written Consent

The rule provides clarity around the list included in the 2018 rule identifying illustrative examples of activities where disclosure of records is permitted. SAHMSA is adding "other payment/health care operations activities not expressly prohibited"—no change of activities are permitted or prohibited.

Consistent with the 2018 final rule preamble guidance, SAMHSA states that it considers case management and care coordination to be treatment and not health care operations. As a result, third-party payers that are Lawful Holders cannot re-disclose Part 2 Records to third-party case managers or care coordinators under the original billing consent obtained by the Part 2 Program; this is inconsistent with HIPAA, as the privacy rules includes activities within both definitions.

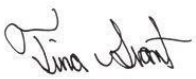
Trinity health urges SAMHSA to reconsider its determination that case management and care coordination are a treatment activity, consistent with HIPAA. These activities are critical to SUD patients since they often have complex cases involving behavioral health co-morbidities. Without this change, third-party payers must obtain a consent from their members before they disclose Part 2 Records to case managers and care coordinators—a barrier that does not exist under HIPAA.

We have years of experience under HIPAA that ensures proper balance of protecting privacy and enabling providers to effectively care for patients and the misalignment between the two regulations impairs patient safety—particularly in light of the national opioid crisis.

Conclusion

Trinity Health appreciates HHS' ongoing efforts to modernize 42 CFR Part 2 and offers our support as a resource as HHS and Congress seek to further align 42 CFR Part 2 and HIPAA. If you have questions on our comments, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



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