



February 26, 2018

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: Confidentiality of Substance Use Disorder Patient Records

Submitted electronically to [PrivacyRegulations@SAMHSA.hhs.gov](mailto:PrivacyRegulations@SAMHSA.hhs.gov)

Dear Assistant Secretary McCance-Katz,

Trinity Health appreciates the opportunity to comment on the confidentiality of substance use disorder patient records regulations and to provide input to the Substance Abuse and Mental Health Services Administration (SAMHSA) 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 at the same time maintaining the privacy and dignity of the individuals we serve.

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. Trinity Health includes 93 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 2,095 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 131,000 colleagues, including more than 7,500 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 22 Clinically Integrated Networks that are accountable for 1.3 million lives across the country.

Trinity Health strongly believes that altering the course of opioid and substance use disorders must include prevention, intervention, treatment and recovery, and we are committed to partnering with all stakeholders to advance important initiatives across these imperatives. As an organization, Trinity Health is also committed to rapid, measurable movement toward value in the delivery of and payment for health care. The Trinity Health Board of Directors have approved our system-wide strategy to "Build a People-Centered Health System" that would be accountable for delivering better health, better care and lower costs for the communities we serve. Our People-Centered 2020 Plan includes initiatives to transform the way we deliver care and the ways we are reimbursed. One of our goals is to have 75 percent of our revenue flowing through alternative payment models (APMs) by 2020. Toward that end, Trinity Health is currently accountable for 1.3 million individuals. This includes participation in seven Medicare Shared Savings Program (MSSP) Track 1 Accountable Care Organizations (ACOs) in fourteen markets, five markets partnering as a Next Generation ACO, and five markets partnering as an MSSP Track 3 ACO. In addition, we have 33 hospitals participating in the Model 2 Bundled Payments for Care Improvement (BPCI) initiative, 11 Skilled Nursing Facilities (SNFs) in Model 3 BPCI, and two hospitals in the Comprehensive Care for Joint Replacement (CJR) program.

Trinity Health believes that aligning 42 CFR Part 2 confidentiality requirements for sharing a patient's substance use disorder records with the requirements in the Health Insurance Portability and Accountability Act (HIPAA) is critical to advancing a people-centered health system. Unlike HIPAA, Part 2 does not allow for sharing or re-disclosure of identifiable substance use disorder information for treatment, payment or health care operations ("TPO") purposes without patient consent. Moreover, Part 2 requires regulated programs to provide a notice to recipients of identifiable substance use disorder ("SUD") information that the information cannot be re-disclosed. From a compliance perspective, the different standards between HIPAA and Part 2 have made it extremely difficult for our hospitals and health systems to know when and how this information may be shared, including within individual hospitals. To that end, Trinity Health believes that the following changes should be made to Part 2.

- (1) **Modification One:** An additional permission should be added to Subpart D-Disclosures Without Patient Consent. The additional permission should align a Part 2 Program's permission to share identifiable SUD information with covered entities and health care providers with the HIPAA permission that permits disclosure without patient consent to covered entities and health care providers for TPO purposes (as those terms are defined in HIPAA).

Clinical leaders across Trinity Health have indicated that Part 2's restrictions create significant patient safety issues – for example, potentially prescribing opioids to a patient with a history of substance abuse because that history is unknown to all providers. Ensuring that opioid and substance use disorders can be treated like other medical conditions will improve patient safety and continuity of care. **At a minimum, patient consent should not be required by Part 2 for disclosures to covered entities and health care providers of the medications prescribed for patients in Part 2 Programs.**

- (2) **Modification Two:** Section 2.32 of Subpart C-Disclosures With Patient Consent should be removed. To further align Part 2 with HIPAA, if patient consent is required by Part 2 (section 2.31) the Part 2 consent should include a statement adequate to place the individual (i.e., the patient) on notice that the information disclosed by the Part 2 Program pursuant to the individual's consent may be subject to re-disclosure by the recipient of the information.

If Part 2 were aligned with HIPAA as proposed above, the requirements to provide recipients of identifiable SUD information a notice that re-disclosure of the information is prohibited would be superseded in many scenarios (as patient consent would no longer be required for continuing to provide the TPO disclosures). Moreover, information recipients are unlikely to have the means or processes in place to comply with a prohibition on re-disclosure and Part 2 Programs have no means to enforce such a prohibition (e.g., law enforcement, family members, public health agencies, etc.). In addition, including in the patient consent for Part 2 Program patients a notice regarding potential re-disclosure of their identifiable SUD information will likely better inform those patients' decisions as to whether or not to consent.

Trinity Health recommends that Part 2 be aligned with HIPAA with regard to disclosing information for treatment, payment, and health care operations purposes. We additionally recommend the elimination of 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. As a result of these 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.

We appreciate SAMHSA's commitment to public health efforts that advance the behavioral health of the nation. If you have any questions on our comments, please feel free to contact me at [wellstk@trinity-health.org](mailto:wellstk@trinity-health.org) or 734-343-0824.

Sincerely,

A handwritten signature in cursive script that reads "Tonya K. Wells". The signature is contained within a thin black rectangular border.

Tonya K. Wells  
Vice President, Public Policy & Federal Advocacy  
Trinity Health