



CENTER *for* **MEDICAL**
INTEROPERABILITY

October 25, 2019

The Honorable Elinore F. McCance-Katz, MD, PhD
Assistant Secretary for Mental Health and Substance Abuse
Substance Abuse and Mental Health Services Administration
Attention: SAMHSA-4162-20
5600 Fishers Lane
Rockville, MD 20857

RE: Confidentiality of Substance Use Disorder Patient Records, SAMHSA-4162-20, RIN 0930-AA32

Submitted Electronically

Dear Assistant Secretary McCance-Katz:

Thank you for the opportunity to respond to the Substance Abuse and Mental Health Services Administration's (SAMHSA) proposed changes to the Confidentiality of Substance Use Disorder Patient Records regulations. The Center for Medical Interoperability (C4MI) appreciates SAMHSA's dedication to improving the clarity of these regulations and to addressing the growing prevalence of substance use disorder, including opioid use disorder, in our nation.

C4MI is a non-profit organization led by health systems with a mission to ***accelerate the seamless exchange of information to improve health care for all***. Modeled after centralized labs from other industries, C4MI serves as a cooperative research and development lab as well as a test and certification resource to address technical challenges and ensure conformance to specifications that enable comprehensive interoperability, data liquidity, and trust. Initial draft specifications have been related to medical devices within the acute episode of care.¹ C4MI's CEO-level board of directors identifies health care industry technology problems that, when solved, will benefit the public good and the health care industry. C4MI membership is limited to health systems, individuals, and self-insured corporations, but we work with a variety of stakeholders, including medical device manufacturers, electronic health record (EHR) vendors, standards development organizations, and others, to design and engineer the technical infrastructure that will enable comprehensive interoperability, data liquidity, and the trust needed to deliver person-centered medical care.

¹ Available at <https://medicalinteroperability.org/specifications/>

C4MI is focused on facilitating the seamless exchange of all health care data through a common platform architecture that enables access to a complete picture of an individual's health for both clinicians and patients alike. Rather than repeat our complete vision here, we encourage you to review our other public comments available on our website.²

C4MI recognizes both the need for caregivers to have the information necessary to inform the correct path of care delivery and the need for patients to have privacy and trust in the health care system. Substance use disorder treatment presents a particularly difficult challenge for policy makers because of the deeply personal nature of the information concerned and the potential implications that can arise if that information is either shared too broadly, like discrimination, or too narrowly, like a drug interaction or overdose. C4MI believes that all data should be controlled by the patient through a consent mechanism. Placing all health care data under the control of the patient, however, raises the same concerns currently faced by SAMHSA and Congress with Part 2: how to ensure that clinicians have the right information at the right time? From a technological perspective, we believe the technology should be able to accommodate both extremes – undersharing and oversharing – to adjust to the appropriate policy. From a policy perspective, C4MI believes there should be a mechanism in place to allow for access to data that may be withheld from the patient if that data or its potential absence could be necessary to determine the appropriate care or prevent patient harm. There could be an exception, for example, that if it is clear that a patient has not shared their complete medical history, a group of clinicians could determine through their professional judgement that the withheld information is necessary for care and break through the firewall to access that information. Such a mechanism would allow for patients to maintain control, but not allow for selective sharing of information that could result in patient harm. We welcome feedback and engagement from all parties to ensure how a trust platform can be implemented to both ensure the flow of all necessary health information to enable better care delivery and protect the privacy and integrity of an individual's personal health information.

As a general matter, C4MI believes that the separate treatment of substance use disorder treatment information as compared to other health care information is antiquated and the law needs to change. C4MI believes that the laws surrounding health care data should be updated and streamlined to allow for universal principles governing health data regardless of where that data is generated or where it resides. The rules should follow the data, not be confined to one practice area or sector of the industry. The rules should also be the same for all pieces of data. Just as the rules governing health data promulgated from the Health Information Portability and Accountability Act (HIPAA) need to be updated, so do the rules and the underlying statute governing Part 2 data. Clinicians, patients, and innovators will all benefit from a single, common set of rules and principles for health data rather than the segmented and conflicting laws and rules that control the exchange of health data today.

C4MI believes that SAMHSA's proposed changes will benefit patients and caregivers by providing more flexibility and clarity around Part 2 data and disclosures. We are particularly appreciative of the clarification that certain disclosures do not trigger Part 2 and the expansion of

² Available at <https://medicalinteroperability.org/publiccomments/>

consent to allow patients to share their information with more than just individually enumerated providers. The Department of Health and Human Services should continue to modernize health data rules and regulations to allow the health care industry to keep pace with the growing needs that public health crises like opioid use have presented, but Congress also needs to review the laws governing health data, including HIPAA and Part 2, to enable comprehensive interoperability, data liquidity, and trust to improve the delivery of health care and its outcomes.

Sincerely,

Center for Medical Interoperability

A handwritten signature in black ink that reads "F.E. Cantwell". The signature is written in a cursive style with a large, prominent "F" and "C".

Ed Cantwell, President and CEO
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