AMERICA'S ESSENTIAL HOSPITALS

January 24, 2023

Melanie Fontes Rainer
Director
Office of Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 509F
200 Independence Ave. SW
Washington, DC 20201

HHS-OCR-0945-AA16: Confidentiality of Substance Use Disorder Patient Records

Dear Director Fontes Rainer:

America's Essential Hospitals appreciates the opportunity to comment on the above-captioned proposed rule related to confidentiality of substance use disorder (SUD) patient records, also known as Part 2 records. We support the proposed changes, which will improve care coordination and increase patient protections for SUD patients. However, challenges exist to its implementation.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating on an average margin about two-fifths that of other hospitals—3.2 percent compared with 7.7 percent for all hospitals nationwide.[1] Essential hospitals' commitment to serving all people, regardless of financial means or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face socioeconomic and sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Seven and a half million people in communities served by essential hospitals have limited access to healthy food, and nearly 16 million live below the poverty line.[2]

Given their missions and patient populations, members of America's Essential Hospitals are on the front lines of SUD treatment and the opioid epidemic. Our patients' limited resources and complex social needs are significant risk factors for SUD.[3] Essential hospitals have responded

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[1] Clark D, Ramiah K, Taylor J, et al. *Essential Data 2020: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. September 2022. https://essentialdata.info. Accessed December 19, 2022.
[2] Ibid.
[3] Susman, Katherine. *The Opioid Crisis: Hospital Prevention and Response*. Essential Hospitals Institute. June 2017. https://essentialhospitals.org/wp-content/uploads/2017/06/Opioid-Brief-1.pdf. Accessed January 3, 2023.

essentialhospitals.org
AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: contact@essentialhospitals.org

by identifying and implementing innovative approaches to care for patients with SUD. As both covered entities and Part 2 providers, essential hospitals are pleased to see Part 2 privacy requirements align with HIPAA, particularly the single consent provision to use and disclose Part 2 records. The proposed change will greatly improve care for patients with SUD.

1. **The Office of Civil Rights (OCR) must address technological barriers to streamlined consent documentation.**

America's Essential Hospitals fully supports the proposed change to require patients to give written consent only once to allow Part 2 programs to use, disclose and redisclose Part 2 records. When patients visit essential hospitals, most assume providers have a complete medical history and an awareness of addictions or substance use to factor into treatment and prescribing. Current requirements to obtain multiple consents to share this information have been a barrier to whole-person, integrated approaches to care. The proposed change to a single consent will improve care coordination and health outcomes for patients with SUD and avoid misdiagnosis, mistreatment, and potentially dangerous drug interactions. It also will take another step toward reducing the stigma of siloed SUD treatment.

We also support the increased patient protections, allowing patients to revoke their consent at any time or limit the use and disclosure of a segment of their Part 2 records. However, implementing documentation of consent (including limited consent and withdrawn consent) within electronic health records (EHRs) will be difficult.

a. <u>The OCR must better coordinate with the Office of the National Coordinator for Health Information Technology (ONC) to implement new consent requirements in EHRs.</u>

Documenting consent to use, disclose, and redisclose Part 2 records, as well as limiting and revoking consent, depends highly on EHR technology and a system's ability to identify and segment certain parts of a medical record. Current rules require an EHR to segment Part 2 records from the rest of the patient's medical record, but the proposed patient protections will require EHRs to further segment individual Part 2 records or sections in a single record. Not all EHR systems have this capability or lend themselves to be upgraded to do so. Switching EHR systems or making significant functionality changes to existing systems can cost millions of dollars and require extensive planning.

Further, making upgrades and updating EHRs is costly and time consuming. Further, providers lose access to EHR systems during updates. This requires that they work offline, which means they could lose access to their patient's medical records and their ability to transmit prescriptions to pharmacies and make referrals. They also must capture patient visit information offline and document it in the EHR later, a time-consuming task. When EHR systems are upgraded with new capabilities, such as documenting consent and segmenting records to share, it not only requires staff training on the new capabilities but time to design, test, modify, and fix the new function. Each new function has an attached cost, so upgrades to EHR systems require planning, funding, and discretion.

We recognize that addressing technological barriers in EHRs is outside the agency's scope, but **OCR must work with other federal agencies, especially ONC, to improve EHR standards and create requirements** so EHR systems can implement privacy rules and better meet the needs of essential hospitals, as well as adapt to future needs. Updates, upgrades, and switching EHR systems require long-term planning, budgeting, and coordination to decide what to upgrade and when to do so. With narrow operating margins, essential hospitals do not

have the luxury of updating their EHR every time there is a new requirement or needed functionality or the ability to switch EHRs when their current system no longer meets their needs. The lack of required standards or functionality has led to some EHRs having limited capabilities, such as segmenting records for privacy reasons. This forces health systems to manage with a subpar EHR system or purchase a new system. Further, **we encourage federal financial support for essential hospitals to upgrade their EHRs as necessary to comply with new Part 2 rules.**

b. OCR should work to streamline overall consent requirements.

The number of patient consent requirements is rapidly growing, given the proposed Part 2 consent requirements; the new consent requirements for services and billing for out-of-network providers under the No Surprises Act; and other consent requirements, such as consent for text messaging, patient portals, and telehealth platforms. While this proposed rule seeks to reduce this burden, the sheer volume of consent requirements likely will confuse patients and might be difficult to manage in an EHR. **OCR should consider providing guidance on how to best streamline these consent forms, and it should work with ONC to create EHR standards that support this effort.**

2. OCR must provide technical assistance to implement consent requirements.

America's Essential Hospitals supports the proposed compliance timeline of 24 months. As OCR acknowledges, implementing these changes will require significant time to design and modify EMRs to account for patient consent decisions and to train staff. OCR should provide technical assistance wherever possible to ensure a smooth and accurate implementation of the Part 2 rule.

a. OCR must provide guidance on consent documentation best practices.

Depending on the EHR system, providers document consent in a variety of ways, from streamlined online processes to paper-based forms that are scanned into the EHR. While hospitals attempt to make these processes as simple as they can for patients, required consent documentation can be extensive (as discussed above), and staff might spend significant time reviewing documentation requirements for patients, particularly at essential hospitals, where the majority of patients have basic or low health literacy.[4] **OCR should provide guidance on best practices to implement consent documentation for Part 2 records that account for the different capabilities of EHRs and varying needs of specific patient populations.**

b. OCR should provide model consent forms.

Essential hospitals care for a significant number of patients with limited English proficiency, requiring translation of consent forms. While a model consent form translated by OCR will be helpful, explaining consent and the patient's option to limit or revoke consent might require individual translation and oral presentation. Access to translation services varies between essential hospitals; some have sufficient medical staff that already provide services in a given

[4] U.S. Department of Health and Human Services. *America's Health Literacy: Why We Need Accessible Health Information*. 2008. https://www.ahrq.gov/sites/default/files/wysiwyg/health-literacy/dhhs-2008-issue-brief.pdf. Accessed January 6, 2023.

language, some have separate translators, and others rely on an external translation service by phone or video. Regardless of how this is delivered, consent documentation will become more time consuming and costly to process as the amount and complexity of the information increases. To lessen this burden and cost, **OCR should provide model consent forms and translate them into common languages.**

3. More guidance is needed on the interaction of federal and state Part 2 laws.

Essential hospitals in states with existing Part 2 laws will have to invest significant time and financial resources into understanding the interaction between federal and state laws and how to incorporate those laws into real-time care decisions. This will require a deeper analysis of both the federal and state laws and integration of their requirements into their EHR systems to comply with all applicable regulations. Subsequent system modifications and staff training to correctly implement these laws will be expensive.

Further complicating matters, several of our member hospitals provide services in multiple states. Their service areas are more fluid than state lines; patients might receive care at several facilities, irrespective of the location of the facility or the provider. Hospitals will have to navigate complex federal and state laws to remain compliant, which will require additional financial investments. More guidance is needed to address these complexities, as well as the application of state laws to out-of-state telehealth consults.

OCR must provide more guidance on the interaction between federal and state Part 2 laws and provide technical assistance to help providers operationalize these requirements.

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The association appreciates the opportunity to submit these comments and looks forward to additional opportunities to work with OCR on this vital issue. If you have questions, please contact Erin O'Malley, senior director of policy, at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO