Minnesota Hospital Association

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January 31, 2023

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW, Room 509F
Washington, DC 20201

Submitted electronically through www.regulations.gov.

RE: Comments on Proposed Rule HHS-OCR-0945-AA16: Confidentiality of Substance Use Disorder Patient Records

Dear Secretary Becerra,

On behalf of our 140 member hospitals and health systems, the Minnesota Hospital Association (MHA) offers the following comments regarding the proposed rule on the Confidentiality of Substance Use Disorder Patient Records.

We greatly appreciate that the Substance Abuse and Mental Health Services Administration (SAMHSA) is taking steps to align substance use disorder (SUD) record requirements under 42 CFR Part 2 regulations with those under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. For many years, MHA has joined other stakeholders in urging for greater alignment with HIPAA to improve care coordination and care delivery. **We strongly support the proposed change to allow a covered Part 2 program to obtain a single consent signed by the patient for all future uses and disclosures for treatment, payment, and operations**.

Many MHA members have cited frustrations with duplicative administrative requirements affecting appropriate clinical care. One recent example from a Minnesota hospital highlights the urgent need for a change in disclosure requirements. A patient was admitted to the hospital with issues relating to opioid addiction and an acute pain flare-up from sickle cell disease. Even though he was seen by an addiction health care provider a few months prior, the inpatient medical team could not see the visit notes due to 42 CFR Part 2 privacy regulations. Therefore, the patient did not receive appropriate care resulting in a longer hospitalization stay. In Minnesota, hospitals and health systems still need to comply with the Minnesota Health Records Act, which has more restrictive consent requirements than HIPAA, however the proposed federal change recognizes a path towards better care integration that can result in improved patient outcomes.

Current practice requires Part 2 programs to provide patients with a notification of the program's obligations to comply with the regulation. This is generally less comprehensive than the corresponding Notice of Privacy Practices (NPP) housed in the HIPAA Privacy Rule. The CARES Act directed the Department of Health and Human Services (HHS) to modify requirements regarding privacy practice on records that are transmitted to covered entities. The proposed rule includes several changes to the NPP document to address both HIPAA covered entities and Part 2 programs.

In 2021, HHS proposed rules that, amongst other provisions, would eliminate the requirement HIPAA covered entities obtain a patient signature of acknowledgement that a copy of the notice of privacy practices (NPP) was furnished. In this proposed rule, CMS re-purposes language at 45 CFR § 164.520(b)(1)(vii) that removes the existing requirement for a covered entity to obtain a written acknowledgement of the receipt of the NPP. We support the proposed change to remove this requirement.

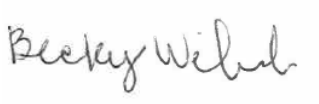
While this proposed rule is a marked improvement from current SUD patient data practices, MHA is still concerned that a gap will remain between 42 CFR Part 2 regulations and HIPAA. HHS is maintaining separate underlying regulatory structures for SUD patient records and all other patient data, meaning electronic health record vendors will need to distinguish between the two types of records. Some SUD patients may not provide consent or revoke their consent throughout the course of their treatment, meaning their record will need to be flagged differently. This is a significant information technology (IT) challenge that is not addressed in the proposal, and HHS should ensure that there is ample time and resources for health IT vendors to update their capabilities and adapt to the evolving operational needs of health care providers.

In terms of new patient rights and protections, in addition to allowing revocation of consent, the proposed rule requires 42 CFR Part 2 programs to provide an accounting of all disclosures in the past six years if requested by the patient. For disclosures specific to treatment, payment, and operations, it would only apply to disclosures made through an EHR three years prior to the request. Although this provision is contingent on the yet to be released final rule addressing HIPAA and HITECH Act implementation, HHS should provide additional guidance on the level of detail necessary to meet this requirement. Given that MHA members currently process a small number of accounting of disclosure requests every year, this potential administrative change may overwhelm current report capacity, especially given the nature of accessing records for TPA purposes that is part of standard care operations. MHA supports strong patient protections; however, these changes must be accompanied by reasonable and clear expectations regarding technology capabilities and administrative processes.

Due to the complicated nature of this proposed rule, MHA encourages HHS to consider a phased-in approach to enforcing compliance. In addition to requiring complex technological changes, many of the notice and transparency provisions will necessitate updating various patient forms and other existing paperwork requirements. Even though the goal of these changes is to streamline and reduce administrative burdens, changing standard operational practices will require investments by hospitals and health systems. Health care professionals will also need education and training on implementing the changes and understanding the distinction between patient records under 42 CFR Part 2 and HIPAA.

Hospitals and health systems across Minnesota provide high-quality behavioral health services and are committed to improving coordination of care. MHA appreciates HHS' ongoing efforts to better align 42 CFR Part 2 with HIPAA, and the opportunity to provide comments. If you have any questions, please feel free to contact me at bwifstrand@mnhospitals.org.

Sincerely,



Becky Wifstrand
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