



Charles N. Kahn III
President and CEO

January 31, 2023

Via electronic submission at <http://www.regulations.gov>

Melanie Fontes Rainer
Director
Office for Civil Rights
Department of Health and Human Services
Attention: SUD Patient Records
Hubert H. Humphrey Building; Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Confidentiality of Substance Use Disorder (SUD) Patient Records; HHS-OCR-0945-AA16

Dear Director Fontes Rainer:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying public and privately held hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's and cancer services.

We appreciate the opportunity to provide the Department of Health and Human Services' (the Department) Office for Civil Rights (OCR) with our views in response to the *Notice of Proposed Rulemaking: Confidentiality of Substance Use Disorder (SUD) Patient Records*, 87 Fed. Reg. 74,216 (December 2, 2022) (Proposed Rule). Hospitals and health systems have significant experience providing care to patients in need of substance use disorder services and the confidentiality of these patients' records is critical -- consistency and uniformity of the regulatory framework for providing this care is key to ensuring that confidentiality.

The FAH agrees with, and appreciates OCR's commitment to aligning the requirements under Part 2 of Title 42 of the Code of Federal Regulations (Part 2) more closely with requirements of the Health Insurance Portability and Accountability Act (HIPAA) rules, including definitions and

substantive requirements. This alignment results in streamlined compliance measures, which allows hospitals and other providers to better treat patients with more comprehensive and complete information, while simultaneously reducing the compliance burden with the relevant regulatory schemes.

While we support alignment with HIPAA and provider compliance efficiency, we have concerns about the Proposed Rule's amendments to 42 CFR § 2.25 regarding accountings of disclosures for treatment, payment, and health care operations. Section 45 CFR § 164.528(a)(1)(i) of the HIPAA Rules currently exempts from an individual's right to receive an accounting of disclosures of protected health information (PHI) those disclosures made by a covered entity to carry out treatment, payment, and health care operations. Section 13405(c) of the HITECH Act states that this exemption shall not apply to disclosures through an electronic health record made by such entity of such information. Section 13405(c)(2) of the HITECH Act required the Department to engage in rulemaking concerning these requirements. Although the Department issued a notice of proposed rulemaking in 2011 (*HIPAA Privacy Rule Accounting of Disclosures under HITECH, May 31, 2011*, 76 Fed. Reg. 31,425), a final rule relating to these provisions has not been adopted by the Department. As such, this accounting is better addressed in such future rulemaking under HITECH, so that the Department can establish a uniform standard for accountings of disclosures concerning treatment, payment, and health care operations.

Although proposed Section 2.25(b) limits the accounting of disclosures for treatment, payment, or health care operations to disclosures made through an EHR – as contemplated by the combined HIPAA and HITECH sections referenced above – the Department should not now make unique rules for Part 2 programs, in effect creating three different roles for accounting of disclosures: (1) covered entities that do not use electronic health records, (2) covered entities that use electronic health records, and (3) Part 2 programs.

In addition to the administrative simplification considerations, tracking these disclosures will create additional burden on providers to account for and disclose what can, in some instances, be hundreds of thousands of disclosures made for treatment, payment, or health care operations purposes. Our members are well-versed in receiving requests from individuals to exercise their rights, which most often are access to records requests, rather than accounting of disclosures requests, and our members are able to readily fulfill such requests to the individual's satisfaction. In our view, the potential burden for the accounting contemplated by the Proposed Rule outweighs the number of requests for accounting of disclosures actually received by our members.

In addition, while we generally support alignment of the notice provisions set forth in Part 2 and HIPAA, the FAH has concerns regarding the proposed amendment to 45 CFR § 164.520(b)(1)(v)(C). The Department has proposed to include a new requirement that would substantially limit a covered entity's ability to update its notice of privacy practices (NOPP) under HIPAA by limiting the revisions that can apply retroactively to those that are "not material or contrary to law." Including a requirement in this section that the updates not be contrary to law is unnecessary because any updates must otherwise comply with HIPAA and Part 2. In addition, including a new materiality threshold in this section would substantially increase the burden on providers and require segmentation of records based on the date the PHI was created and the NOPP in effect at that time. Moreover, this requirement may also incentivize covered entities to over-disclose potential uses or disclosures of PHI thereby making NOPPs more difficult for patients to understand. The requirement to distribute a new NOPP upon a material change is already addressed in 45 CFR § 164.520(b)(3). Additionally, the proposed revisions to 42 CFR § 2.22(b)(1)(v)(C) do not include a corresponding limitation. Based on the statutory goals of Section 3221(i)(2) of the

CARES Act of providing “easily understandable notice of privacy practices,” the FAH believes maintaining the current framework under HIPAA on this point (as proposed in Section 2.22(b)(1)(v)(C)) best accomplishes this legislative intent.

If the goal of the Proposed Rule is to better reconcile Part 2 requirements with the HIPAA Rules, the FAH respectfully requests the Department to consider that (a) the more appropriate forum for rulemaking concerning this type of accounting of disclosures is pursuant to the HITECH Act, for which final regulations on the applicable sections have not been adopted, and (b) the notice provisions under HIPAA and Part 2 should be aligned but without introducing new requirements regarding updates to a provider’s NOPP.

The FAH appreciates the Department’s dedication to aiding Part 2 programs in providing administratively efficient and transparent care. We look forward to continued collaboration with the Department to implement effective policies for providers to continue to provide quality care while maintaining the confidentiality and individual rights of the patients they serve. If you have any questions, please contact me or any member of my staff at 202-624-1534.

Sincerely,

