



October 25, 2019

Elinore F. McCance-Katz, MD, PhD
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
US Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

RE: Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA 4162-20)

Dear Assistant Secretary McCance-Katz:

Thank you for the opportunity to submit comments on the Confidentiality of Substance Use Disorder Patient Records proposed rule.

AHIMA is the national non-profit association of health information management (HIM) professionals. Serving 52 affiliated component state associations including the District of Columbia and Puerto Rico, AHIMA represents over 103,000 health information management professionals dedicated to empowering people to impact health. AHIMA's credentialed and certified HIM members can be found in more than 40 different employer settings in 120 different job functions—consistently ensuring that health information is accurate, timely, complete, and available to patients and clinicians.

We appreciate SAMHSA's intent under the proposed rule to continue to align the regulations with advances in our nation's healthcare delivery system while maintaining important privacy protections for individuals seeking treatment for substance use disorders (SUDs). That said, while we support several of the changes proposed in this rule, we are concerned that such proposed changes do not entirely address the fundamental challenge of Part 2—stringent consent provisions as well as the prohibition against redisclosure of Part 2 information absent specific patient consent.

We recognize there is some question as to whether SAMHSA has statutory authority to permit the disclosure of Part 2 information to HIPAA covered entities or Part 2 programs for treatment, payment, and healthcare operations without a consent executed by the patient. For that reason, we support congressional efforts to authorize further alignment of Part 2 to HIPAA. Such alignment will not only help modernize Part 2 and allow it to keep pace with advances in healthcare delivery but help ensure that clinicians and organizations have all the information necessary to provide safe, effective, high quality treatment, and care.

Although the proposed rule covers a number of topics, we have focused our comments below on several issues critical to ensuring that health information concerning patients with substance use disorders is appropriately shared to enhance care coordination and delivery.

Preamble Guidance on “Sanitization” of Employee Devices

AHIMA appreciates SAMHSA’s guidance included in the preamble on how employees, volunteers, and trainees of Part 2 facilities should handle communications using personal devices and accounts, provided that they do not use such devices in the regular course of business for the Part 2 program. However, we recommend that SAMHSA include clarification that the guidance also pertains to any additional synced devices including mobile devices, laptops, tablets, etc. that may receive synced emails or texts containing patient identifying information to ensure appropriate sanitization of such personal devices. We also recommend that SAMHSA further clarify that if the email or text to an employee’s personal device includes patient identifying information and the employee has forwarded such information to an authorized channel, then deletion of the email or text from the personal account will not be in contravention with any state record retention requirement.

III. Provisions of the Proposed Rule

Non-Part 2 Providers

The proposed rule clarifies that treatment records created by non-Part 2 providers based on their own direct patient encounter(s) will not be subject to Part 2 and clarifies the ability of non-Part 2 providers to segregate any Part 2 records to ensure that new records created by non-Part 2 providers during their own patient encounters are not subject to Part 2 rules.

AHIMA supports SAMHSA’s efforts to reduce confusion and misunderstanding as to the applicability of Part 2 rules to non-Part 2 providers. However, we recommend that SAMHSA provide further guidance as to how providers, health information professionals, and other stakeholders can ensure that they are in compliance with the regulations. For example, it is unclear from the proposed rule whether the “segregation” or “holding apart” requirement applies to claims data. Under certain circumstances, our members have encountered instances where certain electronic health record (EHR) systems that include practice management software may reveal Part 2 information on the claims side even though such data is segregated on the clinical side.

In addition, we continue to be concerned about the pace of certified EHR Technology (CEHRT) data segmentation functionality. While there are important efforts under way to address this issue, uncertainty exists about widespread availability and implementation of such functionality. Standards and functionalities that enable data segmentation, tagging, and privacy labeling are critical to ensuring the privacy of patient data as we increasingly move away from paper-based patient records. We recognize that these concerns may be outside of the scope of the proposed NPRM, however, we recommend that SAMHSA continue to work with the Office of the National Coordinator for Health IT (ONC) to advance development and adoption of Data Segmentation for Privacy (DS4P) standards by health IT developers to further address the needs of both Part 2 providers and non-Part 2 providers in receipt and exchange of Part 2 records.

Consent Requirements

The proposed rule eliminates the requirement to name the specific individual on the consent form to receive patient information on behalf of a given entity and will allow patients to name the entity to which the information is to be disclosed, even in the absence of a treating provider relationship unless

such information is disclosed to entities that facilitate the exchange of health information or research institutions.

AHIMA supports the changes proposed in the rule to assist patients that may want a Part 2 program to disclose protected information to entities for such purposes as eligibility determinations and non-medical services or benefits from governmental and non-governmental entities (e.g.—social security benefits, local sober living or halfway house programs.) However, we recommend that as part of the final rule, SAMHSA provide additional examples or categories of non-medical services or benefits to assist providers and health information professionals in identifying which types of entities these provisions apply to. In particular, we ask that SAMHSA clarify the applicability of §2.31(a)(4)(i) to third-party administrators and/or representatives that operate on behalf of a governmental and/or non-governmental entity. Similarly, it is unclear under the proposed rule the applicability of §2.31(a)(4)(i) in instances where the requirements of §2.15(a)(1) have been met and a patient’s guardian or personal representative authorized under state law may act on behalf of the patient.

Disclosures for Payment and Healthcare Operations

The proposed rule codifies a list of 17 examples of “payment and healthcare operations” for which a legal holder may disclose Part 2 records to contractors, subcontractors and legal representatives and clarifies that this list of activities is not intended for activities related to care coordination or case management.

AHIMA supports the codification of the list of examples relating to payment and healthcare operations as its inclusion within the regulatory text will help reduce confusion as to the permissibility of a particular activity. That said, we are disappointed that care coordination and case management are explicitly excluded from the list of activities as they should be included under the definition of healthcare operations as set forth under HIPAA and are integral activities in providing care to individuals that participate in an integrated health network.¹

Medical Emergencies

The proposed rule broadens the “bona fide medical emergency” exception to allow a Part 2 program to disclose patient identifying information to medical personnel without patient consent, as needed in the event of a natural or major disaster to deliver ongoing substance use disorder services to patients in such disasters.

AHIMA supports this proposed change. We agree with SAMHSA that natural and major disasters pose unique challenges for both patients with substance use disorders and their treating providers. A Part 2 program should be permitted to disclose medical information without individual consent to the extent necessary, to meet a bona fide medical emergency when said Part 2 program is closed due to a natural or major disaster and unable to provide services or prior written consent of the patient.

Should SAMHSA finalize the proposed change, we recommend that the agency provide additional sub-regulatory guidance to Part 2 programs as to how, in the event of a natural or major disaster, patients and other medical personnel in need of such information may best be notified that the program is closed and unable to provide services or obtain informed consent of the patient. The guidance should

¹ 45 CFR 164.501.

include examples of how Part 2 records may be disclosed to medical personnel in need of such information in the event a Part 2 program is closed. We also suggest that SAMHSA work with the HHS Office for Civil Rights to coordinate its communication and outreach efforts regarding §2.51 in the event of a natural or major disaster to ensure broad dissemination to medical personnel as well as health information professionals.

Audit and Evaluation

The proposed rule adds clarification and examples of permitted disclosures to Part 2 records without patient consent for audits and evaluations. We recognize that SAMHSA is intending to improve clarity about what is permissible under §2.53. However, we are concerned that the proposed rule lacks sufficient detail on what specific types and/or categories of activities are included under §2.53(c). For example, we are concerned that activities under the proposed §2.53(c)(1)(ii) and/or §2.53(c)(2) could be used as a means to deny care and/or services to patients with a substance use disorder. For that reason, we recommend that SAMHSA, as part of the final rule provide additional examples of program activities to ensure that such activities are performed in accordance with the regulation.

We thank you for the opportunity to submit comments on the Confidentiality of Substance Use Disorder Patient Records proposed rule. We look forward to working with SAMHSA to ensure successful implementation of 42 CFR part 2. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Vice President, Policy and Government Affairs at lauren.riplinger@ahima.org and (202) 839-1218.

Sincerely,



Wylecia Wiggs Harris, PhD, CAE
Chief Executive Officer
AHIMA