

January 26, 2023

Miriam E. Delphin-Rittmon
Assistant Secretary for Mental Health and
Substance Use
Substance Abuse and Mental Health
Services Administration
5600 Fishers Lane
Rockville, MD 20857

Director Melanie Fontes Rainer
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509-F, HHH Building
Washington, DC 20201

RE: *Confidentiality of Substance Use Disorder (SUD) Patient Records*

Submitted electronically via www.regulations.gov

Dear Assistant Secretary Delphin-Rittmon and Director Fontes Rainer,

On behalf of the American Health Information Management Association (AHIMA), I am responding to the Department of Health and Human Services (HHS), Office for Civil Rights (OCR), and Substance Abuse and Mental Health Services Administration (SAMHSA) Confidentiality of Substance Use Disorder (SUD) records proposed rule.

AHIMA is a global nonprofit association of health information (HI) professionals. AHIMA represents professionals who work with health data for more than one billion patient visits each year. The AHIMA mission of empowering people to impact health drives our members and credentialed HI professionals to ensure that health information is accurate, complete, and available to patients and clinicians. Our leaders work at the intersection of healthcare, technology, and business, and are found in data integrity and information privacy job functions worldwide.

The following are our comments and recommendations on selected sections of the proposed rule.

§ 2.11—Definitions

AHIMA supports the efforts of OCR and SAMHSA to align the definitions of key terms under Part 2 regulations with HIPAA. Government review and alignment of similar definitions across multiple regulations alleviates compliance burden on organizations who need to comply with and understand the important differences between definitions and requirements.

Definition of Intermediary

AHIMA supports the alignment and update of the definition of an intermediary as it relates to Part 2 records.

Definition of SUD Counseling Note

AHIMA is concerned about the creation of an SUD counseling note. As noted in the proposed rule, the creation of this note would be similar to the psychotherapy note definition currently included under HIPAA. Creating a similar, but different definition for records would increase administrative confusion and increase burden as organizations would need robust review processes to determine what is considered a psychotherapy note versus a SUD counseling note. Additionally, these oversight and internal controls would need to be created to manage a small subset of records. As it stands today, the HIPAA psychotherapy note categorization is rarely, if ever, used as psychotherapy notes are not part of the designated record set, and thus those notes are kept elsewhere in the record. The type of information previously envisioned to be included in the psychotherapy note is now included in a “progress notes” or the information is not captured and documented in an electronic health record. If organizations were moved towards utilizing a separate category for SUD counseling notes, it could lead to information either not being documented, or to important information not being captured at all, which is against the principles of interoperability AHIMA and the federal government evangelize.

Definition of De-Identified Data

AHIMA continues to caution the federal government that the limits of data being truly de-identified present privacy concerns for patients. This is increasingly important as it relates to sensitive data like SUD records, as many patients want this information to be the most protected in their health record. With this in mind, it is important to note that all data to an extent can be re-identified and it is important for that to be accounted for as the government makes any mandates related to this type of data.

If the federal government continues to utilize the idea of de-identified data, AHIMA recommends adoption of the HIPAA requirements for de-identified data, as Part 2 programs currently follow the HIPAA standard and are most likely to continue doing so moving forward.

§ 2.13—Confidentiality restrictions and safeguards

HIPAA Security Rule

AHIMA supports government efforts to align all electronic health record security regulations with those already in place HIPAA Security Rule. The HIPAA Privacy and Security Rules are widely adopted across the healthcare continuum. We urge SAMHSA and OCR to pursue further alignment with HIPAA Security Rule requirements where appropriate.

§ 2.14—Minor patients

AHIMA supports placing minors in control of the use and disclosure of their health records when appropriate, however we urge SAMHSA and OCR to further align these requirements with the state-based requirements regarding minor access, consent, and disclosure of their health records. Many states, such as California, have more stringent rules regarding when a minor patient can control different sections of their health record. Thorough review of these requirements and how they should

be reflected in federal policy will strengthen rules governing a minor’s control of their health records. AHIMA urges OCR and SAMHSA to engage with patient advocacy organizations to better understand the full implication of rules related to minor consent and their health record.

§ 2.16—Security for records and notification of breaches (proposed heading)

Part 2 Program Alignment with HIPAA De-Identification Standards

AHIMA supports further alignment of the de-identification standards with the HIPAA Privacy Rule standard. As stated above, we do caution OCR and SAMHSA to re-examine the base minimum standards for de-identified data to fully understand if the data is truly de-identified. AHIMA members who are Part 2 programs have indicated they do align with the HIPAA standard for de-identified data, but we urge OCR and SAMHSA to determine if that standard is stringent enough. It is important to remember when discussing de-identified data, that while it may be anonymized for some algorithms, technology continues to improve to a point where the question of de-identification in perpetuity is truly unknown¹.

Breach Notification Requirements

AHIMA supports the alignment of Part 2 breach notification requirements with the standards outlined in the HIPAA Privacy Rule and Breach Notification Rule. Part 2 Programs have indicated that due to the wide range of medical transactions and data activities underway in a Part 2 facility, they already align with the HIPAA Breach Notification requirements. Requiring Part 2 programs to follow the guidance included in the Breach Notification Rule would not result in an increase in burden placed on these programs as many already follow the Breach Notification Rule requirements.

§ 2.22— Notice to patients of federal confidentiality requirements; and 45 CFR 164.520—Notice of privacy practices for protected health information

Notice of Privacy Practices for Protected Health Information

AHIMA recognizes the need for the Notice of Privacy Practices (NPP) to be updated to reflect the alignment of Part 2 SUD records with the HIPAA requirements for other records. To build patient trust in the health system, there must be increased transparency and notification of the rights that patients have when consenting for the use and disclosure of their health information. This also includes ensuring they are well versed on the repercussions if their information is misused.

Under this proposal, it could result in organizations having to create two separate NPPs that would be provided to a patient depending on where they seek treatment, which has the potential to cause confusion. For example, patients that seek care at a Part 2 facility would be presented with an NPP that includes updated language accounting for their Part 2 records. However, if that same patient were to visit a different part of the facility that is not a Part 2 program, they would then receive a separate – but almost identical – NPP that does not include the Part 2 information, since that section of the facility does not handle Part 2 records. If there is going to be an update to the NPP, AHIMA urges OCR and SAMHSA to pursue a course of action that ensures it is clear to patients, and facilities, where and when they must create and use separate NPP documents.

¹ <https://www.nytimes.com/2019/07/23/health/data-privacy-protection.html>

One potential pathway to remedy this concern is delaying the implementation of an updated NPP until OCR finalizes the revised HIPAA proposed rule released in 2020². The revised HIPAA proposed rule released in 2020 significantly lifts the burden on providers for updating and providing the NPP to patients by requiring providers to demonstrate a patient has received an NPP, instead of receiving signature of receipt. By delaying the updated SUD requirements in the NPP until this proposed change is finalized, providers would be able to more easily adapt to the updated requirements and provide the patients with the notice required under this proposal more easily.

As it relates to the burden calculation used by OCR and SAMHSA for updating the NPP, it is crucial to understand that the updated NPP requirements and the requirements in this rule impact more than just Part 2 programs, as many different providers may come into contact with Part 2 records. As a result, the cost associated with updating the NPP should not be limited to just Part 2 programs, but instead all covered entities (CEs). While some large and better resourced organizations are consistently updating their NPP on a regular basis, some less resourced organizations may only update the NPP when they need to. Additionally, those better resourced organizations would have less cost burden to implement these proposed changes as they have routinely updated the content and completeness of their NPP. Meanwhile, smaller organizations that have less regularly revised their NPP may need to employ or contract outside legal experts to meet the requirements.

§ 2.23 —Patient access and restrictions on use and disclosure (proposed heading)

AHIMA supports removing the requirement to provide written consent or authorization for patients to access their own Part 2 records. Revising this requirement allows for easier flows of data throughout the health system and increases the ability for patients to actively direct their data.

§ 2.24—Requirements for intermediaries (Redesignated and proposed heading)

AHIMA urges OCR and SAMHSA to review the contents of the proposal to allow patients to receive an accounting of disclosure for intermediaries to determine the feasibility, necessity, and burden for implementing this requirement. As outlined in the revised definition of an intermediary, complex interoperability focused organizations such as health information exchanges (HIEs) and health information networks (HINs) will be included in this requirement and will need to provide this information to patients. Many provider organizations also act in multiple roles within the health system, sometimes functioning as both a provider and potentially as an intermediary. This proposed requirement would significantly increase the burden on a provider organization to respond to a patient's request for the accounting of their disclosures and could blur the lines of understanding related to if, and when, they have to provide both an accounting of disclosures from the provider organization and from the intermediary to fulfill a patient request.

Additionally, providers are continuing to wait for additional rulemaking from OCR related to the accounting of disclosures for TPO under the HIPAA law. A lack of clarity from OCR with other unfinished regulatory requirements still to be released will increase confusion on how best to comply with these requirements under Part 2. Waiting to finalize these proposals until there is clear unified clarity across Part 2 and HIPAA would ensure providers can limit their burden in compliance now and in the future.

² <https://www.hhs.gov/sites/default/files/hipaa-nprm-factsheet.pdf>

As it stands today, AHIMA members have indicated that the number of requests they receive from patients for an accounting of disclosures is minimal, but the burden of responding to one of these requests is incredibly burdensome on the provider organization. One member estimated that a single patient's accounting for disclosures could take one staffer a full 40-hour week to complete. That burden will become exponentially larger if they must then do the accounting of disclosures for an intermediary as well.

The burden for an intermediary to respond to such a request from a patient is impossible to estimate. Intermediaries handle millions of interoperability data exchange-based transactions daily. With the advent of more interconnected systems, including the Trusted Exchange Framework and Common Agreement (TEFCA), and the application programming interface (API) provisions coming into effect under the 21st Century Cures Act final rules, even more data will be available for disclosure and use without the intermediary being engaged actively in the consent or disclosure. It would be incredibly difficult for an intermediary to fully log all the individual accesses and know why that data was accessed over the course of a multi-year period. Patients have the right to understand where their data is moving and being accessed but needing to account for all authorized disclosures from a patient defeats the at rest access nature of interoperability outlined by the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare and Medicaid Services (CMS) final interoperability and patient access rules.

It is crucial for SAMHSA and OCR to fully understand the regulatory goals of this proposal and then evaluate feedback from the healthcare continuum to determine if those goals are met. As it stands as written, the goals behind implementing these accounting for disclosure proposals remain unclear. It is important for patients to understand where and how their data is being transferred, but it must be done while maintaining the interoperability pathway outlined by other HHS programs and with the full understanding of burden represented. Intermediaries play an important role in the healthcare ecosystem and to continue encouraging their good-faith activities, it is important for HHS to ensure they are not unduly overburdened with burdensome and potentially under-utilized processes.

§ 2.25—Accounting of disclosures (proposed heading).

As stated above, AHIMA urges OCR and SAMHSA to review and reconsider the structure in which these requirements are outlined for providers in the respect to Part 2 records. The burden related to responding to patient requested accountings of disclosure for providers remains high. A single request for an accounting of disclosures from a patient may take one staffer within an organization a full 40-hour week to respond. Even then, that staffer may not be able to fully respond to the patient's accounting of disclosures because the justification for access and information simply may not exist.

Additionally, OCR and SAMHSA should also ensure no requirement is put in place prior to providing further clarification on the HITECH requirements for TPO disclosure referenced in this rulemaking. Providing clarity in regulatory guidance and rulemaking plays a crucial part in limiting compliance burden. Increased confusion in regulatory requirements puts unnecessary strain on less resourced providers and more capable providers alike. OCR and SAMHSA should ensure these regulatory changes are finalized prior to mandating any additional accounting of disclosures requirements that align Part 2 and HIPAA.

The technical capabilities do not exist today to give providers the information needed to account for why someone within a provider facility may have accessed a patient's record three years prior to the request, as outlined in the proposed rule. Additionally, the staff member who accessed the record most

likely would not remember the reason for access or may no longer be with the provider organization to provide the information. Unless technical capabilities are developed within certified EHR technology (CEHRT) to capture why someone has opened a patient record, providing a full accounting will be impossible.

Additionally, AHIMA members have expressed that requiring these lengthy and burdensome requirements counter the interoperable health system HHS has worked to build. Requiring providers to mark and maintain a full accounting of all access to records will incentivize providers to forego going into a patient's record, even when it may be better for treatment coordination.

Finally, this requirement increases the burden on the provider to implement the policy and procedures needed to respond to these requirements despite the accounting of disclosures being a restatement back to the patient of disclosures they have authorized. While patients are often burdened with much during the course of their care, the accounting of the disclosures they would be requesting in this case are disclosures that they themselves have authorized. While providing such an accounting can be helpful for patients to understand where their data was viewed, it can be difficult at times to understand the value of a patient receiving such an accounting when they themselves approved the disclosure. We recommend OCR and SAMHSA work with both providers and patient advocacy organizations to revise these requirements to better shape them around the interoperability reality created by HHS and to ensure the disclosures actually meets the needs of what the patient is requesting.

§ 2.26—Right to request privacy protection for records (proposed heading)

AHIMA supports the creation of a mechanism in regulatory rulemaking for patients to restrict where and who can access their records in specific situations. Providing patients the ability to request privacy protections builds trust on behalf of the patient in the health system by allowing them to control the use and disclosure of their health record. The shift in language proposed to align Part 2 requirements to those under the HIPAA Privacy Rule would be minimal, as most organizations currently follow the HIPAA Privacy Rule requirements and align with state requirements that govern the use and disclosure of Part 2 records. As OCR and SAMHSA finalize these requirements it is crucial that the ability for a patient to request restriction of disclosure is not mandatory for providers to adhere to when they are otherwise required to provide disclosure. Those requests are documented within in the scope of the patient record and AHIMA urges OCR and SAMHSA to maintain the status-quo of how these documentation and response requirements are currently implemented under the HIPAA Privacy Rule, while also bringing additional Part 2 programs that previously did not need to adhere to these requirements into alignment.

§ 2.31—Consent requirements

AHIMA supports the changes outlined within the proposed rule to further align the requirements governing Part 2 records with the requirements outlined under the HIPAA Privacy Rule. It is important for the government to further align regulation, when possible, to alleviate regulatory burden and create clear, concise regulatory policy. This is especially crucial in the healthcare continuum as more providers are becoming multi-specialty providers and governing both Part 2 treatment programs and standard inpatient/outpatient care. AHIMA supports any opportunity to remove regulatory morass and notes that many Part 2 programs often adhered to both Part 2 and HIPAA Privacy requirements to maintain compliance. This alignment alleviates their need to ensure compliance with two separate programs.

On the question of oral revocations of consent, it is important for OCR and SAMHSA to maintain the ability for patients to revoke consent for the disclosure of their records given the sensitive nature of the

information contained within these records. Providers document oral revocation of consent in much the same way that written revocation of consent is managed. The nature of the highly interoperable health system we have today means that providers document consent decrees within the system in which the records are managed. Maintaining this oral revocation is crucial for ensuring the patient knows they control the movement of their information, especially given that maintaining this process does not significantly impact or over burden the provider.

§ 2.32—Notice to accompany disclosure (proposed heading)

AHIMA supports the proposal to include a notice to accompany disclosure of records to instruct an organization of their ability to redisclose this information at the direction of the patient. It is important for OCR and SAMHSA to engage the technology companies and intermediaries most likely involved in the transportation and receipt of these types of disclosures and the accompanying notices to understand the feasibilities and technical capacities in current technology. As the health system moves away from paper and the transmission of paper through processes like fax machines, having the technical capabilities in place for providers to move this information with the record is crucial. Engaging the organizations that govern this work will give OCR and SAMHSA a clearer picture of understanding related to the ability for an accompanying notice of disclosure to be included with a Part 2 record and consent form.

§ 2.33—Uses and disclosures permitted with written consent (proposed heading)

AHIMA supports the proposal to streamline the use and disclosure process permitted with written consent outlined within the proposed rule. Additionally, the use and disclosure requirements outlined in this proposed rule would assist in limiting the burden faced by providers in data segmentation practices. Aligning the consent and disclosure requirements with those outlined in the HIPAA Privacy Rule allows providers to have all their data governed under one data consent policy, meaning less reliance on data segmentation practices.

AHIMA also urges OCR and SAMHSA to engage in a request for information process to determine the technical and financial needs required to increase coordination of Part 2 data across the health system. Currently, it is unclear what technical or financial needs exist across the health care continuum to ensure coordination and to ensure no single member of the healthcare continuum is overburdened. If it is determined a financial and technical gap exists, AHIMA recommends OCR and SAMHSA pursue a series of programs that provide financial support to programs in need of assistance to participate in this additional coordination.

§ 2.51—Medical emergencies

AHIMA supports the ability for providers, under certain circumstances such as medical emergencies, to access, use, and disclose patient Part 2 data when absolutely necessary. It is important for providers to have access to all points of decision making in a medical emergency to ensure patients are protected physically both in the short and the long-term.

§ 2.54—Disclosures for public health (proposed heading)

AHIMA cautions OCR and SAMHSA from pursuing a public health future of data use and disclosure focused on the current de-identified data standard. While providers currently follow the HIPAA de-identification standard, it is crucial for OCR and SAMHSA to understand that patients may not fully trust

a provider that is transmitting any data to a government agency, especially if that data governs something as sensitive as SUD data. AHIMA urges OCR and SAMHSA to fully understand the realities of de-identified data and to engage patient advocacy focused organizations to understand if transmitting de-identified data to public health entities would jeopardize patient trust in Part 2 programs.

Requests for Comment

§ 2.2 Purpose and Effect

AHIMA does not believe the addition of “use” or “uses” to existing regulatory text would substantively expand the scope of requirements and prohibitions where previously the text stated only “disclosure.” The addition of “use” or “uses” may actually narrow the scope for which Part 2 data can be obtained, as disclosure does not require the implication that the data is being used for TPO and could just be held by an entity.

§ 2.3 Civil and Criminal Penalties for Violations

AHIMA believes there would be significant impact on patient trust if investigative agencies were able to utilize a safe harbor when they unknowingly are in the receipt of Part 2 records after checking whether the program provides SUD services. As OCR and SAMHSA are aware, many patients in SUD treatment are utilizing substances that are illegal to obtain, possess, and use. If a patient believed that their information related to seeking SUD treatment, or admitting continued SUD while in treatment, could be disclosed to an investigative federal government agency, then they may forgo or stop receiving that treatment. SUD treatment and the Part 2 records that accompany that treatment are some of the most sensitive pieces of a person’s health record. If a patient does not believe that information will remain protected and thus could be viewed by an unintended person, then a patient has the potential to forgo treatment to maintain that privacy. It is important for OCR and SAMHSA to engage with patient advocacy organizations to understand the needs of patients to protect that privacy and ensure treatment is not foregone due to a fear of exposure.

§ 2.16 Security for records and notification of breaches

Many Part 2 programs that handle medical records are themselves considered covered entities, either due to the healthcare activities they participate in or are linked to within the healthcare continuum. AHIMA members that are Part 2 programs indicated that many – if not all – of them already follow the HIPAA standards for both breach notification and de-identified data. These statements by AHIMA members lead AHIMA and its membership to believe that the burden placed on Part 2 programs that are not covered entities to align with both the HIPAA breach notification and de-identification standards to be minimal. However, AHIMA members only represent a small subset of the Part 2 community and do not reflect the true scope of all Part 2 programs. As a result, AHIMA recommends OCR and SAMHSA to engage in a broader review of the burden for Part 2 programs to align with these requirements to ensure all Part 2 program viewpoints and circumstances are reflected in this request for information.

§ 2.24 Requirements for intermediaries

AHIMA, consistent with its comments related to the accounting for disclosures requirements above, supports the reorganization and clarification of requirements for entities that facilitate HIE. It is crucial for OCR and SAMHSA to fully understand the feasibility for both Part 2 programs and the intermediaries themselves to complete a full accounting of disclosures for TPO. As previously stated, the

interoperability future outlined by other relevant HHS agencies envisions a health system where consent is given, received, and information is moved at rest with little or no input from the requesting or receiving provider. Due to this outlined system, the expectation exists that millions of transactions will be facilitated by the intermediary daily. As a result, it will be difficult for both the Part 2 program and the intermediary to provide a full accounting of disclosure that would feasibly be usable and helpful to the patient.

§ 2.25 Accounting of disclosures

AHIMA members have indicated that for all healthcare settings, not just those settings handling Part 2 records, patients do not routinely request an accounting of disclosures whether for TPO or non-TPO activities. At the same time, members did indicate that any single request for an accounting of disclosures whether for TPO or non-TPO activities is incredibly burdensome on the healthcare provider. A single accounting for disclosure request could require one staffer more than 40 hours of work to fully account for that disclosure. While an EHR may assist in being able to give providers additional information on who accessed a patient's record, it is difficult for that provider to understand why the record was accessed. This is increasingly problematic the further in the past the disclosure needs to be accounted for, resulting in the provider being unable to fulfill the accounting of disclosure completely.

§ 2.26 Right to request privacy protection for records

AHIMA members that exist as Part 2 members have indicated that a patient's request to restrict access to a record is common and usually aligns with state law's that mandate patients be granted the ability to restrict access for reasons such as adolescent age. While data segmentation challenges remain due to technical feasibility surrounding the data itself, many Part 2 programs who additionally function as other healthcare providers can cope with these challenges to meet a patient's privacy needs and concerns.

§ 2.31 Consent requirements

AHIMA members who serve as Part 2 programs have indicated that data segmentation is largely not needed when handling consent requirements for records such as those that would be considered "SUD counseling notes." As previously noted above, most patient data that would be included in this category is already included in the larger record and is not segmented out. This is due both to the need for this information to be stored with the record coded as a different note type, or a technical limitation that makes Part 2 record segmentation impossible.

On the question of intermediaries and tracking consent, Part 2 providers will need to include indication in the consent for use and redisclosure information that their Part 2 records may be submitted to an intermediary. In the consent form, patients would then be able to indicate whether they provide consent for disclosure to the intermediary. For additional information on how an intermediary would accept or track patient consent for data redisclosure, AHIMA recommends OCR and SAMHSA consult nationwide HINs, as well as ONC, to understand how current state HINs and the TEFCA could impact this landscape.

Finally, on the question of oral consent, Part 2 programs are most likely to document oral consent through the Part 2 record itself, while others may ask patients to follow up an oral consent with a written or updated consent form. These activities ensure the Part 2 program has a record of the consent process and can audit and evaluate their own consent practices.

§ 2.33 Uses and disclosures permitted with written consent

If OCR and SAMHSA were to pursue requiring consent to be included with Part 2 record exchange, it is important for health IT end users to be engaged early in the process to understand the technical feasibility of exchanging a copy of consent with information. As it stands today, very limited capability exists to exchange a copy of consent with other pieces of Part 2 information. It is crucial for both providers and health IT developers be engaged early on to ensure that if this is to be required in the future, that the technical capabilities exist to accomplish this goal.

Finally, AHIMA recommends OCR and SAMHSA ensure that requirements are in place requiring programs to inform HIEs, and HIEs to follow, a patient's request to revoke consent for distribution of their information for TPO. If patients are not able to stop the exchange of their information once it is released to an HIE, they will hesitate to consent to information being released to an HIE or HIN. It is crucial for OCR and SAMHSA to ensure that redisclosure and exchange stops across the healthcare ecosystem once a patient no longer wants it to exist. This is to protect both patient privacy and health record accuracy. If a patient's data is out of date at one provider and the patient cannot revoke consent for that information to be exchanged by an HIE, then they will continue to fight a losing battle to ensure every subsequent record is correct as the HIE may still be exchanging the incorrect information.

§ 2.54 Disclosures for public health

As stated above, AHIMA urges OCR and SAMHSA to determine whether the current de-identification standard ensures Part 2 SUD data is truly anonymized and cannot be linked back to a patient at a future date. The de-identification standard for data within healthcare continues to evolve and change overtime as technology and artificial intelligence is better able to reidentify patients. To ensure patient trust in the health system is maintained, OCR and SAMHSA must ensure de-identified data remains anonymous.

AHIMA looks forward to continuing to support this important work to relieve both patient and provider burden across the health system. If AHIMA can provide any further information, or if there are any questions regarding this letter and its recommendations, please contact Andrew Tomlinson, Director of Regulatory Affairs, at andrew.tomlinson@ahima.org.

Sincerely,



Lauren Riplinger, JD
Chief Public Policy & Impact Officer
AHIMA