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April 11, 2016

Acting Administrator Kana Enomoto
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Room 13N02B
Rockville, Maryland 20857

RE: Confidentiality of Substance Use Disorder Patient Records (SAMSHA 4162-20)

VIA E-MAIL

Dear Acting Administrator Enomoto:

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 effective health information management, information governance, and applied informatics. 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 providers. AHIMA provides leadership through education and workforce development, as well as thought leadership in continuing HIM research and applied management for health information analytics.

We appreciate SAMSHA's intent under the proposed rule to facilitate information exchange within new healthcare models while addressing the privacy concerns of patients seeking treatment for a substance use disorder. However, AHIMA believes that SAMSHA should align 42 CFR part 2 with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to ensure greater consistency in the access, use and disclosure of substance use disorder records to improve care coordination and produce quality outcomes.

Although the proposed rule covers a number of topics, we have focused our comments below on several issues that AHIMA believes are critical to ensuring that patients with substance use disorders have the ability to participate in and benefit from new integrated healthcare models without fear of putting themselves at risk of adverse consequences.

Definitions

Treating Provider Relationship

AHIMA believes that further clarity and guidance is needed on the definition "treating provider relationship" as it is currently defined in the proposed rule. For instance, the proposed definition currently states that a treating provider relationship may be evidenced by making an appointment or via a telephone consultation. What if the individual does not show for his or her appointment—is the treating provider relationship terminated? How does the treating provider verify that the individual making the appointment is in fact the individual seeking treatment? What if a family member makes the appointment for the individual—does that mean the treating provider relationship has begun even though it was not the individual herself that sought the health-related assistance?

AHIMA is also concerned that the proposed rule does not address the fact that many states define "treating provider relationship" differently. Would this proposed definition preempt state law definitions? AHIMA is concerned that the proposed definition may generate confusion and therefore asks SAMSHA to provide clarity as to how the proposed definition intersects with the state-level definition. AHIMA also recommends SAMSHA try to align the proposed definition with a consensus state-level definition of "treating provider relationship" to avoid further confusion.

Records

AHIMA is concerned about the definition of "records" in the proposed rule, which includes "any information, whether recorded or not, received or acquired by a part 2 program relating to a patient." In particular, AHIMA seeks greater clarity of this definition from SAMSHA. For example, does this definition include any record including billing information? Are such things as e-mails, voice recordings, texts, photos, and video also considered part of the record? We also seek guidance on what constitutes unrecorded information and how such information can be included as part of the "record."

Applicability

AHIMA appreciates that SAMSHA, when considering options for defining what information is covered by 42 CFR part 2, rejected the option of defining covered information based on the type of substance use disorder treatment services rather than the type of facility providing the services. AHIMA had previously submitted comments expressing our concern that such an option could negatively impact providers. Therefore, we are pleased that SAMSHA has abandoned this option under the proposed rule.

Confidentiality Restrictions and Safeguards

AHIMA appreciates that SAMSHA proposes to permit, in certain circumstances, the inclusion of a general designation in the "To Whom" section of the consent form.

That said, AHIMA is concerned about SAMSHA's proposal under §2.13(d) that would allow patients who have included a general designation in the "To Whom" section of their consent form be provided, upon their request by the entity without a treating provider relationship, a list of entities to which their information has been disclosed pursuant to the general designation.

As a member of the GetMyHealthData campaign, AHIMA has long advocated that consumers' access to their health information is essential to improved health and healthcare. We agree with SAMSHA that the list of disclosures should be limited to disclosures made within the past two years. We also appreciate that entities named on the consent form that disclose information to their participants under the general designation must respond to requests for a list of disclosures in 30 calendar days or less upon receipt of the request so as to align such efforts with patient access to their health information under HIPAA. That said, we do recommend that SAMSHA align this requirement with HIPAA and allow an entity unable to provide such disclosures within 30 calendar days, to be able to extend the time no later than an additional 30 days. We also recommend that to extend such time, the entity must, within the initial 30 days, inform the participant in writing of the reasons for the delay and the date by which the entity will provide such disclosures. Additionally, we recommend that only one extension be permitted per disclosure request.

AHIMA also recommends that SAMSHA does not include the suggested verbiage in the proposed rule for requesting such disclosures because HIPAA has shown us in the past that entities construe such language as a necessary requirement when an individual requests such information, thereby hindering his or her ability to obtain such information contrary to the intent of the proposed rule. Rather, AHIMA suggests that SAMSHA, as part of this proposed rule or in guidance at a later date, recommend that certain criteria be included as part of an individual's request for such disclosures.

Additionally, AHIMA is concerned about the ability of health information exchanges (HIEs) to meet the disclosure obligations proposed under the rule. In particular, sustainability remains a challenge for many state HIE programs.[1] Requiring HIEs to provide a list of disclosures at this time may not only be administratively cumbersome but could place additional financial constraints on HIEs that are already under fiscal limitations.

Consent Requirements

AHIMA appreciates SAMSHA's intent to address concerns regarding the current consent requirements under 42 CFR part 2.

Given the changes proposed here to the consent requirement, AHIMA believes that consent forms will need to be updated and recommends that SAMSHA consider issuing guidance at a later date that includes suggested criteria that may be included in a consent form. AHIMA would be happy to assist SAMSHA with HIM-related expertise in developing such criteria.

AHIMA would also like to note that while the proposed rule does not address changes to the revocation or refusal of consent under §2.31, the refusal or revocation of consent remains a challenge in cases of an electronic health record (EHR) for an entire health system. If a primary care physician, as a member of a health system, has access to the health system's EHR, it is often difficult to prevent complete access to the patient's record.

[1] Office of the National Coordinator for Health Information Technology. *Evaluation of the State HIE Cooperative Agreement Program* (Publication No. HHSP2337010T/OS33547). Washington, DC: NORC at the University of Chicago, 2016.

Prohibition on Re-disclosure

AHIMA appreciates SAMSHA's intent to clarify that the prohibition on re-disclosure only applies to health information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, as indicated through standard medical codes, descriptive language, or both, and allows other health-related information shared by the part 2 program to be re-disclosed if permissible under other applicable law. AHIMA also appreciates the proposed clarification by SAMSHA in the proposed rule that if the data provenance reveals that the information would identify, directly or indirectly, an individual as having or having had a substance use disorder, the information would be prohibited from being re-disclosed.

However, AHIMA is concerned that this requirement in the proposed rule will in turn require HIM professionals to have clinical knowledge regarding certain medical conditions and medications beyond current qualification requirements in order to identify information that would directly or indirectly identify an individual as having been diagnosed, treated, or referred to treatment for a substance use disorder. This is of particular concern in general medical facilities where HIM professionals may not be as familiar with such substance use disorder information compared to a substance use disorder treatment clinic or similar behavioral health facility.

AHIMA is also concerned that data segmentation policies in EHRs will not be sufficiently mature when this rule is implemented to allow for certain health information to be shared and other sensitive health information to be prohibited from re-disclosure. While there are important efforts under way to facilitate technical solutions to this problem, uncertainty exists about widespread availability and implementation of such functionality. Consequently, we remain concerned that despite SAMSHA's intent to clarify what types of health information is prohibited from re-disclosure, at least until more robust data segmentation policies are in place, many providers will continue to prohibit the re-disclosure of the patient's entire record.

Medical Emergencies

AHIMA appreciates SAMSHA's intent under the proposed rule to adapt the medical emergency exception to give providers more discretion to determine when a "bona fide medical emergency" exists. Under current law, to parse out certain data based upon a service is unwieldy and unmanageable. It creates patient safety issues, such as the lack of access to a patient's complete data, and can be technically difficult to accomplish.

Deciding what information to make available for a medical emergency will continue to be a challenge as emergencies may be viewed differently by different people and what may be viewed as an emergency in "real time" may not be viewed as an emergency after time elapses. This could result in additional risks for unintentional disclosures of information that may not be medically necessary, but when considering the situation in real time, it is more beneficial to have more information than insufficient data so appropriate, quality care may be provided. AHIMA will continue to advocate for safeguards to be implemented to ensure that access is limited to the "minimum necessary" guidelines.

However, AHIMA is concerned about SAMSHA's recommendation under the proposed rule for providers to consider whether an HIE has the capability to comply with all part 2 requirements, including the capacity to immediately notify the part 2 program when its records have been disclosed pursuant to a medical emergency. While we agree that it is important that HIEs have the policies, protocols, and

technologies in place to appropriately protect patient identifying information, we are concerned that should an HIE be unable to comply with part 2, it may be underutilized, thereby hindering care by making it more difficult for information to be delivered at the right time in the right hands at the proper setting.

Finally, AHIMA believes that any changes to 42 CFR part 2 should be implemented with transparency and education for providers, healthcare institutions, HIM professionals, patients, and other interested stakeholders. As you know, 42 CFR part 2 was last substantively updated in 1987 and the healthcare industry has evolved dramatically since then. Consequently, it is important that SAMSHA provide appropriate resources, tools, and educational materials once the rule has been finalized to ensure that stakeholders are sufficiently prepared for its subsequent implementation.

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 SAMSHA to ensure successful implementation of 42 CFR part 2. Should you or your staff have any additional questions or comments, please contact Lauren Riplinger, Senior Director, Federal Relations, at lauren.riplinger@ahima.org and (202) 839-1218, or Pamela Lane, Vice President, Policy and Government Relations, at pamela.lane@ahima.org and (312) 233-1511.

Sincerely,

Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA
Chief Executive Officer