Netsmart Statement:
SAMHSA Proposed Rule for Confidentiality of Substance Abuse Disorder Patient Records
March 15, 2016

General Comment

Netsmart commends the Substance Abuse and Mental Health Services Administration (SAMHSA) for its efforts to address the complex and varied privacy desires of consumers with a history of treatment for substance use disorders (SUD). The input received by SAMHSA in the June 14, 2015 listening session is reflected to a large degree in the Notice of Proposed Rulemaking (NPRM), Confidentiality of Substance Use Disorder Patient Records.

The intent of the proposed rule is to protect patient privacy, while updating and simplifying the consent process for the sharing of SUD medical records in new integrated care settings like Health Information Exchanges (HIEs), Accountable Care Organizations (ACOs) and Medicaid Health Homes. However, many of the proposed rule's provisions are not viable today, but may be in the future when technology and standards are developed uniformly across all electronic health record (EHR) and HIE vendors.

We believe the proposed rule needs further modifications to:

- More accurately and pragmatically reflect the current state of technology in the field
- Protect the interests of consumers with a history of diagnosis, treatment or referral for SUD who wish to consent to disclose their medical records to their treating providers today using currently available EHR and HIE technology - just like patients with any other illness or chronic disease.

A Framework for Comprehensive, Equal Care for All

To put into context how to address the needs of consumers with SUD records, we believe it is helpful to have a framework to define the needs and desires of these consumers, and the timelines in which they can be achieved.

Assumptions

To think about what is needed, we addressed the following assumptions:

- People with any chronic disease and/or physical health/behavioral health/substance use disorder will receive higher quality care if all clinicians involved in their care can share data to coordinate care.
- Some consumers believe that the sharing of their SUD treatment data could potentially impact their employment, housing and family lives, and thus are reluctant to do so.
- Other consumers with SUD treatment data want to share their data more openly

Consumer Types and Goals

Using these assumptions, we then segmented the population of consumers with SUD treatment data into three main categories, with differing desires on sharing of sensitive data:

- ***Consumer A: Wants to share his or her SUD data freely among their treating providers (subject to HIPAA protections just as for others with a non-SUD diagnosis).*** Any consumer with SUD clinical data that wishes to share that data today without constraint should be able to opt-in to do so in any care environment in the same manner as someone with a disease such as diabetes. Today, Consumer A cannot share his or her SUD information freely in an HIE. The consent and re-disclosure requirements imposed under Part 2 by SAMHSA are too restrictive.
- ***Consumer B: Wants to share only segments of his or her data among their treating providers.*** This is *not* achievable with today's technology, and will require federal regulations requiring that all EHR vendors and HIE vendors modify their systems to perform, respond to and manage this type of segmented data. This requirement cannot be applied today only to Meaningful Use-certified systems, as many behavioral health and SUD treatment providers do not use certified systems because they (the providers) are not fully eligible for Meaningful Use incentive funding. There are other significant problems with this approach, including provider concern about data integrity if they believe consumers are editing clinical data (we think other respondents will address this point in more detail). We also believe that a robust system capable of supporting this type of segmented data will not be available for 5-10 years at the earliest – a timeframe during which the U.S. healthcare system will undergo further significant change.
- ***Consumer C: Does not want to share any data.*** This consumer can choose to opt-out (or not opt-in) to an HIE for sharing their data today.

Economic and Health-Related Discrimination

The ultimate goal of consent should be that any person – whether suffering from mental illness, diabetes, a SUD or multiple co-occurring conditions – be able to share his or her health data with their healthcare providers, utilizing today's technology, with equal simplicity, regardless of their diagnosis, **if they so desire**. If someone does not wish to do so, they should have the clear option to either opt-out or choose not to opt-in to sharing that information.

Current Part 2 regulations and those in the proposed rule effectively discriminate against Consumer A and Consumer B on either or both economic and healthcare terms. A consumer covered by private insurance (or who can afford to pay for private care or who is covered by commercial insurance) can consent to share their data without limitation if their treating providers do not receive federal funds that cause them to be classified as a Part 2 organization. However, current and proposed Part 2 rules prevent a consumer with a lower income who utilizes Medicaid from receiving that same care – in effect denying this group of consumers the benefits of comprehensive, coordinated care.

In addition, a consumer receiving treatment for diabetes can consent to share his or her data among their treating providers freely with the protection of HIPAA. But if that same person also has a history of SUD treatment and receives other treatment from a treating provider subject to 42 CFR Part 2, they cannot consent to receive the same care as the person with diabetes alone, creating a non-level healthcare access playing field for persons with a history of SUD treatment.

Technology Requirements

Advances in technology are needed to meet the needs of Consumer B, who desires to share only segments of his or her medical data, and this will take a significant amount of time. Federal regulatory changes will be needed to assure that all HIEs and all EHR vendors – regardless of whether or not their solutions support SUD treatment – can support the proposed segmentation and consent standards. *All vendors, including those supplying technology to hospitals and primary care, must be required to meet the same standards. All existing systems and HIEs will need to be upgraded to meet these standards. Many regional HIEs will need additional public or private financing to meet those standards, or once again they will refuse to accept SUD data subject to 42 CFR Part 2 protections.*

The primary reason all EHR vendors and HIEs – including those utilized by hospitals and primary care – need to meet the same standards is due primarily to the re-disclosure prohibition set forth in the existing and proposed regulations. Downstream segmentation is required for these vendors because they must continue to maintain the Part 2 information in segregated form since SAMHSA does not address the re-disclosure prohibition in the proposed rule.

The ability to handle consent expirations, revocations and segmentations will require modifications to most HIEs in the country. Changes to EHRs will need to be facilitated through the Office of the National Coordinator for Health Information Technology (ONC) and Meaningful Use Stage 3 or 4 requirements so that all vendors can support the content in a standard format. Changes to non-Meaningful Use-certified EHRs will need to be managed by other regulatory bodies because most substance use treatment providers are not eligible for Meaningful Use funding. We estimate that these changes will take 5-10 years to promulgate to the point where data segmentation will be usable in the market.

Key Recommended Changes

Given the framework outlined above, Netsmart has concerns and recommendations that will be communicated in more detail during the 60-day public comment period. Here are several:

- We recommend alignment of current and proposed consent and re-disclosure provisions to expressly allow consumers to consent to disclose and re-disclose SUD treatment records to all participants in HIEs, including Record Locator Services (RLSs), which are part of the HIE infrastructure, subject to existing HIPAA regulations and consumer consent. This will allow authorized treating providers in the HIE more direct and timely access to health information already authorized via consent to the HIE. As national standards for EHRs and HIEs evolve to support more elaborate management of specific records, this may be updated – but any update should not prevent consumers who want to share their own data today from doing so. Consumers that do not wish to participate can opt-out and continue to operate in the same fashion as they do today.

- Included in the preamble of the proposed regulations is a proposed alternative approach to the interpretation of the consent process. The alternative approach would leave Section 2.31 as written, but create a new definition of "organization" under Section 2.11. The new definition would allow for disclosures to an organization that is not a treating provider, but that serves as

an intermediary in implementing patient consent by providing information to its participants who do have a treating provider relationship. The organization would be allowed to further disclose the information to the participants, and the consent executed by the patient would specify the level of re-disclosure among the participants. In our view, the issue of re-disclosure could be treated differently under the alternative approach, and could limit the ability of a patient to consent to share their data with treating providers in an HIE. We recommend that this approach be modified or removed from the proposed regulations.

- Most HIEs and EHRs today do not support data segmentation. As a result, the easiest way for HIEs to react to 42 CFR Part 2 providers is to exclude them. To ensure that the broadest possible universe of patients receives fully-integrated, connected care, Netsmart urges SAMHSA to work within the realities of today's environment, assuring the regulations do not block persons from receiving care because of data segmentation. We recommend adopting regulations now that simplify consent while protecting patient privacy, and incorporating more complex structures such as data segmentation in a broader mandate or one related to other requirements in order to allow sufficient time for implementation.

- All patient information must be available in order to provide fully-integrated and informed care. The proposed requirements for consent relating to how much and what kind of SUD information is to be disclosed prevents providers from receiving the "full picture." The new standard would limit the ability of providers to share all necessary health information, and would instead result in the piece-meal transmission of critical data. Consumers should be given the option to consent to the disclosure of all records to their treating providers, and not have to specify SUD-related information in the consent.

Enabling persons to share information with their treating providers with appropriate but updated privacy safeguards is key to treatment and recovery for consumers who have a SUD (or a history of SUD, but who are being treated for other disorders). Simplified disclosure rules will also improve the quality and breadth of SUD treatment, mitigate the negative impact of co-occurring conditions, significantly enhance patient safety and reduce the stigma associated with SUD.

As the leading knowledge and technology partner for behavioral health, addiction treatment, public health, and other health and human services providers nationwide, Netsmart serves providers that deliver life-changing services to more than 25 million persons each day. Many of these persons have co-occurring behavioral, substance use and physical health disorders that require integrated, coordinated care and services.

We thank SAMHSA for the progress made so far, and look forward to providing more detailed comments to the proposed rule during the public comment period.

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