Netsmart

February 28, 2018

PrivacyRegulations@SAMHSA.hhs.gov
Substance Abuse and Mental Health Services Administration (SAMHSA)
Department of Health and Human Services
Attn: Mitchell Berger
5600 Fishers Lane
Room 18E89C
Rockville, Maryland 20852

RE: Comments in Response to 42 CFR Part 2 Listening Session

Dear Mr. Berger:

The following are the comments of Netsmart Technologies, Inc. (Netsmart) in response to SAMHSA's Listening Session held on January 31, 2018. The Listening Session provided an opportunity for the public to provide input to SAMHSA concerning the effect of 42 CFR Part 2 on ''patient care, health outcomes, and patient privacy'' as well as potential regulatory changes and future sub-regulatory guidance.

Netsmart provides electronic health records (EHRs) and integrated care technology to behavioral health, care at home, senior living and social services providers. Our clients include 600,000+ users in more than 25,000 provider organizations across the U.S. Part 2 is of major concern to our clients and their ability to share critical healthcare information with other providers in the continuum of care.

Recent History and Modification of Part 2

SAMHSA previously modified Part 2 on January 18, 2017 (Amended Rule), which was intended to update and modernize Part 2 and facilitate information exchange within new healthcare models, while addressing the privacy concerns of patients seeking treatment for a substance use disorder (SUD). While the Amended Rule created new opportunities for the exchange of SUD treatment information under Part 2, there still existed substantial limitations and restrictions which prevent the inclusion of such data within health information exchanges (HIE), accountable care organizations (ACO), and other integrated care environments and models.

Subsequently, SAMHSA issued a final rule on January 3, 2018, that, among other things, added to permitted disclosures for payment and healthcare operations purposes by certain lawful holders of information (Final Rule). Unfortunately, the Final Rule now grants recipients of Part 2 protected information more latitude for payment and healthcare operations than is provided to programs and healthcare providers who receive Part 2 information for treatment purposes. This disconnect – the ability to more easily share SUD information for non-life-threatening payment and operations purposes, while continuing to limit the exchange of SUD information to treat the patient – needs to be addressed by SAMHSA. With the recognition that business and administrative purposes are now allowed under the Final Rule, Part 2 should be revised to reflect the ability to share information for treatment, care coordination, and referrals. The consent provisions impose an insurmountable barrier for coordination of care, treatment and referrals among healthcare providers – even under the provisions now contained in the Final Rule.

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The Goal of Consent

We believe that 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 their health data with their healthcare providers, utilizing today's technology, with equal simplicity, if they so desire. If someone does not wish to share their data, they should have a clear option to either opt-out or not opt-in to sharing that information.

This position is based on three basic assumptions:

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

Here are the basic scenarios:

- **Persons who want to share their SUD data freely among their treating providers** (Subject to HIPAA protections just like 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 physical condition such as diabetes.
- **Persons who want to share only segments of their data with their treating providers.** As described below, this is not achievable with today's technology, and would necessitate that federal regulations require all EHR and HIE vendors to modify their systems to manage this type of segmented data.
- **Persons who do not want to share any data.** This consumer must be able to choose to opt-out or not opt-in to an integrated care setting for sharing their data.

Existing Part 2 consent requirements impede persons with a SUD or history of SUD treatment from receiving coordinated, integrated care.

Part 2 Discriminates

Despite previous modifications, Part 2 continues to discriminate against those with a SUD. First, if a patient suffers from a SUD as opposed to another medical condition, then his or her Part 2 information cannot be included in the general medical record. Part 2's obscure requirements imposed upon that type of information, including both the prohibition against redisclosure and specificity in identifying all recipients, make it necessary to segment or segregate the SUD data. Other medical conditions often associated with stigma, including AIDS/HIV and mental illness, are not subject to these overly-restrictive and stringent restrictions. If a patient wants to share those and other types of information not covered by Part 2, then he or she can do so under HIPAA and applicable law. Part 2 prevents the patient from determining who gets his/her information and creates a gulf between SUD treatment and SUD patients.

Second, Part 2 discriminates against patients who suffer from SUD and seek treatment at private non-federally funded facilities, as compared to those patients who obtain treatment at a federally-assisted program. Patients that obtain SUD treatment from a facility that is not federally-assisted do not face the negative limitations on the exchange of their information because Part 2 does not apply to those facilities. Their information can be freely shared with other healthcare providers, and their care is coordinated for more effective and cost-efficient whole-person treatment.

Part 2 Inhibits a Full Response to the Opioid Epidemic

Part 2 jeopardizes patient safety because of the limitations imposed upon SUD information for treatment and for all uses and disclosures of SUD information. Currently, there are no direct means to share SUD information for purposes of addressing dangerous drug side effects, interactions or overutilization. Instead, the process entails a complex consent process that cannot include all providers involved in the patient's care, and omits certain safety measures such as prescription drug monitoring programs (PDMP).

For example, SUD treatment information that could indicate a drug-drug interaction or identify the risk of prescribing an opioid to someone who is addicted to opioids cannot be shared with another healthcare provider absent a Part 2-compliant consent. This is problematic because the patient may not want the provider to know of an opioid addiction if they are engaging in drug-seeking behavior and thus may not agree to execute a consent. In addition, even if the patient desires to share the SUD treatment information with their other healthcare providers, the complex Part 2 requirements related to identifying all potential recipients in advance or ensuring all potential recipients are a member of the same integrated environment makes such a process virtually impossible.

Part 2 Does Not Treat SUD in Parity with Medical/Surgical Conditions

The federal Mental Health Parity and Addiction Equity Act (Parity Law) imposes an obligation upon insurers to treat behavioral health conditions (mental health and SUD) on par or equally with medical and surgical conditions with respect to benefits and conditions of reimbursement. When analyzing how the Parity Law applies, it is recognized that generally the criteria and specifications used for mental health and SUD should be similar to those and applied similarly to medical and surgical conditions. This concept recognizes SUD as a disease of the mind that could be and should be addressed the same as a disease of any other part of the body. In contrast, Part 2 imposes a separate and unequal restriction on the sharing of SUD information that is not applied equally upon medical and surgical conditions or treatment.

Generally, mental health information (other than certain psychotherapy notes) and medical information can be shared under HIPAA for most treatment purposes without authorization. Those patients suffering from non-SUD conditions have the ability to ensure that their healthcare information can be shared to ensure proper treatment. Those patients with SUDs cannot ensure that level of sharing and collaboration, regardless of the effort they or their treatment providers put forth. Part 2 acts as a barrier to full exchange of that data that is not on par with or equal to the requirements imposed upon medical conditions.

Current Technology Cannot Address the Part 2 Limitations

Under current Part 2 regulations, providers, including those in integrated care settings – HIEs, ACOs and Integrated Health Homes – are required to segment out SUD treatment information from the health record to prevent its disclosure to other treating providers not in the same integrated care setting.

Data segmentation is complex and expensive to implement. While some EHR providers, including Netsmart, can segment data, most EHR and HIE providers would need to modify their systems to do so. The cost of modifying all these systems would be significant – well beyond the estimate provided by SAMHSA in its January 2017 Final Rule.

Best case, even if mandated from the federal level, Netsmart believes that a robust system capable of supporting this type of segmented data would not be available for 7-10 more years. In the meantime, most providers and HIEs do not have the resources to modify their systems to support it.

Consent2Share was intended to make it possible for a person to choose which portions of their health information can be shared with other providers. While a laudable goal, there are significant resource, cost and technology challenges to implementing Consent2Share. Every healthcare provider—every hospital, physician practice, specialty medical practice, ACO, Medicaid Health Home and others—would need to modify their existing EHR systems to accept Consent2Share. They would also have to train their staff on special consent requirements applicable to SUD-related records with Consent2Share, and train patients with Access 1 opioid addiction disorders on how to use it.

In its January 2017 Final Rule, SAMHSA estimated a $250 million cost to implement Consent2Share. Based on the size of our own Netsmart client base and that of other technology providers, we think the cost would be 3-4 times higher, in an approximate range of $3 billion to $4 billion. Also, the List of Disclosures requirement under the Amended Rule will add to those costs because of the need to track recipients and provide that list to patients upon request.

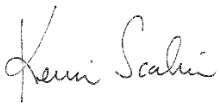
A SAMHSA official speaking in a breakout session the 2018 ONC Annual Meeting acknowledged that there has been “very low” nationwide implementation levels for Consent2Share, and that only one health information exchange and no hospitals in the U.S. have implemented it

Data segmentation and Consent2Share place a burden on the patient, their treating providers and integrated care entities, making it operationally expensive, and with today’s technology, extremely costly to transfer and manage SUD data. In our view, this is discriminatory, preventing people with a SUD from benefiting from coordinated, integrated care and case management, which in turn, exacerbates the stigma often associated with SUD. In fact, some HIEs, won’t accept the health data of patients who have a history of SUD treatment because they lack the technology or financial resources to comply with current consent and data segmentation requirements.

In short, we believe that widespread adoption of Consent 2 Share is not feasible because of technology limitations and the considerable costs associated with implementation.

Netsmart is encouraged by the steps that SAMHSA has taken to integrate Part 2 information into the larger medical realm. Further action is needed to ensure that treatment is among the allowable uses, disclosures and re-disclosures necessary for the treatment of the whole-person. We look forward to working with SAMHSA towards this goal.

Sincerely,



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