

February 17, 2017

**SUBMITTED ELECTRONICALLY (<http://www.regulations.gov>)**

The Substance Abuse and Mental Health Services Administration  
Department of Health and Human Services  
Attn: Danielle Tarino  
SAMHSA  
Room 13E89A  
Rockville, Maryland 20857

**Re: Comments on Supplemental Notice of Proposed Rulemaking for 42 C.F.R. Part 2 (RIN 0930-AA21)**

Dear Ms. Tarino:

The following are the comments of Netsmart Technologies, Inc. (Netsmart) on proposed revisions to Confidentiality of Substance Use Disorder Patient Records found at 42 C.F.R. Part 2 (Part 2), which were published in a Supplemental Notice of Proposed Rulemaking (SNPRM) on January 18, 2017. Netsmart provides expertise, technology, and healthcare connectivity and integration solutions that help addiction treatment, behavioral health and other human services providers deliver effective, outcomes-based services and care to more than 25 million persons nationwide. Netsmart clients include 500,000 users in 24,000 provider organizations across all 50 states.

SAMHSA issued the SNPRM to clarify Part 2 as amended by the concurrently issued Final Rule. Questions raised by commenters on the Proposed Rule highlighted varying interpretations on lawful holders and their contractors and subcontractors' use and disclosure of Part 2 information for purposes of carrying out payment and health care operations activities. SAMHSA seeks comment on proposals in the SNPRM to consider whether an abbreviated notice would be appropriate as it relates to the re-disclosure prohibition. In addition, it seeks input on whether to expand the ability of a recipient to share Part 2 information under § 2.33 (Disclosures permitted with written consent). SAMHSA also questions whether to revise § 2.53 (Audit and Evaluation) to expressly address further disclosures by payors, funders, and their contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or Children's Health Insurance Program (CHIP) audit or evaluation. SAMHSA also seeks comments on the following for its consideration in future rulemaking and guidance: (1) additional purposes for which lawful holders should be able to disclose Part 2 information; and (2) further sub-regulatory guidance that SAMHSA and other agencies could provide to help facilitate implementation of Part 2 in the current healthcare environment.

## Proposed Abbreviated Notice Relating to the Prohibition on Re-Disclosure

The prohibition on re-disclosure under 42 C.F.R. § 2.32 is a major barrier to the robust exchange of health information by Part 2 programs with other health care providers through health information exchanges (HIE), integrated health homes, accountable care organizations (ACO), or other integrated care environments. The Final Rule created a new option for substance use disorder (SUD) patients to consent to the disclosure of their information within HIEs, ACOs, and other integrated care environments by utilizing a generalized designation in the consent form. That new process granted access to Part 2 information by health care providers with a treating provider relationship following the patient's consent. The continued utilization of the lengthy notice under § 2.32 threatens to negatively impact that new process for exchanging Part 2 information. In addition, the reliance upon the old notice language will continue to negatively impact the exchange of Part 2 information outside those integrated care environments.

**Netsmart believes that the lengthy formal notice currently required under the Final Rule causes confusion among recipients of Part 2 information on what information may be shared or re-disclosed.** SAMHSA's clarification in the Final Rule that the prohibition on re-disclosure only applies to information that would identify an individual as a person with an SUD, while concurrently allowing other health-related information to be re-disclosed, is difficult to fulfill because of the current wording of the notice. **The current notice language creates heightened concern by recipients of Part 2 information that goes beyond the limitations as clarified by SAMHSA. This discourages the flow of critical health information which is otherwise allowed under the Final Rule, and further prevents the admirable goals which were the motivation for revisions now set forth under the Final Rule.** Health care providers will not receive the full health record and will be hamstrung in their efforts to effectively treat the patient because of unnecessarily lengthy and complicated language set forth in the current notice. This creates additional clinical risks, inability to coordinate care, and barriers to integrated care. As such, Netsmart requests that the proposed shortened notice language be implemented so that recipients and other lawful holders are not confused in what health information can and cannot be re-disclosed.

## Proposed Revisions to 42 C.F.R. § 2.33

SAMHSA seeks comments on the proper mechanisms to convey the scope of the consent to lawful holders, contractors, subcontractors, and legal representatives, including downstream recipients of Part 2 information, given current electronic data exchange technology. SAMHSA proposes new regulatory text under § 2.33 requiring lawful holders that engage contractors and subcontractors to carry out payment and health care operations using or disclosing Part 2 information to include specific contract and subcontract provisions requiring contractors and subcontractors to comply with the provisions of Part 2.

SAMHSA noted that the list of payment and health care operations activities set forth under proposed § 2.33 is similar to the HIPAA Privacy Rule's definition of the terms "payment" and "health care operations," although SAMHSA is not proposing to adopt those definitions in their entirety. The payment and health care operation activities listed in this section do not include activities related to the patient's diagnosis, treatment, or referral for treatment. SAMHSA believes it is important to maintain patient choice in disclosing information to health care providers with whom they will have direct contact.

For these reasons, SAMHSA's position is that this proposed revision not include care coordination or case management. In addition, disclosures to contractors, subcontractors, and legal representatives to carry out any other purposes are not permitted under the proposed revision.

The SNPRM appears to attempt to expand the uses or disclosures pursuant to a consent by broadening the parties that are contemplated by the designation set forth in the "To Whom" section of a consent. The proposed § 2.33 signals an intent to allow for disclosures that would traditionally be considered re-disclosures by the recipient (known as the "lawful holder") of the Part 2 information, but only for payment and health care operations purposes. This ability to share with contractors and subcontractors is similar to the HIPAA Business Associate relationship with Covered Entities or the Qualified Service Organization ("QSO") relationship with Part 2 programs. It allows for downstream recipients to engage in services on behalf of the recipient identified in the consent without the need for an additional consent. Such services include data analytics and support services. Because of this similarity with QSOs and Business Associates, Netsmart requests clarification on whether it is SAMHSA's intent to directly apply Part 2 to these contractors and subcontractors similar to what was accomplished under the HIPAA Privacy and Security Rules for Business Associates.

Commenters to the Proposed Rule noted that QSOs themselves, as well as state Medicaid programs often use software vendors and other contractors, subcontractors, and legal representatives to carry out administrative and claims processing functions. These relationships could potentially fall under the existing QSO framework but are not easily structured, especially with respect to third parties such as Medicaid. In addition, ACOs often engage analytics companies to provide support in identifying those high-risk patients who would benefit from care management and other services. Those relationships may or may not fall under Part 2 exceptions in the Final Rule. In order to ensure that these processes may be carried out without unnecessary impingement by way of the Final Rule, Netsmart supports this clarification as proposed by SAMHSA which will ensure exchange of Part 2 information for critical payment and operations purposes.

In addition, Netsmart supports any proposed revision that will reduce the paperwork and unnecessary time and expense imposed upon Part 2 programs for purposes of seeking and obtaining patient consent where not necessary. These clarifications should result in less time being spent by Part 2 providers on filling out consents and paperwork, and more time focused on patient well-being and treatment.

**Ironically and unfortunately, the proposed regulatory revision would not allow for re-disclosures for treatment purposes. This means that the patient's Part 2 information may be re-disclosed by payors, plans, and other entities for health care operations or payment purposes, but could not be re-disclosed by a physician or health care provider that received the information for treatment purposes. Netsmart encourages SAMHSA to revisit the re-disclosure prohibition as applied to treatment purposes. Health care providers are almost universally considered "covered entities" under HIPAA, and there is a long-established mechanism under the HIPAA Privacy Rule that addresses not only payment, health care operations, but also treatment, including the recipients' ability to disclose protected health information for those purposes.**

## Proposed Revisions to 42 C.F.R. § 2.35

SAMHSA recognized in the Final Rule the importance of audits and evaluations, and made clear that disclosures of Part 2 information to ACOs and similar CMS-regulated entities to carry out Medicare, Medicaid and CHIP audit and evaluation activities are permitted. Public comments in response to the Proposed Rule requested further clarity regarding the permitted disclosures of Part 2 information for audit and evaluation purposes. Commenters noted that contractors, subcontractors, and legal representatives may conduct audit and evaluation activities on behalf of those third parties. Such entities may not be CMS-regulated, and may be conducted for private payors as well as for Medicare and Medicaid programs. In addition, commenters noted that audits and evaluations may include quality improvement activities, as well as efforts related to reimbursement and financing.

In response, SAMHSA proposed revisions to § 2.53 to expand the scope of the exception to the consent requirement to allow for private payors and federal, state, and local funders to access the Part 2 information for audit and evaluation purposes. In addition, proposed § 2.53 incorporates some of the language from proposed § 2.33 relating to the ability of the recipient to re-disclose Part 2 information to contractors, subcontractors, or legal representatives.

The proposed revisions to § 2.53 further expand the ability to share and re-disclose Part 2 information for important audit and evaluation purposes. These disclosures and re-disclosures are necessary to ensure the efficient operation and provision of health care and treatment. The revision will result in less time and expense imposed upon Part 2 programs, which must obtain patient consent (in certain instances) for the benefit of third parties to which it is not clear disclosure and re-disclosure is allowed under the Final Rule. Furthermore, the continued expansion of opportunities to disclose Part 2 information is a worthwhile goal for data exchange and the further integration of Part 2 information into the medical/surgical realm.

### Additional Requests for Comment

SAMHSA has requested additional comments on other purposes for which lawful holders should be able to disclose Part 2 information. SAMHSA also seeks comment on whether there is further sub-regulatory guidance that could provide to help facilitate implementation of Part 2 in the current healthcare environment.

The Final Rule is a step in the right direction. The inclusion of Part 2 information in an integrated care environment and the SNPRM provide additional clarity about the ability to share such information for payment, health care operations, audit, and evaluation purposes. **However, the primary issue continues to be the inability of Part 2 programs to share information for treatment purposes when the patient so desires it. It seems counterintuitive to provide clarification that allows for more expansive uses, disclosures, and re-disclosures for payment and health care operations purposes while not allowing for the same expansive exchange of critical health care information among and between health care providers that are already governed by stringent HIPAA privacy and security requirements. Netsmart requests that SAMHSA address this disparity by crafting corresponding uses, disclosures, and re-disclosures for treatment purposes.**

In light of the modifications to the “To Whom” requirements for a Part 2 consent, coupled with the addition of the List of Disclosures requirement, Netsmart believes that further education and training on these new provisions and Part 2 as a whole will be necessary. Sub-regulatory guidance and other materials and resources must be available for this massive transition, including information and support for Part 2 programs, other health care providers, payors, and their contractors and subcontractors.

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 patient. We look forward to working with SAMHSA towards this goal.

Sincerely,

A handwritten signature in black ink that reads "Kevin Scalia". The signature is written in a cursive, flowing style.

Kevin Scalia  
Executive Vice President  
Netsmart  
4950 College Blvd.  
Overland Park, Kansas 66211  
kscalia@ntst.com  
516-241-2575