April 11, 2016

SUBMITTED ELECTRONICALLY (http://www.regulations.gov)
The Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
Attention: SAMHSA-4162-20
5600 Fishers Lane
Room 13N02B
Rockville, MD 20857

Re: Comments on Proposed Revisions to 42 C.F.R. Part 2 (SAMHSA-4162-20)

Dear Ms. Enomoto:

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 Notice of Proposed Rulemaking (NPRM) on February 9, 2016. 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 in provider organizations across all 50 states.

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 June 14, 2015 listening session hosted by SAMHSA is reflected to a large degree in the NPRM.

As noted in the NPRM, the Part 2 regulations had not been substantively updated since 1987. Since that time the health care system has seen tremendous development and advancements in the areas of care integration, sharing and exchange of health information, coordination of care, and an emphasis upon performance-based reimbursement and clinical quality measures. Federal reimbursement and incentive programs have supported the creation of Health Information Exchanges (HIEs), Accountable Care Organizations (ACOs), and Coordinated Care Organizations (CCOs). At the same time, there has been a heightened recognition of the need to fully treat patients with mental health and SUD conditions, along with co-occurring disorders, with the twin goals of improving the health and reducing health care delivery costs to this high-risk, high-utilizer population. Furthermore, the President has highlighted the dangerous opioid and heroin abuse epidemic that has gripped all corners of our country. These factors have combined to place behavioral health, and particularly SUD, at the forefront of the national conversation and as a critical component of the health care system in the United States.

In order to participate in this sea change of transformation in health care, it is now necessary for SAMHSA to address the limitations imposed under existing Part 2 regulations. SAMHSA has taken some steps in the past to attempt to address the technological and legal hurdles to integration and coordination of health care information, but as SAMHSA itself recognizes in the NPRM, SUD information is still not included within these systems.

The stated intent of the proposed rule is to modernize the key provisions of Part 2 because behavioral health care, including SUD treatment, is essential to the overall health of Americans; because the costs of untreated SUD, both personal and societal, are substantial; and because there continues to be a need for confidentiality protections that encourage patients to seek treatment without fear of compromising their privacy. SAMHSA has attempted to balance these concerns to facilitate information exchange within new and emerging integrated health care models, while at the same time respecting the privacy concerns of patients seeking SUD treatment.

Netsmart echoes these important concepts, but adds an additional element to the discussion: patient choice. Whether and to what extent a patient desires to share any information, particularly SUD treatment information, is fundamentally a decision that should lie with the patient and not the Part 2 program, SAMHSA, or the health care system. Certain patients may have heightened concerns over the use or disclosure of their SUD treatment information. Those patients should have the right to withhold their information – any health care information, including SUD treatment information – from HIEs, ACOs, and CCOs.

Correspondingly, other patients recognize the value and benefit of sharing their health care information, including SUD treatment information, with all of their treating health care providers. Those patients should also be given a legitimate opportunity to do so, in order to access the full scope and range of benefits available under integrated care models. A third alternative, for those patients that only want to share a portion of their health care information, poses special issues which must first be addressed from a technology perspective. We believe that all three patient perspectives need to be addressed by SAMHSA.

Any consumer with SUD treatment information that wishes to share that data today without constraint should be able to do so in any integrated care environment in the same manner as someone with a disease, such as diabetes. Today, such a consumer cannot share his or her SUD treatment information freely in an HIE, ACO, or CCO because the consent and re-disclosure requirements imposed under Part 2 by SAMHSA are too restrictive. In addition, as explained below, the proposed revisions to Part 2 still impose too many limitations upon the free flow of SUD treatment information and would not allow this consumer to share her or his data in a manner that is effective.

Alternatively, a consumer who does not want to share any treatment information can easily and effectively carry out his or her desires under current or proposed Part 2

regulations. This consumer can choose to opt-out (or not opt-in) to an HIE for sharing their SUD treatment information.

A third situation would involve a consumer who wants to share only segments of his or her data among their treating providers. Unfortunately, this is not achievable with today's technology. While certain electronic health record (EHR) vendors, such as Netsmart, are able to segment data, many other EHR vendors and HIE vendors will need to modify their systems to perform, respond to and manage this type of segmented data. Netsmart believes that a robust system capable of supporting this type of segmented data will not be available for 5-10 more years, rendering the potential for this type of data exchange moot for the near future.

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.

The ultimate goal of consent should be that any person – whether suffering from mental illness, diabetes, an SUD or multiple co-occurring conditions – be able to share his or her health data with their health care 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. With this context in mind, Netsmart submits the following substantive comments on the proposed revisions to Part 2.

1. **Modification to Consent Requirements (42 C.F.R § 2.31)**

   A. Electronic Consent

Under the proposed revisions set forth at 42 C.F.R. § 2.31, electronic consent would be acceptable. Netsmart acknowledges this improvement to the consent process. However, there are unanswered questions raised by this change.

First, we seek guidance on what will be required of providers in order to obtain competent, valid, and informed consent for the release of SUD treatment information. For decades, SUD programs have utilized a standard consent form to authorize use or disclosure of SUD treatment records. Under this new electronic form, those programs will need to understand what will be necessary to comply with not only Part 2, but other legal requirements relating to a valid consent.

Second, if SAMHSA intends for electronic consent to simply be a digitally-stored image of a paper consent form, then the benefits of electronic processes will not be maximized. Netsmart requests that SAMHSA identify the signatory and enforceability considerations of an electronic consent, through reference to other existing law, such as the federal E-

SIGN law as well as by way of sub-regulatory guidance issued by the administration.

Third, in order to avoid confusion among various programs, between Part 2-covered providers and related entities that may not be considered part of the program, and the front office staff that serves these providers, we suggest that SAMHSA prepare a model or template consent form – in both paper and electronic formats. Such guidance would also serve to educate other health care providers that may not have the familiarity, experience, expertise or technical assistance to understand Part 2 and its unique requirements.

B. To Whom Limitation

For purposes of carrying out the exchange of SUD treatment information within an HIE, one of the most troublesome aspects of current Part 2 is the requirement set forth under 42 C.F.R. § 2.31(a)(4) that the consent must include the names of the recipient(s) to whom the SUD treatment information is being disclosed. The current interpretation placed upon this subsection has imposed substantial limitations on the inclusion of SUD treatment information within HIEs by requiring an updated list of HIE participants. Each time a new participant is added to the HIE, the list of participants must be updated and provided to the patient. This poses undue burdens upon the HIE and the record locator services (RLS) utilized by HIEs which may identify a provider as a Part 2 program, and has resulted in the vast majority of HIEs in the country excluding SUD treatment information. This, in effect, denies the benefits of integrated care to a segment of the population. The proposed revision would appear to address the issue and allow for the exchange of SUD treatment information in certain limited circumstances. Before addressing those circumstances, Netsmart would like to express its support for the continued limitations upon disclosure of SUD treatment information to payors and law enforcement. The loosening of restrictions should not be expanded beyond that which is necessary for the effective treatment of the patient. Reimbursement by health insurance plans and disclosures for law enforcement purposes are legitimate reasons for disclosure, but should only be accomplished with a consent that clearly identifies each recipient. Or, as an alternative, Netsmart proposes an exclusion of SUD treatment information from criminal or law enforcement proceedings. This exclusionary rule could accomplish the goal of protecting SUD patients and encouraging treatment without negative repercussions.

However, for quality of care purposes, we agree with the proposed revisions allowing for disclosures to treating providers through a less burdensome identification process. The proposed revision allowing the use of a consent to an entity that does not have a treating relationship with the patient, but facilitates the exchange information such as an HIE or a research organization, should provide for greater ease in exchanging health care information to those that have a treating relationship. A “treating provider relationship” is defined to mean regardless of whether there has been an in-person encounter, the patient agrees to be seen by the provider, and the provider agrees to do so. In an HIE environment, the treatment relationship could be satisfied by having the provider attest to

having a treating provider relationship in an HIE policy or other similar mechanism.

The general designation of participants or class of participants, limited to those who have a treating relationship who may access the SUD treatment information, should be further clarified. When defining the new general designations under the proposed rule, we recommend that SAMHSA turn to the excellent guidance on this topic under other existing law. For example, the authorization required under the Health Insurance Portability and Accountability Act (HIPAA) requires the identity of the recipient or class of recipients to be identified.[1] By referencing existing law and guidance – particularly a law that Part 2 programs must already comply with – would ease the transition to this new form of consent and reduce regulatory compliance issues. This would help ensure continuity across all settings of care. Netsmart recognizes that the proposed revisions to Part 2 do not align with HIPAA, and it is not our intent to press for such an alignment. Rather, in areas where Part 2 has been modified and that modification may draw questions or concerns, we request that SAMHSA reference other commonly known and easily accessible forms of guidance for the benefit of Part 2 programs and patients.

In light of this new form of consent allowing the designation of treating providers and the transition from the current utilization of two different types of consent – one form for traditional uses and disclosures of SUD treatment information[2] and a second form of consent for disclosures for law enforcement purposes[3] - to the use of three different forms of consent, we request clarification from SAMHSA on the need to maintain the variety of forms currently specified under section 2.31(a)(4)(iv). In particular, in what context does SAMHSA envision the specification of the individual participants[4] or the names of the participants with a treating provider relationship[5] in an HIE or research institution when the general designation could be utilized simply referencing the class of participants[6]? If these are not options that will be utilized by Part 2 programs, then Netsmart believes they should be removed from the proposed rule to avoid confusion on the part of providers, patients, HIEs and research institutions.

Another area of concern among Part 2 programs is the allocation of responsibility for identifying whether a recipient does, in fact, satisfy the "treating provider relationship" standard. Once the consent reflecting a general designation of recipients holding such a treating provider relationship has been executed and relied upon by the Part 2 program, there is no method by which the program can ensure that the recipients are properly authenticated by the HIE or research institution. Because that process is completely beyond the control of the program, the proposed rule, or guidance issued by SAMHSA, should specify that the responsibility for properly determining the treating provider

[1] *See* 45 C.F.R. § 164. 508(c)(1)(iii).
[2] 42 C.F.R. § 2.33.
[3] 42 C.F.R. § 2.35.
[4] 42 C.F.R. § 2.31(a)(4)(iv)(A).
[5] 42 C.F.R. § 2.31(a)(4)(iv)(B).
[6] 42 C.F.R. § 2.31(a)(4)(iv)(B).

recipients falls upon the entity that facilitates the exchange of health information, such as an HIE, or the research institution. In the vast majority of cases, those entities will exercise more, if not substantially all, control over the decision-making process. Because those entities control that decision and because the Part 2 programs will not, the proposed rule and/or subregulatory guidance by SAMHSA should specify that the HIE or research institution, as well as the recipient representing that it holds a treating provider relationship with the patient as referenced under 42 C.F.R. § 2.31(a)(4)(iv), be allocated all liability and responsibility for ensuring that the recipient is actually a treating provider and that the disclosure to that party is appropriate under Part 2. The Part 2 programs should not shoulder this burden and should not be required – explicitly or implicitly – to independently verify that the recipients possess a treating relationship.

If organizations that facilitate health information exchange, such as HIEs, ACOs, or CCOs, or research institutions are authorized to receive SUD treatment information using the new consent process, what, if any, limitations are imposed upon those entities relating to that information? Is the reference point the currently written section 2.31(a)(4)(iv)(C)? The reference in that section to a research institution would indicate that the disclosure would not be limited to treatment purposes. Netsmart seeks clarification on this important issue.

There are a number of legitimate non-treatment related purposes for disclosing SUD treatment information to an HIE, ACO, CCO or research institution. And there would also be several legitimate non-treatment related purposes for those entities disclosing the information to treating providers. More detail on the purposes for disclosure should be identified under the proposed rule. It may be SAMHSA's desire to address these issues within section 2.31, or it could potentially address those issues utilizing existing or modified Qualified Service Organization (QSO) provisions.[7] The QSO provisions could be revised to address this and other issues identified herein. For the most part, SAMHSA did not modify the QSO provisions in the NPRM.

Similarly, how does SAMHSA envision the exchange of SUD treatment information by an HIE with other HIEs? In order to participate in fully-integrated care, health information should be available where the patient is located or where the patient has traveled to obtain his or her care. For example, if an elderly patient resides in Illinois but winters in Florida, how will an HIE in Illinois be able to share health information with the HIE in Florida? The exchange would take place between two exchange entities, neither of which would possess a treating provider relationship. This problem would also arise in border communities or larger metropolitan areas where two different state HIEs could be utilized simultaneously. A patient who resides in a community on the border of two states could have health care providers which operate in both states. Typically, HIEs have been developed on a state-by-state basis, so this patient and his or her treating providers would be involved in two separate HIEs. How would those HIEs share SUD treatment information?

[7] 42 C.F.R. § 2.11.

The Preamble set forth in the NPRM includes an alternative mechanism to address the "To Whom" requirement. This alternative maintains the current language of section 2.31, but adds a definition of "organization" under section 2.11.[8] Netsmart believes that the To Whom issue is of such vital concern among not only Part 2 programs and their patients, but also all members of the health care system, that relying upon a definition rather than spelling out the process for consent in the body of the rule itself will not be as clear as it otherwise should and could be. The issues raised above regarding the new consent process, coupled with what would otherwise be a major shift in consent process under Part 2, demands a fuller, more detailed approach. As such, Netsmart disagrees with the proposed alternative approach, which would only have modified the definitions set forth under section 2.11.

C. From Whom Limitation

In light of the revision to the consent provision expanding the To Whom limitation, SAMHSA has attempted to tighten up the From Whom limitation found at 42 C.F.R. § 2.31(a)(2). At first glance, this tightening up of the provision appears to make sense. However, taken in conjunction with SAMHSA's retention of the stringent re-disclosure prohibition, there would appear to be significant hurdles to fully integrating SUD treatment information.

The NPRM provides that a general designation of which SUD programs may disclose the Part 2 information is expressly prohibited. The consent form must "specifically name the part 2 program(s) or other lawful holder(s) of the patient identifying information permitted to make the disclosure."[9] This overly-restrictive interpretation of the consent requirement will significantly hamper the exchange of SUD treatment information within HIEs. For example, if Primary Care Physician ("PCP") A receives SUD treatment records via a properly executed consent from a Part 2 program via the HIE, the process would appear to be allowed if PCP A had a treating provider relationship with the patient. However, if PCP B, also a participant in the same HIE, requests records, there would be a disconnect. The Part 2 program could still respond to the request via the HIE. But it does not appear that PCP A could respond to PCP B's request with any SUD records that it had previously received from the Part 2 program, particularly in light of the re-disclosure prohibition, which is addressed in the comments below.

The proper means to address this disconnect would be for the consent to allow for the disclosure of SUD treatment information from the Part 2 program to the HIE and the participants in the HIE that possess a treating provider relationship, but also allow for the disclosure from the HIE and treating providers in the HIE to other treating providers in the HIE by utilizing a bi-directional consent. The consent could identify the From Whom parties as with the Part 2 program and as participants with a treating provider relationship with the patient. However, as currently written and interpreted, the From Whom provision requires individual parties to be identified. As such, "participants with

[8] Notice of Proposed Rulemaking, Vol. 81, No. 26 dated February 9, 2016 (hereinafter "NPRM") at p. 7001.
[9] NPRM at p. 6990.

a treating provider relationship" would likely not be permissible. We request that SAMHSA revise and/or interpret section 2.31(a)(2) to allow for these necessary and appropriate exchanges to take place.

2. **Prohibition on Re-Disclosure (42 C.F.R. § 2.32)**

Current and proposed revisions to Part 2 would retain the prohibition against re-disclosing SUD treatment information. The inability to re-disclose data has the potential to disrupt effective exchange of data within an HIE. As referenced above, the re-disclosure prohibition will likely prevent the disclosure of SUD treatment information from one non-SUD provider to another non-SUD provider within an HIE, absent some form of specific consent. In addition to this critical interruption in the free flow of patient data, the re-disclosure prohibition also has the potential to continue to prevent the inclusion of SUD treatment information within HIEs, ACOs, CCOs, and research institutions. To implement and operationalize the re-disclosure prohibition, each provider – SUD or medical/primary care – must have an EHR solution that will segregate the SUD treatment information and segment it so as to prevent it from being included in general medical record of the patient, which may be re-disclosed.

While certain behavioral health EHRs, like Netsmart, allow for data segmentation, other EHRs do not. Most HIEs and EHRs today do not support data segmentation and, in our view, will not be able to fully do so for 5-10 more years. As a result, the easiest way for HIEs to react to Part 2 programs 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, ensuring 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 in other requirements in order to allow sufficient time for implementation. Meaningful Use regulations could provide both an incentive and a penalty for all EHRs to include this functionality. However, most behavioral health care providers, including Part 2 programs do not qualify for Meaningful Use incentives. Netsmart also encourages the expansion of Meaningful Use to allow behavioral health care providers to adopt this technology.

Regardless of whether EHR solutions support SUD treatment, 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. Based on the tenuous financial condition of many regional HIEs, funding will need to be provided to most of them to meet the standards, or they will continue to refuse to accept SUD data subject to Part 2 protections. Downstream segmentation is required for all vendors because they must continue to maintain the Part 2 information in segregated form in light of the re-disclosure prohibition.

From the perspective of the non-SUD treatment provider, not only will upgrades and modifications be necessary to EHR systems, but staff and health information managers

must be educated on how to identify Part 2 protected information, how such information may be used or disclosed, and to what extent it must be segmented. The burden those providers must bear is heightened because not all information received from a Part 2 program is subject to the re-disclosure prohibition. Rather, a more subjective approach must be taken regarding the data and only that which could be used to identify a patient as suffering from an SUD cannot be re-disclosed. Thus, in certain situations, information such as a patient's medical history and vital signs would not be subject to the prohibition because they do not, on their face, indicate an SUD. However, if that same information is linked to a Part 2 program in some manner, then it could not be re-disclosed. Providers who have little to no prior experience with Part 2 will have difficulty in making such decisions, even with proper training and resources.

Finally, all patient information must be available in order to provide fully-integrated and informed care. The re-disclosure prohibition prevents providers from receiving the "full picture." The 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 separately consent for the re-disclosure of SUD-related information.

3. Listing of Disclosures (42 C.F.R. § 2.13)

In order to balance out the modified consent requirements, SAMHSA is imposing two (2) new requirements. First, that upon request, the patient may receive a list of the participants in the HIE or research institution that have received the information.[10] Second, that upon request, the patient may receive a list of disclosures to whom their information has been made during the prior two (2) years.[11]

Netsmart is concerned about the administrative burden that this new obligation would impose upon Part 2 programs. Because the identity of participants in the HIE, ACO, CCO, or research study would be under the control of the HIE, ACO, CCO, or research institution, the Part 2 program would not be the best or appropriate source of that information. Imposing the duty to provide such a listing upon the Part 2 program and not upon the entity facility would make the exchange of health information unduly burdensome for the program and potentially provide for less than complete or accurate information to the patient. Netsmart proposes modifying this listing burden to impose the duty directly upon the HIE, ACO, CCO, or research institution to provide the listing to the patient. In order to address confidentiality concerns of the patient, we would be open to allowing such a listing compiled by the entities to be submitted to the Part 2 program, which in turn could be required to provide it to the patient.

The listing of disclosures will impose a complex burden upon all parties involved in the disclosure and receipt of SUD treatment information. The disclosing party – if it is not a

[10] 42 C.F.R. § 2.13(d)(2).
[11] 42 C.F.R. § 2.13(d)(1).

Part 2 program – would need to know that the information being disclosed is subject to Part 2. As referenced above, there may be a question of whether this type of disclosure would be prohibited as a re-disclosure. This becomes more complex if further disclosures or re-disclosures take place. Each recipient could potentially need to be included in the listing of disclosures.

Updates to 42 CFR Part 2 standards are essential to providing integrated, coordinated care in a fast-evolving, value-based healthcare system. We appreciate the opportunity to provide comments about the NPRM, and look forward to next steps in the process.

Sincerely,

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