Netsmart Detailed Analysis
HHS/SAMHSA Notice of Proposed Rulemaking (NPRM)
Confidentiality of Substance Use Disorder Patient Records
Published in the Federal Register (August 26, 2019)
Link to Netsmart Comment Filing
Link to Current 42 CFR Part 2 Statute
Link to Text of Proposed Rule
Link to HHS Proposed Rule Fact Sheet

The U.S. Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Notice of Proposed Rulemaking (NPRM) on August 26, 2019 to modify 42 CFR Part 2 (Part 2), the regulations governing the confidentiality of substance use disorder (SUD) patient records.

Netsmart has been a strong advocate for federal regulatory and legislative actions to update components of Part 2 that impede the ability of our clients and other providers from delivering fully-informed diagnosis and treatment to persons with a SUD or history of SUD treatment. The changes SAMHSA proposes in this NPRM move the needle further toward health care equity for persons with SUD, while falling short in some areas.

Here is a detailed analysis of key provisions of the NPRM and a link to the Netsmart comment filing. If you have input and observations from provider perspective, please contact Dave Kishler (dkishler@ntst.com).

Revised Definition of "Records" that Limits Application of Part 2
The NPRM proposes to limit the application of Part 2 to only what SAMHSA has defined as a "record". Thus, the term "information" has been removed throughout the regulations and is no longer utilized when addressing the sharing of Part 2 covered data by downstream recipients (those third parties that have received the Part 2 data pursuant to a valid consent, court order, or applicable Part 2 exception). This is critical because SAMHSA is now limiting the application of Part 2 to the paper or electronic record generated and shared by the Part 2 program. SAMHSA appears to take the position that the data pulled from the record – the "information" -- is not the focus of Part 2 protections any longer.

If the Part 2 program shared a "record" – either paper or electronic – then the Part 2 protections against redisclosure would continue to apply. In those situations, as addressed in greater detail below, the recipient would be obligated to protect the Part 2 record from redisclosure by segregating the paper record or segmenting the electronic record.

The NPRM provides an example of a treating provider who received SUD treatment information from a Part 2 program pursuant to a valid consent. (Note that due to statutory requirements, Part 2 has retained consent for all disclosures). The NPRM states that the treating provider may include information that has been orally communicated by the Part 2 program to the provider within her or his provider-generated record and he or she would not have to prevent against redisclosure of his/her record under Part 2's redisclosure prohibition. Thus, under the NPRM, if the Part 2 program shared the SUD "information" via a telephone call or an in-person consultation with the provider, the information would no longer be protected under Part 2 if the recipient included that information in the record that she or he generated as part of the direct treatment interaction with the patient. This modification would have the effect of permitting the provider to share or redisclose the provider-generated record with third parties if allowed under HIPAA or applicable state law.

Impact: This proposed modification goes a long way in reducing the limitations under Part 2 upon redisclosure. Downstream redisclosures by a treating provider who received Part 2 information orally and incorporated it into his/her own record would not be protected under Part 2 and would need only comply with HIPAA and/or state law. Paper or electronic records would continue to be protected under Part 2. The distinction between oral and paper or electronic exchange of SUD information is an interesting one and unfortunately seems to perpetuate old communication methodologies, such as using fax to share records instead of email or other forms of secure electronic communication. With the push towards the interoperable electronic exchange of health information, this proposed revision, while favorable in that it reduces unnecessary Part 2 limitations and restrictions, may create a reliance upon oral communication and transcription, which is inherently less accurate than electronic sharing of records.

<u>Application of Part 2</u>
In a further departure from existing law, the NPRM proposes to also permit downstream treating providers to "record" information about a SUD and treatment as part of the patient encounter into his or her self-generated record and no longer be subject to the redisclosure prohibition. This proposed modification would appear to allow the treating provider to take the "information" out of the Part 2 "record", create the treating provider's own new patient record, and share that new record without following Part 2 limitations. The further sharing of the record would need to comply with HIPAA and applicable state law. Those Part 2 records that the provider received in paper or electronic form would need to remain under Part 2 protections and would be segregated or segmented to avoid inadvertent redisclosure. The NPRM goes into great detail and provides a history of the Data Segmentation for Privacy (DS4P) architecture as well as discussing Consent2Share as methods for addressing the segregation and segmentation of Part 2 records.

Impact: The proposed opportunity for a recipient who is a treating provider to "record" information from a record validly shared by a Part 2 program is unclear and the description provided by Assistant Secretary McCance-Katz on this subject did not clarify it fully. However, it appears that if the treating provider reviews the Part 2 program record, transcribes information from that record which has been validly shared pursuant to patient consent, and inserts it into his or her own treatment record, then the Part 2 redisclosure limitations would not apply. It will be necessary to obtain clarification from SAMHSA, but it would appear that copying the relevant and necessary "information" from the Part 2 program record and pasting it into the treating provider's record would satisfy the "recording" of SUD

information that avoids application of Part 2 to the provider's record. On a less positive note, SAMHSA still seems in support of Consent2Share as a means of addressing data segmentation.

Revisions to Redisclosure Prohibition

The NPRM also proposes to remove "superfluous" language that stated patient information protected by Part 2 included information "that identifies a patient as having or having had a [SUD] either directly, by reference to publicly available information, or through verification of such identification by another person". SAMHSA stated that the deletion of this language was in alignment with the Part 2 protections against redisclosure which should only apply to Part 2 "records" and not "information" in the general sense.

Impact: SAMHSA stated that this proposed revision was necessary because downstream non-Part 2 providers were redacting any SUD information out of their data files because of concerns about Part 2. There is a distinction again here between records and information. In addition, this proposed modification appears to remove a problematic requirement that applied the redisclosure prohibition to any information that could be linked to SUD treatment, diagnosis, or referral and a patient by use of external data or reference. This modification would now likely permit a downstream recipient to share SUD information without worrying about the redisclosure prohibition if the information did not expressly link the patient with SUD treatment, diagnosis, or referral. This may mean that if the information does not patently make that link between the information on its face with the patient and/or SUD treatment, then Part 2 would not likely apply even if the link between the patient and SUD diagnosis, treatment, or referral could be made by external sources, such as Google or another resource.

Disclosures by Lawful Holders Without Consent

The modifications to Part 2 in the January 2018 Final Rule allowed for a lawful holder of Part 2 records to share them with their contractors, subcontractors, and legal representatives without patient consent, but only for purposes of payment and health care operations. The 2018 modification did not spell out all permitted payment and operations activities.

In the current NPRM, SAMHSA now expressly sets forth each payment and health care operation activity permitted under this exception to the consent requirement, and also includes any other payment or health care operations activities not expressly prohibited. This means is that recipients of Part 2 records pursuant to a valid patient consent would now be able to share those records with contractors, subcontractors, and legal representatives without obtaining an additional patient consent for what might be considered a redisclosure. However, this new provision would not permit the sharing of Part 2 records for care coordination or case management.

Impact: Under the proposed modification, lawful holders would be able to share Part 2 records with their contractors and subcontractors for payment and operations purposes without needing to obtain a new patient consent for each of those disclosures/redisclosures. This proposed change would extend the payment and health care operations exceptions to their greatest length so far without requiring additional consent.

Changes to Consent Requirements

The NPRM also modifies the provisions of section 2.31 of the current Part 2 statute that specify the requirements for a valid consent. In its 2017 Final Rule, SAMHSA modified the consent requirements for specifying the name of the recipient (the "To Whom" provision) to permit sharing of information to an intermediary such as an HIE or research entity with one consent, but then permitting the HIE or research entity to redisclose the SUD information to participating members of the HIE or research group without additional patient consent pursuant to a general designation.

In order to permit disclosures to third parties that are not health care providers, the consent provision would now allow for the consent to state either the name of the individual(s) or the entity or entities to whom the disclosure is made. This provision was added to assist patients in sharing information with third parties such as the Social Security Administration for determination of benefits, or to a sober living facility or halfway house for non-medical services.

Impact: This modification removes the unduly burdensome identification currently required under Part 2 for recipients of SUD records for non-treatment purposes. Instead of specifying an individual for a disclosure for these purposes, the patient may now identify the entity or entities. The broadening of the To Whom requirement to permit this type of description is legally no different than expanding the To Whom requirement to permit sharing pursuant to a general designation as was advocated for previously and which is permissible in an HIE. It may be worth pushing this argument further to see if SAMHSA would expand the To Whom provision to permit more general designations.

Expansion of Activities Considered Audit and Evaluation

SAMHSA has greatly expanded the activities which will be considered audits or evaluations under current statute section 2.53. That section permits a Part 2 program to share patient records with an entity conducting audits or evaluations without the need for patient consent, subject to certain confidentiality safeguards.

The NPRM expands the types of activities that may be conducted under this section without patient consent and expressly includes a variety of recipients of the records that may not have been traditionally considered to be audit and evaluation entities. SAMHSA's stated goal was to broaden the exception beyond individual program performance to allow for evaluation across programs to identify if any agency or payor action was necessary to improve care and outcomes. As such, the NPRM permits government agencies and third-party payors access to patient records without consent for periodic reviews and evaluations for purposes such as identifying agency or health plan actions or policy changes aimed at improving outcomes for SUD patients, targeting resources for better patient care, or adjusting Medicaid or other insurance to provide adequate coverage or payment.

While these new exceptions would not permit the sharing of Part 2 records for care coordination, it would allow disclosures without consent for activities related to reviews of appropriateness of treatment, medical necessity, and utilization. The NPRM also clarifies that sharing of SUD records within an organization with different service lines or components for audits and evaluations by the organization of the non-Part 2 service lines or components is permissible.

The NPRM also confirms that quality assurance entities for purposes of the audit and evaluation exception include accreditation or certification bodies that focus on quality assurance. Finally, the NPRM permits the sharing of records to federal, state, and local government agencies as well as their contractors, subcontractors, and legal representatives, for purposes of conducting legally-mandated audits and evaluations.

Impact: SAMHSA has grasped that the terms “audit” and “evaluation” are not defined anywhere and have utilized that ambiguity to create as broad of an interpretation as possible. Many of the activities considered health care operations under HIPAA have been included here and no longer require patient consent. Coupled with the ability of lawful holders to share SUD information with contractors, subcontractors, and legal representatives, the agencies, payors, and bodies may now have the greatest latitude possible under the statute.

Medical Emergencies

Currently Part 2 permits a program to share information without patient consent in the event of a medical emergency. In the past this exception has been interpreted to apply only to disclosures for a clinical emergency where sharing of SUD information is necessary to provide life-saving care.

The NPRM proposes to expand the definition of a medical emergency to include natural disasters and events in which a Part 2 program is closed and unable to provide services or obtain written consent from the patient. The state of emergency would have to be declared by state or federal authorities and would only last until the program could resume operation. In the event of such a disaster SUD information could be shared with medical personnel without consent.

Impact: The way that this proposed modification is written sets the stage for the possibility of the declaration of a national emergency by a President to at least temporarily set aside the Part 2 requirements. The NPRM notes that the Federal Emergency Management Agency (FEMA) grants the President the authority to declare a major disaster for any natural event, regardless of cause, that is determined to have caused damage of such severity that it is beyond the combined capabilities of state and local governments to respond. The proposed rule would appear to only apply to situations in which the Part 2 program is closed and unable to provide services or obtain patient consent. As currently written, the proposed modification may not be expansive enough to permit the declaration of the opioid epidemic as a national disaster such that Part 2 protections would not apply.

OTHER PROPOSED MODIFICATIONS

Disclosures for Research

Currently, Part 2 only permits disclosures for research purposes pursuant to patient consent or to a HIPAA covered entity or business associate or in the event that the recipient is subject to the Common Rule, which protects human research subjects.

The NPRM broadens the research exception to allow research disclosures without consent from a HIPAA covered entity or business associate to third parties who are not HIPAA

covered entities or business associates and not subject to the Common Rule, provided that any such data would only be disclosed in accordance with HIPAA. In addition, research disclosures may be made to the members of a workforce of a HIPAA covered entity for purposes of employer-sponsored research, where the covered entity requires the workforce to comply with HIPAA or the Common Rule. Finally, research disclosures would be permitted to recipients who are covered by Food and Drug Administration (FDA) regulations for the protection of human research subjects in clinical investigations, where done so in compliance with applicable FDA regulations.

Disclosures to PDMPs

SAMHSA had previously issued guidance that opioid treatment programs (OTPs) should not share information with prescription drug monitoring programs (PDMPs). The NPRM announces a change in SAMHSA's position and a move towards permitting the sharing of SUD records with PDMPs. SAMHSA now believes that permitting Part 2 programs and OTPs to share dispensing data with PDMPs would allow for greater patient safety, better treatment, and better care coordination. Under the proposed rule, OTPs and lawful holders of their records may now report the required data to PDMPs when dispensing medications. However, the disclosure would require patient consent to do so.

Disclosures to Prevent Multiple Enrollments

The NPRM proposes to expand Part 2 to make non-OTP providers with a treating provider relationship with a patient eligible to query a central registry to determine whether that patient is already receiving opioid treatment through a member program. The addition of non-OTPs to the list of eligible entities for querying of central registries is expected to prevent duplicative enrollments and prescriptions for excessive opioids.

Undercover Agents and Informants

Finally, the NPRM proposes to lengthen the effective date of court orders authorizing placement of an undercover agent or informant in a Part 2 program from 6 months to 12 months, with the opportunity to further extend the period with a new court order. In addition, the NPRM proposes to commence the 12-month period upon placement of the undercover agent or informant – rather than commencing upon entry of the court order, which can take place long before the agent or informant is placed at the program.

Confidential Communications

A separate NPRM was issued simultaneously with the NPRM described above. This separate NPRM proposes to modify the standard for court ordered disclosures of SUD records for the purpose of investigating "an extremely serious crime" by dropping the phrase "allegedly committed by the patient." This update corrects an earlier technical error from the 2017 rule-making, in which this phrase was inadvertently added to regulatory text without notice or public comment.