Netsmart Summary/Impact
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. We thank SAMHSA for its actions toward integrating SUD treatment with the healthcare continuum. 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 brief summary and impact of key provisions of the NPRM (***Bolded*** type added for emphasis). Netsmart filed formal comments on the NPRM. If you have input and observations from provider perspective, please contact Dave Kishler (dkishler@ntst.com).

Oral Communication Permissible…But Not Electronic
The NPRM indicates that a treating provider (such as a person's primary care physician) may include information that has been ***orally communicated*** to them by a Part 2 program (with patient consent) within the health record they generate, and disclose that information to selected third parties. However, the treating provider would still be obligated to protect the Part 2 record from redisclosure by segregating the paper record or segmenting the electronic record.

Impact: This proposed modification removes some limitations on redisclosure of Part 2 information to other parties, including other treating providers. ***However, the Part 2 data could be shared only orally, not electronically or via paper records, which would continue to be protected under Part 2. This proposed method is a significant limitation to the interoperable, accurate electronic exchange of health information. It***

is also counter to SAMHSA's stated intent to update Part 2 regulations to reflect advances in the healthcare delivery system, including integrated healthcare models and the use of electronic exchange of patient information.

Downstream Treating Provider Recording of Part 2 Information
The NPRM proposes to permit downstream treating providers (such as a primary care physician) to record in writing information about a SUD and treatment as part of patient diagnosis and treatment. This information would no longer be subject to the Part 2 redisclosure prohibition. However, Part 2 records that the provider received in paper or electronic form from a Part 2 program would remain under Part 2 protections and would need to be segregated or segmented to avoid inadvertent redisclosure.

Impact*:** It appears that if a treating provider reviews a Part 2 program record and transcribes information from that record ***(validly shared with patient consent) into to their own treatment record, Part 2 redisclosure limitations would not apply. Pending clarification from SAMHSA, it appears that copying and pasting relevant information from the Part 2 program record into the treating provider's record would satisfy the "recording" of SUD information and preclude the application of Part 2 to the provider's record. ***While a step forward toward fully-informed diagnosis and treatment, this method fails to leverage the value of integrated healthcare information technology for secure, seamless transition of care and health data. In addition, the NPRM outlines continued support for Consent2Share as a means to address segregation and segmentation of Part 2 records. It continues to be Netsmart's view that Date Segmentation for Privacy (DS4P)/Consent2Share is not a viable, affordable technology as evidenced by very limited use after many years and likely cost of more than $1 billion for providers to adopt it.***

Disclosures by Lawful Holders Without Additional Consent
The modifications to Part 2 by SAMHSA in the January 2018 Final Rule allow 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.

The current NPRM lists 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.

Impact*:** This proposed change would extend the payment and health care operations exceptions to their greatest length so far without requiring additional consent. ***However, this new provision would still not permit the sharing of Part 2 records for care coordination or case management. This denies healthcare equity for persons with a SUD or history of SUD by excluding a vital piece of the person's health history. It also heightens the risk level for unintended harm by their doctors and other clinicians involved in their treatment.

Disclosures to Central Registries and PDMPs
Non-OTP (opioid treatment program) providers will become eligible to query a central registry to determine whether their patients are already receiving opioid treatment through a member program.

OTPs will be permitted to enroll in a state prescription drug monitoring program (PDMP) and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.

Impact: SAMHSA now believes that permitting non-OTP providers to query a central registry and OTPs to report prescribing or dispensing Schedule II to V medications into PDMPs will enable greater patient safety, better treatment and better care coordination. ***However, the disclosure would require patient consent to do so.***

Sharing Information with Third Parties
A SUD patient may consent to disclosure of their Part 2 treatment records to an entity not providing healthcare or treatment to the patient (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure. This change allows patients to apply for benefits and resources more easily, such as when using online applications that do not identify a specific person as the recipient for a disclosure of Part 2 records.

***Impact*:** This modification removes the unduly burdensome identification currently required under Part 2 for recipients of SUD records for non-treatment purposes.

Expansion of Audit and Evaluation Activities
The NPRM expands the scope of permitted disclosures for audits and/or evaluations, which today are already permissible under Part 2 without the need for patient consent subject to certain confidentiality safeguards.

Impact*:** Netsmart agrees with the expansion of sharing of SUD records for audits and evaluations subject to confidentiality safeguards. ***However, we will urge SAMHSA to add care coordination as a permitted disclosure. This is essential to enable to enable treating providers to deliver fully-informed, coordinated care that positively impacts health outcomes and reduces patient risk.

Other Provisions of the NPRM

- Medical Emergencies: Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services will meet the definition for a "bona fide medical emergency" for the purpose of disclosing SUD records without patient consent under Part 2. This ensures clinically appropriate communications and access to SUD care in the context of declared emergencies resulting from natural disasters.

- *Disposition of Records:* When a SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for "sanitizing" the device if/when the Part 2 program discontinues operations, by deleting that message. This change will ensure that the personal devices of employees will not need to be confiscated or destroyed in order to sanitize per Part 2.
- *Confidential Communications:* The standard for court-ordered disclosures of SUD records for the purpose of investigating "an extremely serious crime" will be revised, by dropping the phrase "allegedly committed by the patient." This update corrects an earlier technical error from the 2017 rulemaking, in which this phrase was inadvertently added to regulatory text without notice or public comment.
- *Undercover Agents and Informants:* Court-ordered placement of an undercover agent or informant within a Part 2 program will be extended to a period of 12 months from the date the agent or informant is placed in the Part 2 program, and courts will be authorized to further extend the period of placement through a new court order. This addresses Department of Justice concerns that the current policy is overly restrictive to some ongoing investigations of Part 2 programs.

Legislation a More Direct Route for Change

While the Proposed Rule takes important steps forward toward enabling care coordination for patients with a substance use disorder, it doesn't go far enough. As a long-time member of the Partnership to Amend 42 CFR Part 2, Netsmart is advocating for passage of *The Overdose Prevention and Patient Safety Act (H.R. 2062)* and the *Protecting Jessica Grubb's Legacy Act (S. 1012)*, identical bipartisan bills that would align 42 CFR Part 2 regulations with HIPAA solely for the purposes of health care payment, operations AND treatment. The legislation also increases penalties for information breaches and strengthens patient protections around criminal proceedings by only allowing disclosure to law enforcement with a court order; prohibiting disclosure to initiate or substantiate any criminal charges against a patient or to conduct an investigation against a patient; and excluding from evidence in any proposed criminal proceedings any SUD patient record that is mistakenly, wrongfully, or intentionally used or disclosed.