SAMHSA Notice of Proposed Rulemaking
42 CFR Part 2

KEY COMMENTS

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Comments on the first of the US Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) Notices of Proposed Rulemaking (NPRM) to modify 42 CFR Part 2 (Part 2) are due no later than October 25, 2019. The NPRM makes many proposed changes to Part 2 which allow for ease of sharing of SUD records for treatment, payment, and health care operations in certain circumstances.[1]

This document identifies the key areas in need of comment and proposes the general substance of each comment. To be most effective, we recommend that comments on the NPRM focus on four critical areas:

1. Reduce Barriers to Care Coordination and Treatment
2. Encourage Accurate Exchange of Information
3. Support and Broaden Audits and Evaluations
4. Fully Abolish the Anachronistic Redisclosure Prohibition

Key Comments for NPRM

1. Reduce Barriers to Care Coordination and Treatment

The NPRM proposes to modify section 2.31 that specifies 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 treating providers without additional patient consent pursuant to a general designation.

In order to permit disclosures to third parties that are not health care providers, SAMHSA has proposed that the consent provision now permit either the name of the individual(s) or the entity or entities to whom the disclosure is made to be listed. 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.

[1] The second NPRM related to Part 2 was also issued on August 26, 2019. That NPRM relates to certain language permitting access to confidential communications under 42 C.F.R. § 2.63. The comments upon that proposed rulemaking are due by September 25, 2019.

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 currently permissible in an HIE. It is also not legally different than adapting the same position with respect to treatment purposes. Disclosures for non-essential purposes such as administrative enrollment arguably are not as critical as disclosures for life-preserving treatment purposes. Here, section 2.31 can and should be modified to permit disclosures for essential care coordination and treatment purposes using a broader To Whom provision, similar to that proposed for disclosures to third parties who are not health care providers.

In addition, the modifications to Part 2 in 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.

The continued exclusion of care coordination or any type of treatment activity from the exceptions to the Part 2 consent requirement is contrary to SAMHSA's stated goal of integrating care and giving each health care provider a complete record on which to base treatment and care. Further, it places limits on legitimate health care communication and coordination that is not imposed upon the arguably less essential, and certainly less life-threatening, disclosures for payment and health care operations.

SAMHSA should and must add care coordination and case management to the list of permissible purposes under the exception to the Part 2 consent requirement. These purposes can be added to the laundry list now set forth under section 2.33.

2. <u>Encourage Accurate Exchange of Information</u>

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 and can be redisclosed without consent.

Under the NPRM if the Part 2 program shares 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 which included the *oral* communication with third parties if allowed under HIPAA or applicable state law. However, electronic or paper records would still be restricted under Part 2 and would need to be segmented or segregated from the rest of the medical record.

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. The focus of comments on this section should be to emphasize the need for accurate, complete, and efficient electronic exchange of information rather than perpetuating old, outdated forms of communication that are inherently less reliable.

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 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. Comments should be submitted to further clarify and expand this exception to the Part 2 consent requirement. 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. Will copying the relevant and necessary "information" from the Part 2 program record and pasting it into the treating provider's record satisfy the "recording" of SUD information that avoids application of Part 2 to the provider's record? Comments on the NPRM could confirm this interpretation and broaden the exception to permit portions, summaries, or other extractions from the record to be redisclosed without consent.

3. <u>Support and Broaden Audits and Evaluations</u>

SAMHSA has greatly expanded the activities which will be considered audits or evaluations under 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 proposes to expand 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.

This proposed modification turns the exception for audits and evaluations into a greater opportunity for the disclosure of Part 2 information to government agencies, third-party payors, and accrediting and certifying bodies. 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.

With respect to comments on the NPRM, there are two potential avenues with respect to these proposed modifications. First, the tactic may be to stay aligned with SAMHSA's approach and focus on additional activities that may be considered an "audit" or "evaluation" by relying upon the examples provided. The second approach would be to use the examples of enlarging both the audit and evaluation exception and the payment and health care operations exception for contractors, subcontractors, and legal representatives as the foundation for an argument that treatment purposes should be included in the exceptions crafted (as more fully described under section 1, above). This second approach could seek the addition of treatment as a valid purpose for redisclosure without consent as an essential and legitimate reason for the exchange of SUD records and/or information just as has been done under the audit and evaluation and payment and health care operations exceptions.

4. Fully Abolish the Anachronistic Redisclosure Prohibition

The NPRM also proposes to remove "superfluous" language in section 2.12 that stated records 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.

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. 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.

While a step in the right direction, this proposed deletion could go further and completely eliminate the redisclosure prohibition. The statute upon which Part 2 is based, 42 U.S.C. § 290dd-2, does not contain an express redisclosure prohibition. Our prior legal research has concluded that neither the statute nor legislative history prevents SAMHSA from fully eliminating the redisclosure prohibition. While consent would still be necessary under the statute for the initial disclosure by the Part 2 program to a third party, the limits placed upon downstream recipients could be removed or substantively reduced to permit sharing of the SUD information and/or records for valid treatment, payment, and health care operations purposes. Those downstream redisclosures would fall under HIPAA protections, which are robust in nature and also familiar to those entities and individuals who will be engaging in the redisclosures. Comments should seek the full removal of an old, outdated, and unsupported limitation on uses and disclosures for those purposes by downstream recipients, such as HIPAA covered entities.

Conclusion

There are other technical corrections and comments that are needed with respect to the NPRM. Those comments will be set forth in a separate document as they are not perceived to be as critical to the areas identified above, or as important to the areas of mutual concern among Partnership members.