Netsmart

October 25, 2019

SUBMITTED ELECTRONICALLY (http://www.regulations.gov)

Elinore McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Comments on Proposed Revisions to 42 C.F.R. Part 2
(SAMHSA- 4162–20)
RIN 0930–AA32

Dear Dr. McCance-Katz,

The following are the comments of Netsmart Technologies, Inc. (Netsmart) on proposed revisions to Confidentiality of Substance Use Disorder Patient Records regulations found at 42 C.F.R. Part 2 (Part 2), which were published in two separate Notices of Proposed Rulemaking in the Federal Register on August 26, 2019. These comments are in response to the Notice of Proposed Rulemaking (NPRM) that made several proposed substantive revisions to Part 2 to continue aligning the regulations with the integration of the health care system, while retaining important privacy protections for individuals seeking treatment for substance use disorders (SUDs).[1]

Netsmart is the technology partner -- and bridge to the rest of health care -- for human services and post-acute provider organizations nationwide. We provide electronic health records (EHRs), health information exchange and other solutions for substance use and addiction management, behavioral health, child and family services, developmental disabilities, autism, home care, hospice, palliative care, skilled nursing, assisted living, independent living, long-term acute care hospitals and inpatient rehabilitation facilities. Our clients include more than 560,000 providers in 30,000 facilities that improve the quality of life for more than 25 million persons each day.

[1] The other Notice of Proposed Rulemaking published contemporaneously with the NPRM on August 26, 2019, related solely to a correction to an erroneous modification to Part 2 included in the 2017 final rule.

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Comments on the Notice of Proposed Rulemaking

Netsmart thanks the Substance Abuse and Mental Health Services Administration (SAMHSA) for its actions towards integrating SUD treatment with the rest of the health care continuum.

While this NPRM takes additional steps in the right direction, it does not fully address the needs of persons seeking SUD treatment, persons with a history of SUD treatment, or their health care providers seeking to provide them with fully-informed diagnosis, treatment and coordinated care. Most of the proposed modifications relate to the recipients of SUD information or are for non-treatment purposes such as payment and health care operations --- and not inclusive of care coordination and case management, two critical elements to improving health and health care outcomes.

Below are comments by Netsmart regarding specific areas of the NPRM in need of clarification or further modification.

1. Encourage Accurate Exchange of Health Care Information

Under the NPRM, if the Part 2 program shares SUD information via a telephone call or an in-person oral consultation with a patient's non-Part 2 treating provider ("treating provider"), the information would no longer be protected under Part 2 if the treating provider included that oral communication in the record it generated as part of a direct treatment interaction with the patient. This modification to Part 2 would permit the receiving provider to accept the oral communication, prepare his/her own record, and then share or redisclose that provider-generated record which included the oral communication with third parties if allowed under HIPAA or applicable state law. **However, electronic or paper records created by the Part 2 program would still be restricted under Part 2 and would need to be segmented or segregated from the rest of the medical record.**

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. In order to achieve targeted, effective health care, there must be accurate, complete, and efficient electronic exchange of information. The NPRM has the effect of perpetuating old, outdated forms of communication that are inherently less reliable. Under this proposed scenario, health care providers will seek information from Part 2 programs via telephone or other means of oral communication. The Part 2 program may provide information which the health care provider will attempt to transcribe into written form. However, the oral communication will not otherwise be confirmed and through the dialogue process information may be recorded inaccurately. Once entered into the provider's records, it may be shared within the provider and to other downstream health care providers and other third parties – all of whom will rely upon the inaccurate information with potentially deadly consequences. One example of the pitfalls of relying on oral communication is in the area of medication errors, a major problem in any setting. The use of digital technology allows for medication interaction checking that avoids errors caused by misunderstanding/mistyping of drugs with similar-sounding names.

From a compliance perspective, the proposed exception for oral communications will prove difficult for Part 2 programs and treating providers. Compliance, privacy, and legal advisors

will be hesitant to permit Part 2 program staff to communicate with other health care providers orally. First, the Part 2 program will need to confirm the existence of a consent identifying the health care provider as a proper recipient of the oral communication. If a Part 2 program releases information orally without a written record and there is a subsequent incident involving the patient in question due to a misunderstanding or inaccurate transcription of the oral communication, the Part 2 program would be forced to attempt to defend itself against allegations without the benefit of a paper or electronic record. Further, if both a written record and an oral communication is shared by the Part 2 program with the treating provider, a process will be needed to reconcile the two in the treating provider's system.

In a further departure from existing law, the NPRM proposes to also permit 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 be segregated or segmented to avoid inadvertent redisclosure.

We ask that SAMHSA clarify the parameters of the proposed modification for a recipient who is a treating provider to "record" information from a record validly shared by a Part 2 program. Is it permissible for a treating provider to review the Part 2 program record, transcribe information from that record (which has been validly shared pursuant to patient consent), and insert it into his or her own treatment record? 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? What other hard copy and electronic transfer methodologies does SAMHSA envision as satisfying this proposed exception? SAMHSA should provide detailed guidance to ensure Part 2 programs and treating providers are aware of the permissible means to transfer SUD information.

2. Reduce Barriers to Care Coordination and Treatment

The NPRM proposes to modify section 2.31 that specifies the requirements for a valid consent. In order to permit disclosures to third parties who are not health care providers, SAMHSA has proposed the "To Whom" 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. This modification removes the unduly burdensome identification requirement 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.

Netsmart believes it would be in the patient's best interests to be able to share SUD records for non-treatment purpose as well as for treatment purposes. There is little to no legal distinction between broadening the To Whom requirement for

non-treatment and treatment purposes under Part 2. In fact, it could be said that sharing SUD records with a health care provider would be more protective of patient confidentiality because the health care provider receiving the SUD records would typically be a covered entity under the Health Insurance Portability and Accountability Act (HIPAA) and need to ensure the privacy and security of the records that it receives.

We encourage SAMHSA to expand the To Whom requirement to permit sharing pursuant to a general designation previously advocated and 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. **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 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. In the current NPRM, SAMHSA now expressly sets forth each payment and health care operation activity permitted under this exception to the consent requirement. It also includes any other payment or health care operations activities not expressly prohibited. This means 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 list now set forth under section 2.33.

3. Support and Broaden Audits and Evaluations

SAMHSA has greatly expanded the activities which will be considered audits or evaluations under section 2.53. This 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 which 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.

Unfortunately, this new exception would not permit the sharing of Part 2 records for care coordination. However, it would allow disclosures without consent for activities related to reviews of appropriateness of treatment, medical necessity, and utilization. **It is difficult to understand why care coordination (which would be beneficial to the patient) is not permitted, but utilization review and medical necessity determinations for reimbursement of services would be permitted.** Care coordination should be added to the list of permitted audit and evaluation activities which would involve communication for similar, if not even more beneficial, purposes.

Comments on Additional Part 2 Revisions Outside of Those in the Notice of Proposed Rulemaking

1. Align Part 2 with HIPAA for Disclosures for Treatment, Payment, and Health Care Operations

The NPRM also proposes to remove "superfluous" language in section 2.12 which 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 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.

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. (See p. 5 of attached Legal Memorandum of Gerald E. DeLoss). 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.

We believe that HHS/SAMHSA has the ability to modify Part 2 to permit either or both new consent processes for sharing of Part 2 Information for treatment, payment, and health care operations purposes. First, HHS/SAMHSA could permit the use of an "opt out" consent process which would grant a patient control over their information by execution of a consent that would remove the patient's Part 2 Information from the exchange by and between Part 2 programs and HIPAA covered entities. Generally, the "opt out" consent process originates

with a default position that patients agree to participate in the sharing of their information. The patient is provided detailed information at intake which describes the uses and disclosures permitted and how the exchange of health information takes place. If the patient agrees with the use and disclosure of his or her health information as specified during the intake, the patient need not do anything and the exchange of health information proceeds in accordance with applicable law as explained to him or her. In this scenario, the exchange of Part 2 Information would be limited to treatment, payment, and health care operations purposes and only by and between Part 2 programs and HIPAA covered entities. If the patient disagrees with this position, he or she may execute a consent which removes him or her from that health information exchange process or "opts" them out of the process. The use or disclosure of his or her Part 2 Information would only be permitted with consent or as otherwise permitted under Part 2.

2. Acknowledge and Permit Patient Choice

The proposed rule attempts to balance privacy concerns with the ability to share information within new and emerging integrated health care models. Netsmart echoes these important concepts, but whether and to what extent a patient wants to share her/his information, particularly SUD treatment information, is fundamentally the patient's. Patients with heightened concerns over the use or disclosure of their SUD treatment information should have the right to withhold their information. Correspondingly, other patients recognize the value and benefit of sharing their health care information. Those patients should also be free to do so in order to access the full scope and range of benefits available under integrated care models.

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, a history of SUD, and are being treated for other illnesses or diseases. 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 to enable any person to share his or her health data with their health care providers, if they so desire. Updates to 42 CFR Part 2 standards are essential to providing integrated, coordinated care in a fast-evolving value-based health care system. We appreciate the opportunity to provide comments about the NPRM and look forward to next steps in the process.

Sincerely,

Kevin Scalia
Executive Vice President, Corporate Development
Netsmart

Enclosure