April 11, 2016

Ms Kana Enomoto
Acting Administrator
Substance Abuse and Mental Health Services Administration
1 Choke Cherry Rd
Rockville, MD 20857

Dear Ms. Enomoto:

Thank you for the opportunity to comment on the Proposed Rule on the Confidentiality of Substance Use Disorder Patient Records (RIN 0930-AA21). ASAM supports the rule's goals of updating the 42 CFR Part 2 regulations to better align them with advances in the US health care system while retaining privacy protections.

Established in 1954, ASAM represents more than 3,700 physicians and associated professionals dedicated to increasing access and improving the quality of addiction treatment. Our members specialize in the treatment of addiction and practice in a wide range of primary care and specialty care settings.

The existing 42 CFR Part 2 regulations underscore that the need for confidentiality and the right to privacy are important protections for individuals trying to determine if treatment should be pursued. The autonomy of the potential patient, personal dignity, and courage to engage the treatment system was fostered by the right to consent to the dissemination of information about their substance use.

However, the advent of Electronic Health Records and other advances such as Accountable Care Organizations present new challenges to addiction professionals who both want the best overall care for their patients and the utmost of privacy from those who would discriminate against them based on their health condition. Please find below our comments and recommendations to further strengthen this proposed rule from that perspective.

KEY PROVISIONS IN THE PROPOSED RULE

ASAM applauds the Substance Abuse and Mental Health Services Administration (SAMHSA) for including the following proposals in the proposed rule.

Comment [SH1]: Are there other proposals in the rule the working group would like to support?

- *Protection Against Fishing by Third Parties*

  The proposed rule under Section §2.13 removes the concept, "The regulations do not restrict a disclosure that an identified individual is not and has never been a patient." As the rule outlines, this proposal protects the options of a patient by mitigating against fishing by third parties. Alternatively, if a patient asserts that they are or have been a client at a given program, a release of information will have to be signed by the patient, thereby respecting patient consent.

  Thus, this approach fosters truth telling by the patient and protects the patient against fishing by others and we urge that it be included in the final rule.

- *Confirmation that the patient understands the consent*

  Currently, the consent requirements do not include any requirement that the patient confirms their understanding of the information on the consent form Fortunately, the proposed rule addresses this shortcoming and Section §2.31 states:

  > *SAMHSA proposes to add two new requirements related to the patient's signing of the consent form. The first would require the part 2 program or other lawful holder of patient identifying information to include a statement on the consent form that the patient understands the terms of their consent. The second would require the part 2 program or other lawful holder of patient identifying information to include a statement on the consent form that the patient understands their right, pursuant to §2.13(d), to request and be provided a list of entities to which their information has been disclosed when the patient includes a general designation on the consent form. In addition, the part 2 program or other lawful holder of patient identifying information would have to include a statement on the consent form that the patient confirms their understanding of the terms of consent and §2.13(d) by signing the consent form.*

  While such statements may become rote and lose their meaning and people early in treatment may sign a document without fully understanding it, ASAM appreciates that the proposed rule makes an effort to establish the right of a patient to be given sufficient information to assess whether they should be agreeing to release information and to whom.

PROPOSED MODIFICATIONS FOR INCLUSION IN THE FINAL RULE

While ASAM supports the rule's goals of updating the 42 CFR Part 2 regulations to better align them with advances in the US health care system while retaining privacy protections, we have some concerns with some of the proposals in the rule, which we outline briefly below and then describe in greater detail. Our concerns include the following 6 issues:

1. Definition of "program"
2. Qualified Service Organization's definition of "population health management"
3. Fines and penalties
4. Who information is disclosed to
5. The lack of a sample consent form and sample notice to patients of federal confidentiality requirements
6. Ability of researchers to access data sets

1. Definition of "program"

We have significant concerns with the definition of "program" in the proposed rule. We are concerned the rule may create regulatory confusion and contradictions by including three descriptions of covered part 2 entities – providing some, primarily providing and only providing substance use disorder (SUD) diagnosis, treatment and referral to treatment.

First, the definition under Section §2.11, appears to include any provider or program that provides *some* SUD services as a part 2 program. In this section the rule defines "program" as:

> *(1) An individual or entity (other than a general medical facility or general medical practice) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or*
>
> *(2) An identified unit within a general medical facility or general medical practice that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or*
>
> *(3) Medical personnel or other staff in a general medical facility or general medical practice whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.*

Examples of the breadth of this definition's applicability include:

- By including the term "referral to treatment" within the definitions of services covered by part 2 programs, the regulations would cover all Screening, Brief Intervention and Referral to Treatment (SBIRT) programs under part 2 restrictions.
- A community behavioral health organization that describes on its website that it offers SUD treatment services could be covered by the part 2 definition of program.
- A psychiatric hospital that provides SUD treatment to some of its patients and advertises its SUD services would meet the criteria of a part 2 program.

Additionally, language in Section §2.12 appears to extend part 2 restrictions to all Office-Based Opioid Treatment (OBOT) providers. Section §2.32 extends part 2 to include programs that treat illnesses that may be caused by substance use and specifically mentions cirrhosis and pancreatitis, if there is no mention of some other cause of these illnesses.

However, at other times, the regulations describe part 2 covered programs as those that *primarily* provide substance use disorder detoxification, treatment, and referral. And, at other points, the rule states that part 2 programs "only" provide SUD diagnosis, treatment and referral to treatment. For example, in Section §2.13 the rule states,

> *The presence of an identified patient in a health care facility or component of a health care facility which is publicly identified as a place where only substance use disorder diagnosis, treatment, or referral for treatment is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of this part or if an authorizing court order is entered in accordance with subpart E of this part. The regulations permit acknowledgement of the presence of an identified patient in a health care facility or part of a health care facility if the health care facility is not publicly identified as* ***only*** *a substance use disorder diagnosis, treatment, or referral for treatment facility, and if the acknowledgement does not reveal that the patient has a substance use disorder. [emphasis added]*

Recommendation

- Under the proposed rule, providers and their lawyers are left to try parse out which programs and practices are completely, partially or not covered by part 2. ASAM recommends resolving this potential regulatory confusion by including reference to 42 U.S. Code § 290dd–2, which clearly states that "***any*** *program or activity relating to*

substance abuse education, prevention, training, treatment, rehabilitation, or research" is protected (emphasis added).

The term "any" resolves these ambiguities and protects all information about patients' substance use diagnosis, treatment and referral to treatment from unauthorized disclosure. It would protect all substance use information from use in criminal justice investigations and proceedings and non-health care service related insurance, not just those records in part 2 defined programs that "hold themselves out" to be substance use programs.

2. Qualified Service Organizations

The proposed rule revises the definition of Qualified Service Organization (QSO) to include "population health management." However, the rule does not define the term.

In Section §2.11 the proposed rule states:

> *Any QSOA executed between a part 2 program and an organization providing population health management services would be limited to the office or unit responsible for population health management in the organization (e.g., the ACO, CCO, patient-centered medical home (sometimes called health home), or managed care organization), not the entire organization and not its participants (e.g., case managers, physicians, addiction counselors, hospitals, and clinics). Once a QSOA is in place, 42 CFR part 2 permits the part 2 program to communicate information from patients' records to the organization providing population health management services as long as it is limited to information needed by the organization to provide such services to the part 2 program. An organization providing population health management services may disclose part 2 information that it has received from a part 2 program to its participants (other than the originating part 2 program) only if the patient signs a part 2-compliant consent form agreeing to those disclosures.*

We are concerned with the rule's proposal to prohibit a population health management office/department/function from sharing part 2 information with case managers unless a part 2 consent has been given. It is difficult to understand how population health management (or specific clinical care management) could be provided without involving case managers.

Recommendations

1. Define "population health management"
2. Permit disclosure to case managers without requiring the patient to sign a part 2-compliance consent form agreeing to the disclosure
3. Utilize the "any program or activity" language of the law and harmonize part 2 with HIPAA and HITECH. Adopting the HIPAA Business Associate regulations to cover the obligations of individuals or entities that provide services to covered entities would greatly simplify part 2, and would be consistent with the 1992 law.

Comment [SH2]: Do we have a preferred definition of "population health management" we would like to recommend for them to use?

Comment [SH3]: There were conflicting comments from the working group on this recommendation with some members believing it should be moved under HIPAA and HITECH and others objecting to doing so

3. Fines and penalties

The proposed rule proposes to continue in Section §2.3 a set of penalties for infractions of part 2 that were included in 42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3 in §2.1 and §2.2.

The current law has questionable enforcement authority. United States Attorneys are responsible for prosecuting cases involving the unauthorized or improper disclosure of patient records. However, the sanctions for such violations and the fines were set forth in 42 USC 290ee-3(f) and 42 USC 290dd-3(f). The prosecutorial obligation is based on the Department's responsibility to enforce all federal criminal statutes 28 USC 516. Sections 290ee-3 and 290dd-3 were eliminated on July 10, 1992 by Public Act 102-321. Even though 290dd-2 was included as Section 543 in Public Act 102-321, there was a statutory drafting error, and the fines were eliminated and only reference Title 18. Specifically, the penalties provision now reads, "Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with Title 18." No mention of privacy law violation fines, penalties, or offenses exist in Title 18. Thus, the current confidentiality obligations have no enforcement authority. Entities receiving unauthorized information would likely not be subject to penalties unless a common law breach of privacy lawsuit is filed. By contrast, violators of HIPAA privacy regulations are subject to hefty fines, revocation of professional and facility license or certification, and patients may sue violators for unauthorized disclosure under state laws.

Recommendation

- ASAM recommends moving Part 2 under HIPAA & HITECH; violators of HIPAA privacy regulations are subject to hefty fines, revocation of professional and facility license or certification, and patients may sue violators for unauthorized disclosure under state laws.

Comment [SH4]: Per the above, there were conflicting views among the working group on if 42 CFR should be moved under HIPAA

4. Who information is disclosed to

Comment [SH5]: Not all working group members may share the below opinion and invite comments

Unfortunately, despite acknowledging that harm to the recipient of SUD services due to inappropriate disclosure is a real threat, the proposed rule exposes the patient in treatment in a part 2 program to the very harm it is tasked to discourage by broadening the application of the "To Whom" rubric on the consent form.

SAMHSA proposes to define the term "treating provider relationship" to provide that regardless of whether there has been an actual in-person encounter, "(a) a patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity" and "(b) the individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition." Based on this definition, SAMHSA considers an entity to have a treating provider relationship with a patient if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.

In the case of an entity that has a treating provider relationship with the patient whose information is being disclosed, SAMHSA is proposing under Section §2.13 to permit the designation of the name of the entity without requiring any further designations (as is required for an entity that does not have a treating provider relationship with the patient whose information is being disclosed). For example, the consent form could specify any of the following names of entities: Lakeview County Hospital, ABC Health Care Clinic, or Jane Doe & Associates Medical Practice.

In other words, if given clinician is a part of a clinical network, whether consolidated in one place or dispersed geographically, that network can receive the patient's part 2 information. In

addition, the Proposed Rule allows the designation of a health information exchange (HIE) and a clinician within that HIE who has a clinical relationship with the patient.

The rule's proposal is to allow a general designation of an individual or a class of participants that must be limited to those participants who have a treating provider relationship with the patient whose information is being disclosed, but because the notion of a treating provider relationship is expansive, the patient should have a clear understanding that they are not necessarily disclosing to a specific clinician or a limited number of clinicians, but possibly to a system or a network.

Although Section §2.13 allows the patient who has consented to disclose their patient identifying information using a general designation to request a list of entities to which their information has been disclosed, the Proposed Rule puts the burden on the patient. The patient must put his or her request in writing and the disclosures over two years old are exempted. Thus, a person in recovery trying to reconstruct their lives has a short period of time to determine who has received their personal substance use disorder treatment history.

What is also limiting about the list of disclosures is that the named entity on the consent form pursuant to a patient's general designation (the entity without a treating provider relationship that serves as an intermediary) only has to disclose the name of the entity to which the disclosure was made. Given that entities vary in size and complexity, the individual within the entity who requested the personal identifying information may never be known by the patient.

Incidentally, the proposed rule is silent on who pays for list of disclosures. Thus, the patient may be charged a fee just to ascertain who has received unconsented information about their personal identifying information.

Recommendations

- Require disclosure in plain language to the patient making clear that their part 2 information may be disclosed to a system or network
- Extend the period after which disclosures are exempted from 2 years to 5 years

Comment [SH6]: We developed these recommendations based on the comments but input is welcomed

5. The lack of a sample consent form & notice in the Proposed Rule

Unlike the existing regulations, the proposed rule has no sample consent form under Section §2.13 of Subpart C. The lack of a sample consent form means that each program will have to develop one of its own. This also means that there will be a variation in form and content, although the proposed rule does specify specific elements of the consent form. To this latter point, the proposed rule is quite explicit on the description of the substance use disorder information that may be disclosed. By making this more salient, it appears to compel the program to go into greater detail than what was previously required under current regulations. The previous language was generous enough. The new language seems unnecessarily stark and prejudicial. The preamble states that SAMHSA is considering developing a sample consent form later; in the meantime, if the proposed rule takes effect 180 days after the publication of the final rule, there will be no new consent form that can be used in the interim.

Additionally, although the proposed rule, like the existing 42 CFR Part 2, requires a notice to patients of federal confidentiality requirements under Section §2.22, unlike the current regulations, it offers no sample notice. Absent a sample notice, there will likely be a wide variety of choices, content and character, as long as the required elements within Section §2.22

are included. It is not clear how important the sample notice was, but without it, programs are left with the required elements and their own devices.

Recommendation

- Maintain the use of the existing consent form under current regulations
- Include in the Final Rule a sample notice to patients of federal confidentiality requirements under Section §2.22

6. Research

The proposed rule's research section improves upon existing rules, but concerns remain. The proposed regulations will permit analysis into Federal data sets with appropriate Institutional Review Board (IRB) reviews. However, managers of all other administrative data sets such as Health Information Exchanges, Accountable Care Organizations, state Medicaid agencies, commercial insurance companies, Medicare Advantage plans, etc. would not be able to make their data accessible to researchers because they could not authorize access to lawfully acquired part 2 data that reside in their administrative data sets.

Recommendation

- Allow research of additional administrative data sets such as Health Information Exchanges, Accountable Care Organizations, state Medicaid agencies, commercial insurance companies, Medicare Advantage plans with appropriate IRB reviews.

In closing, thank you again for the opportunity to provide comments on these important proposed regulations. We look forward to continuing to work with SAMHSA to ensure individuals are able to access high quality addiction treatment while ensuring they are protected from discrimination.

Sincerely,

R. Jeffrey Goldsmith, MD, DLFAPA, FASAM
President, American Society of Addiction Medicine