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in the news

Health Care

April 2016

SAMHSA Seeks Comment on Proposed Changes to Address Barriers to Information Sharing

In this Issue:

The Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), is seeking comments by April 11, 2016 on a proposed rule[1] to make significant changes to 42 CFR Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records (Part 2), which governs the substance abuse records of certain federally funded alcohol and drug abuse treatment programs (Programs).

Health information exchanges (HIEs), accountable care organizations (ACOs), clinically integrated networks (CINs) and other integrated/coordinated care entities that believe the current restrictions contained in Part 2 have hampered their efforts to improve quality of care and decrease costs through integration and coordination of care should consider the proposed changes carefully to determine whether the proposed rule adequately addresses the current barriers to necessary information sharing. These entities should carefully consider whether the general designation provisions in a consent form are sufficient to permit necessary data sharing and whether implementation of the accounting-like requirements will be operationally and financially feasible.

These entities should also evaluate whether the changes to the medical emergency exception are sufficient or whether additional guidance is needed. HIEs will need to evaluate whether the requirement to provide information about the medical emergency back to the Part 2 program immediately after the disclosure can be accomplished without incurring significant costs, or whether continuing to impose such requirements will effectively restrict HIEs

[1] 81 Fed. Reg. 6988 (February 9, 2016); https://federalregister.gov/a/2016-01841

from obtaining and transmitting critical Part 2 information to providers in a medical emergency.

The following are some of the more significant proposed changes and clarifications:

1. The consent requirements would change significantly to permit, under certain circumstances, a consent form to identify recipients of Part 2 information who are treating providers through a "general designation," e.g., "all of my treating providers" rather than having to name each specific provider, and patients would be able to sign consents electronically. However, patients would be provided the right to obtain a list of the providers who obtained their information pursuant to such a general designation.

2. In recognition that health care providers have predominately adopted electronic health records systems and other health information technology, the proposed rule amends its current security provisions to include electronic records and to clarify that entities covered by Part 2 must have formal policies and procedures in place to address the security of paper and electronic records, including destruction of such information permanently and irreversibly.

3. SAMHSA proposes to give providers more discretion to determine when a "bona fide medical emergency" exists such that a patient's Part 2 information can be disclosed without prior consent but continue to require that Part 2 programs immediately document in writing specific information about a medical emergency.

4. To address confusion as to when Part 2 applies, the proposed rule clarifies that the prohibition on re-disclosure only applies to other information that would directly or indirectly identify that the person had been treated for a substance abuse disorder; it does not apply to general health-related information or non-substance use disorder information, provided such information does not reveal that the person sought substance abuse treatment.

5. The proposed rule expands the ability for lawful holders of Part 2 information, including HIEs, ACOs and other similar integrated/coordinated care entities, and not just the Part 2 program director, to disclose information for scientific research purposes. The proposed rule also permits researchers holding Part 2 data to link to data sets from federal data repositories. SAMHSA is seeking comment on whether or not to expand this provision to non-federal data repositories.

6. The proposed rule clarifies that a general health care provider or facility is not a Part 2 program unless the provider or an identified unit within a facility holds itself out as providing substance abuse treatment, diagnosis or referrals, or if certain health care professionals are to provide such services and they are identified to the public as such.

Consent Requirements

The Part 2 regulations were written to encourage individuals with substance abuse disorders to seek needed treatment by protecting the information in their substance abuse records so that such individuals would not be made more vulnerable than individuals who do not seek treatment.

However, Part 2 has not undergone substantive changes for almost 30 years. Since that time, health care delivery models and health information technology have undergone significant changes, with a focus on coordination of care among providers and improvement of quality through electronic exchange of patient information. According SAMSHSA, the agency that enforces Part 2, the primary goal of the proposed rule is to modernize Part 2 by allowing electronic information exchange within the new models of

integrated care, such as ACOs, and other integrated/ coordinated care entities, like CINs, as well to a patients various treating providers through HIEs, while still protecting patients' privacy.

To modernize Part 2 and to facilitate integrated care efforts, SAMHSA proposes to make substantial changes to the consent requirements. Under the current regulations, a consent form must include, among other things, the following:

- The name or title of the individual or the name of the organization to which disclosure is to be made (referred to in the proposed rule as the "To Whom" section of the consent).
- How much and what kind of information is to be disclosed.
- The specific name or general designation of the program or person permitted to make the disclosure (referred to in the proposed rule as the "From Whom" section of the consent).

SAMHSA proposes to amend the requirements applicable to the "To Whom" section to permit the listing of certain recipients through a general designation. For example, in the event that an entity employs or provides privileges to one or more of an individual's treating providers, then the treating provider relationship is imputed to the entity and the consent form can list the imputed treating entity by name, e.g., the "ABC Hospital," without having to further name the specific treating providers within such entity who will access the Part 2 records.

If an entity that seeks to obtain Part 2 records though a consent does not have a treating provider relationship with the patient and does not otherwise employ or provide privileges to a treating provider, then the consent form would have to identify the recipient by name, e.g., the "Community HIE." However, the consent form could then generally designate providers with a treating provider relationship with the patient, e.g., to the Community HIE and to "my treating providers." This proposed change attempts to address the concern that if a provider joins a HIE or other integrated/ coordinated care entity like an ACO or CIN, after a patient has "consented" then the provider would have to obtain an updated consent, which can create such administrative burdens that HIEs and other care coordination entities have determined not to attempt to include Part 2 information in their systems.

When an integrated/coordinated care entity, like an ACO, HIE or a CIN, does not have a treating provider relationship with the patient, and uses a general designation to include treating providers in the "To Whom" section of a consent, the proposed rule requires these entities to take additional steps. Under the proposed rule, these entities would have to have some type of mechanism in place to confirm that any provider seeking to obtain Part 2 records has a treating provider relationship with the patient, such as a method for patients to designate treating providers through a patient portal.

In an attempt to address privacy concerns with the proposed general designation, the proposed rule incorporates a requirement similar to the accounting of disclosures rule under the Health Insurance Portability and Accountability Act and its implementing regulations (HIPAA). Under this proposed requirement, non-treating provider entities that rely on the general designation would have to provide affected patients with a list of the treating providers who have obtained their information pursuant to that general designation within the previous two years. In recognition that this requirement could require entities to implement significant procedural or technical changes, these accounting-like requirements would not take effect until two years after the effective date of the final rule.

In an effort to further ensure that patients understand these

new consent terms, SAMHSA is also proposing to require that consent forms include a statement affirming that the patient understands the terms of his or her consent and that signing a consent form containing a general designation provides a patient with the right to obtain, upon request, a list of the providers who have obtained their Part 2 information.

Medical Emergency Exception

Currently, many coordinated care entities rely on the current Part 2 medical emergency exception to obtain necessary Part 2 information in emergency circumstances. SAMHSA proposes to give providers more discretion in determining when a medical emergency exists such that a patient's Part 2 information can be disclosed without prior consent.

The Part 2 exception currently states that Part 2 information may be disclosed without consent for the purpose of "treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention."[2] However, according to SAMHSA, Part 2's governing statute refers to disclosure ''to medical personnel to the extent necessary to meet a **bona fide** medical emergency."[3] The proposed rule would incorporate the statutory language and permit disclosures to medical personnel to the extent necessary to meet a bona fide medical emergency in circumstances where the patient's prior consent cannot be obtained. SAMHSA asserts that, by changing the definition of a medical emergency to align with the statute, providers are given more discretion to determine when a medical emergency has occurred.

SAMHSA proposes to continue to require that Part 2 programs immediately document in writing specific information about a medical emergency. In recognition that many HIEs rely on this exception, the proposed rule recommends that Part 2 programs consider whether an HIE has the technical capabilities to facilitate the Part 2 program's ability to comply with these requirements, including the ability to notify the Part 2 program immediately if Part 2 information has been disclosed pursuant to the medical emergency exception and to provide the Part 2 program with all of the information it needs in order to document the medical emergency.

For More Information

For questions regarding this information, please contact one of the authors, a member of Polsinelli's Health Care practice, or your Polsinelli attorney.

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[2] 42 CFR Section 2.51.

[3] 81 Fed. Reg. at 7003.

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