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EXPERT ANALYSIS

Confidentiality of Alcohol and Drug Abuse Patient Records: Impact of the Revisions To 42 C.F.R. Part 2

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Since the advent of health information exchanges and integrated care networks, the federal regulations governing the confidentiality of substance use disorder, or SUD, records have stood as a barrier to sharing such records with other health care providers and plans.

The recently announced final regulations under 42 C.F.R. Part 2 take a step toward integrating SUD information into the rest of the health care system.

The Substance Abuse and Mental Health Services Administration recently released final regulations and a supplemental notice of proposed rulemaking under the "confidentiality of alcohol and drug abuse patient records" regulations set forth at 42 C.F.R. Part 2. The final rule and SNPRM were published in the Federal Register on Jan. 18.

The final rule substantially revises the existing regulations, which had not been modified since 1987. Many of the provisions of the final rule are similar to those set forth in a proposed rule that was published in early 2016. For those areas not fully addressed, SAMHSA issued the SNPRM.

The implementation of the final rule is somewhat uncertain because of the new administration's imposition of a regulatory freeze ordered by way of a
Jan. 20 memorandum. The memorandum postpones all the former administration's rules for 60 days.

The final rule was scheduled to take effect Feb. 17, and SAMHSA has announced that its effective date will be March 21. The comment period for the SNPRM closed Feb. 17.

Part 2 has not been substantively updated for almost 30 years. SAMHSA's stated intent in modifying Part 2 was to make it easier for patients in substance use disorder programs (dubbed Part 2 programs) to share their records with treating health care providers through clinically integrated care networks, health information exchanges and accountable care organizations. Many of the changes summarized below reflect SAMHSA's intent.

CONSENT REQUIREMENTS: THE 'TO WHOM' PROVISION

Part 2 programs must obtain a patient's written consent to share Part 2 information for most purposes, including treatment, payment and health care operations purposes, which the Health Insurance Portability and Accountability Act would allow without an authorization.

In addition, Part 2 generally required that the written consent form specify, among other things, the name or title of the individual or the name of the organization to which the disclosure was to be made.

The recently announced final regulations under 42 C.F.R. Part 2 take a step toward integrating SUD information into the rest of the health care system.

As a result, Part 2 has interfered with patients' ability to share their records with other health care providers. The final rule attempts to alleviate this restriction while maintaining the legislatively mandated consent requirement.

The final rule revises the "To Whom" requirement under the consent provision[1] to allow for a consent to be executed to an intermediary, such as a health information exchange, which does not have a treating provider relationship with the patient, to allow for a disclosure pursuant to a general designation.

The general designation only identifies the recipients as those participants in the HIE that possess a treating provider relationship with the patient who is executing the consent.

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.

That designation would allow for the disclosure to past, present, and future providers that have or had a treatment relationship with the patient without specifically identifying each by name or title. Thus, if the patient executed such a consent and a new provider entered the HIE, a new consent would not be necessary to permit disclosures to that provider.

The revision somewhat addresses a concern raised by those that believed HIEs were unable to include Part 2 information because of the logistics in identifying each participant in the HIE and then updating the consent each time a new participant joined the HIE.

This new opportunity for disclosure is allowed only if the intermediary can track and generate a list of disclosures. The list of disclosures is a new requirement under the final rule, and it requires the intermediary (not the Part 2 program) to identify the recipients of the Part 2 information for up to the prior two years.[2]

The list of disclosures is more robust than the accounting of disclosures currently required under HIPAA.

Although the Health Information Technology for Economic and Clinical Health Act imposed a duty to account for disclosures for treatment under HIPAA, similar to the list of disclosures, that requirement has not yet been implemented fully for covered entities. The HITECH Act was passed in 2009 to promote the adoption of health information technology.

Thus, with respect to medical providers, HIEs have a less difficult compliance burden than for the behavioral health providers, which generally have not received the corresponding financial assistance for adoption of health information technology.

This places behavioral health again at a disadvantage to the medical field because of more stringent confidentiality requirements with less financial support.

In addition, the list of disclosures must be implemented as soon as the intermediary wants to begin utilizing the general designation under the consent process. This may result in significant delays due to the technological burden.

Note, however, that while SAMHSA does not prohibit it, the agency requests that costs for the list of disclosures not be passed on to the patient. These are areas that will need to be addressed as implementation of the final rule takes place.

CONSENT REQUIREMENTS: THE 'FROM WHOM' PROVISION

The consent requirements under Part 2 are similar to those for authorizations under HIPAA. The party from whom the Part 2 information is being disclosed (the "From Whom") must be generally identified in a compliant consent.

SAMHSA chose not to adopt the restrictive requirements proposed for the "From Whom" element under the proposed rule. The proposed rule sought to impose a new duty to specifically identify the party disclosing the SUD information.

This is important for purposes of sharing Part 2 information within an integrated care environment such as an HIE. The structure left in place by SAMHSA maximizes the benefit of the general designation allowed under the newly created "To Whom" provision coupled with a multiparty, bidirectional consent by allowing for disclosure and potentially re-disclosure to and among the participants in an integrated care environment such as an HIE.

It appears that the consent process under the final rule would permit disclosure from the Part 2 program to the intermediary, to the treating provider, and then to another treating provider within the HIE or integrated care environment directly.

This mechanism would appear to address the concern raised by commenters that the existing and proposed rule result in data segmentation and continued exclusion from HIEs.

PROHIBITION ON RE-DISCLOSURE OF SUD INFORMATION

Part 2 has historically prohibited a recipient of Part 2 information from disclosing the information to a third party without consent or pursuant to a regulatory exception or allowance.

This "re-disclosure prohibition" is an additional barrier for Part 2 information to be included in HIEs and other integrated care environments because participants are not able to disclose the information once it had been disclosed to them.

The final rule now makes clear that only data that directly or indirectly identifies a patient as suffering from an SUD is subject to this prohibition. This clarification may not be meaningful. Any information that could potentially identify the patient as suffering from an SUD, such as name, diagnosis, medications or vital signs, if accompanied by the name of the Part 2 program, would be subject to the prohibition.

Thus, the context and not necessarily the data itself is the determining factor of whether data could be re-disclosed. This may be difficult for electronic systems to flag or segment and will likely result in continued exclusion of Part 2 information from HIEs and integrated care environments.

The preamble to the final rule confirms that the disclosure from one treating provider to another in an HIE would be considered a re-disclosure. Thus, the consent process described above using the "From Whom" provision that was retained from the existing regulation is necessary to avoid the prohibition.

MEDICAL EMERGENCIES

The final rule attempts to align the language of the medical emergency section with that set forth under the statute. Section 2.51 was modified to create language closer to that set forth in the U.S. Code.

The stated intent was to allow for a broader allowance for the disclosure of Part 2 information for these limited purposes by giving providers more discretion to determine when a "bona fide medical emergency" exists.

Many commenters on the proposed rule requested examples of emergency situations to minimize confusion among providers as to the circumstances under which medical emergencies would be considered valid.

In response, SAMHSA has announced plans to provide the requested examples in sub-regulatory guidance following the publication of the final rule.

RESEARCH

The final rule modifies the research exception to permit data protected by Part 2 to be disclosed to qualified personnel for the purpose of conducting scientific research by a Part 2 program or any other lawful holder.

The consent process under the final rule would permit disclosure from the Part 2 program to the intermediary, to the treating provider, and then to another treating provider within the HIE.

The researcher must provide documentation indicating compliance with certain requirements related to other existing protections for human research, such as HIPAA and the so-called Common Rule regarding the protection of human subjects.

SAMHSA also revised the section to address data linkages to enable researchers holding Part 2 information to obtain linkages to other datasets, provided that appropriate safeguards are in place.

Specifically under the final rule, Part 2 information may be disclosed by the Part 2 program or other lawful holder for the purpose of conducting scientific research if the individual designated as director, managing director or chief executive officer — or his designee — makes a determination that the recipient of the Part 2 information:

- If a HIPAA-covered entity or business associate has obtained and documented authorization from the patient or a waiver or alteration of authorization consistent with the HIPAA Privacy Rule.
- If subject to the Common Rule has provided documentation that the researcher is in compliance with the requirements of the Common Rule or that the research qualifies for exemption.
- If both a HIPAA-covered entity or business associate and a subject to the Common Rule has met the requirements of the paragraphs above.

If neither a HIPAA-covered entity nor business associate or a subject to the Common Rule, this section does not apply.[3]

The researcher is fully bound by the regulations and, if necessary, will resist in judicial proceedings any efforts to obtain access to patient records.

Further, the researcher may not re-disclose Part 2 information except back to its source. The researcher may only publish aggregate Part 2 information in any research publications.

Finally, the researcher must maintain and destroy Part 2 information in accordance with the final rule' security policies and procedures as well as other applicable law.

The final rule imposes new requirements for data linkages. Researchers conducting research that requests linkages to data sets from a data repository holding Part 2 information must have the request reviewed and approved by an institutional review board.

The researcher must also ensure that Part 2 information is not provided to law enforcement agencies or officials.

Data repositories are also subject to restrictions under the final rule. The data repository is fully bound by the final rule and, after providing access to the researcher, must destroy or delete the linked data from its records, including sanitizing any associated hard copy or electronic media, to render the Part 2 information nonretrievable in a manner consistent with the new security policies and procedures established under the final rule.[4]

The data repository must also ensure that Part 2 information is not provided to law enforcement agencies or officials.

The final rule aligns much of the requirements of Part 2 with HIPAA and the Common Rule, but it retains some of the more restrictive requirements.

PATIENT-IDENTIFYING INFORMATION

The final rule attempts to align this definition with the definition of "protected health information" under HIPAA.

However, note that any information that could identify a patient as suffering from an SUD or receiving treatment for the same would still be protected under the final rule.

As such, this definition does not result in an alignment with HIPAA for purposes of uses or disclosures of Part 2 information and is not viewed as particularly critical to the revisions made to Part 2.

QUALIFIED SERVICE ORGANIZATIONS

Part 2 allows for disclosures by Part 2 programs to third parties that provide services to the Part 2 program much in the same way that business associates provide services to covered entities under HIPAA.

Similar to business associates, qualified service organizations must enter into QSO agreements with Part 2 programs to allow for the sharing of Part 2 information.

The final rule narrows the ability to utilize the QSO arrangement. For instance, care coordination and medication management are no longer acceptable purposes for using a QSO agreement. The preamble to the final rule provides that a QSO may not be used to avoid the use of an appropriate consent in a treatment context.

The final rule did expand the accepted uses of a QSO agreement to include population health management.

However, this allowance is not applicable to any exchange of SUD information for treatment purposes on an individual basis.

In conjunction with the final rule, the SNPRM was also issued to address the exchange of Part 2 information by contractors and subcontractors of third-party payers and other lawful holders of the information.

SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING

SAMHSA sought comments to address questions regarding restrictions on lawful holders and their contractors', subcontractors' and legal representatives' use and disclosure of Part 2 information.

These uses and disclosures primarily relate to payment and health care operations purposes. They would also address re-disclosures by payers, funders, and their contractors, subcontractors and legal representatives for purposes of carrying out a Medicaid, Medicare or Children's Health Insurance Program, or CHIP, audits or evaluations. The deadline for comments was Feb. 17.

Commenters' questions on the proposed rule highlighted varying interpretations on lawful holders and their contractors' and subcontractors' use and disclosure of Part 2 information for purposes of carrying out payment and health care operations activities.

SAMHSA sought comment on proposals in the SNPRM to consider whether an abbreviated notice would be appropriate under Section 2.33 (disclosures permitted with written consent).

SAMHSA also questioned whether to revise Section 2.53 (audit and evaluation) to expressly address further disclosures by payers, funders and their contractors, subcontractors and legal representatives for purposes of carrying out a Medicaid, Medicare or CHIP audit or evaluation.

SAMHSA also sought comments on the following for its consideration in future rulemaking and guidance:

- Additional purposes for which lawful holders should be able to disclose Part 2 information.
- Further sub-regulatory guidance that SAMHSA and other agencies could provide to help facilitate implementation of Part 2 in the current health care environment.

The final rule takes a step toward the full integration of SUD records with medical records. Providers, researchers, HIEs, and most importantly, patients, will now be able to share necessary information. The result is expected to be better treatment and better patient outcomes while retaining heightened confidentiality protections.

NOTES

1 42 C.F.R. § 2.31(a).

2 42 C.F.R. § 2.13(d).

3 42 C.F.R. § 2.52(a).

4 42 C.F.R. § 2.52(c).

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