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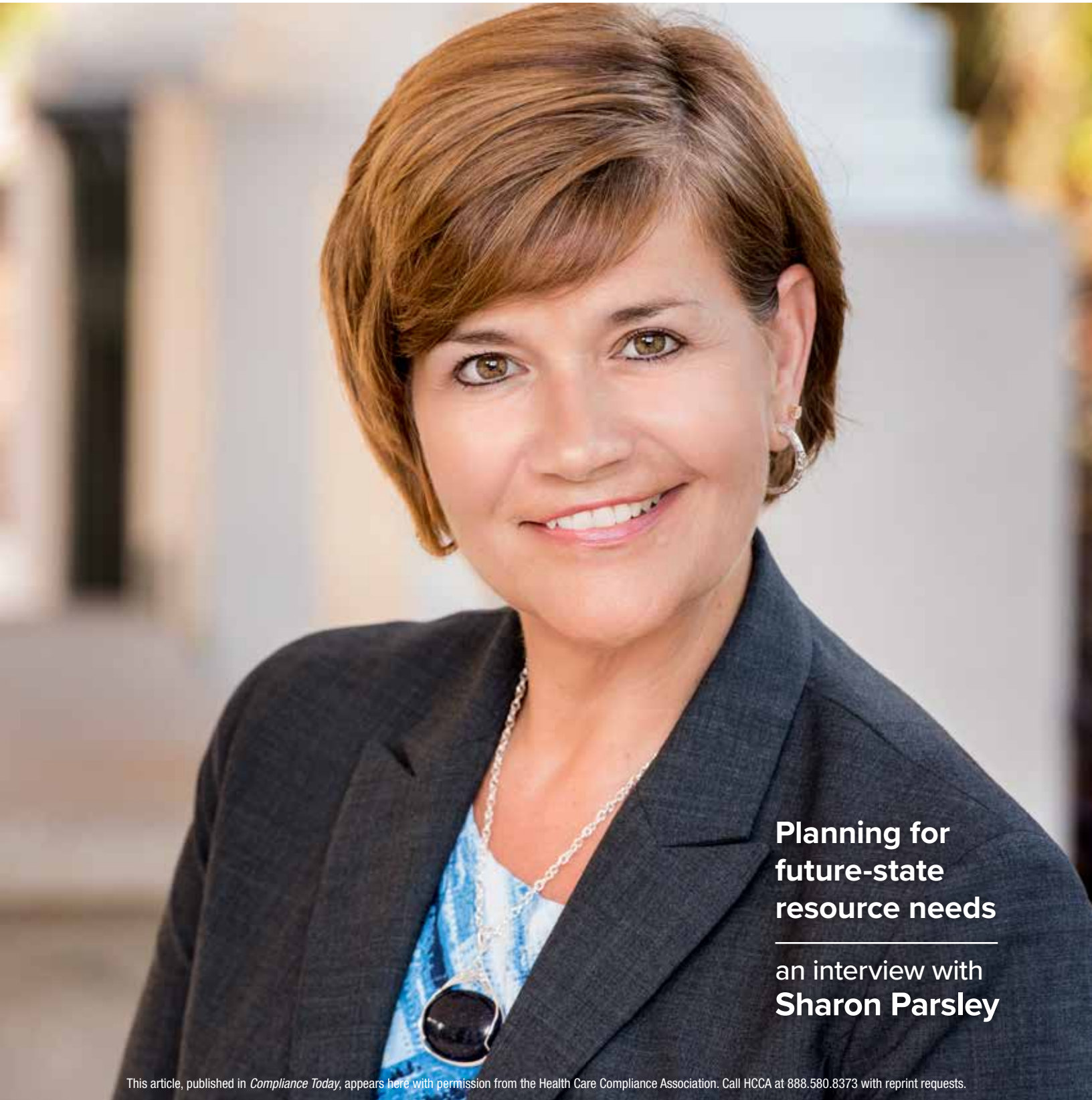

Planning for future-state resource needs

an interview with **Sharon Parsley**

by Hannah E. Grantham, JD and Tenny Soleymani, JD

SAMHSA: New substance use disorder disclosure requirements

» Opioid epidemic renews confidentiality concerns with Substance Use Disorder records.
» SAMHSA's Final Rule updates and modernizes its confidentiality (Part 2) regulations.
» The Final Rule attempts to better align Part 2 with HIPAA, yet remains more narrowly focused.
» Permitted disclosures facilitate payment and healthcare operations, and audits and evaluations.
» Compliance officers need to be aware of new and future Part 2 disclosure requirements.

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As the national opioid epidemic continues to spread, there is a renewed focus on safeguarding the confidentiality of medical records for patients with mental health and substance abuse issues. Nearly 30 years ago, Congress recognized the stigma associated with substance abuse patients and their reluctance to seek treatment due to fears of prosecution.[1] To combat growing concerns about the potential use of substance use disorder (SUD) information against individuals, the Department of Health & Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) issued the Confidentiality of Substance Use Disorder Patient Records regulations (45 CFR Part 2 or Part 2) in 1987.[2] The purpose of the regulation was to ensure that a patient receiving SUD treatment in a federally assisted program (Part 2 program) would not be more vulnerable because of the existence of their patient record than an individual who chose not to seek such treatment. In 2017, SAMHSA published the first substantive update to those regulations since 1987.


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Shortly thereafter, SAMHSA built upon that rule and its associated comments and issued another final rule in 2018 to further update and modernize the Part 2 regulations.[3] The final rule attempts to better align the Part 2 regulations with the advances in the US healthcare delivery system, such as the use of integrated healthcare models and the exchange of electronic health information, while also maintaining core privacy protections for individuals seeking SUD treatments.

The Part 2 regulations protect any information that could be used to identify an individual who has been diagnosed or has received SUD treatment at a Part 2 program. Part 2 regulations apply to programs that hold themselves out as providing, and actually provide, SUD diagnosis, treatment, or referral for treatment.[4] These regulations also apply to other "lawful holders" of patient identifying information under Part 2. A

lawful holder of Part 2 patient identifying information is an individual or entity who has received such information as the result of a Part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as permitted under the Part 2 statute, regulations, or guidance, and therefore, is bound by 42 CFR Part 2.

SAMHSA previously received numerous public comments that emphasized the need for improved information flow between providers and greater uniformity regarding confidentiality restrictions and regulations. In an attempt to address some of these comments, the final rule provided clarifications and some technical corrections to the Part 2 regulations. Additionally, the 21st Century Cures Act[5] required the Secretary of HHS to convene a stakeholder meeting to determine the effects of the Part 2 regulations and provide another opportunity for SAMHSA to receive input on the Part 2 implementation.

Compliance officers should remain cognizant of SAMHSA's regulatory changes as they relate to the HIPAA Privacy Rule[6] and Omnibus Final Rule. Because substance abuse treatment programs are governed by both Part 2 and HIPAA regulations, they must ensure that disclosure of protected information is compliant under both rules. Between Part 2 and the HIPAA Privacy Rule, there are key differences between the uses and disclosures of protected information. For example, the SAMHSA Part 2 regulations generally require that disclosures be limited to the information necessary to carry out the specific purpose of the disclosure. Under the HIPAA Privacy Rule, a covered entity may not use or disclosure protected health information (PHI) except as permitted or required by the Privacy Rule. Therefore, Part 2 Programs should not disclose SUD information unless consent is obtained and/or disclosure is permitted under a Part 2 regulation exception.

After this first step, the Part 2 program will need to confirm that the disclosure is permissible under the Privacy Rule. SAMHSA recognizes the need to increase interoperability between providers and enhance patient privacy protections. As such, the final rule attempts to align Part 2 and the HIPAA Privacy Rule to the extent possible. However, SAMHSA notes that Part 2 and its governing statute are separate and distinct from HIPAA.[7] Under their authorizing statute, the Part 2 regulations are required to provide more stringent federal protections than other health privacy laws, acknowledging the heightened risks surrounding SUD records.

This article discusses some key changes to the final rule, effective February 2, 2018: the abbreviated prohibition on re-disclosure notice, further disclosures permitted with written consent, and disclosures for audits and evaluations.

Abbreviated notice of prohibition on re-disclosure

Part 2 regulations require lawful holders to provide covered parties with a notice prohibiting re-disclosure of patient identifying information that they receive pursuant to a patient's written consent. This written notice should accompany each disclosure to those parties and contain the following language:

> This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent

of the individual whose information is being disclosed or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.

The final rule amends 42 CFR § 2.32, allowing lawful holders to provide an abbreviated prohibition notice to accompany the SUD disclosures instead of the language above. The shortened notice can be used any time Part 2 regulations require a notice of prohibition on re-disclosure. The abbreviated language states: "42 CFR Part 2 prohibits unauthorized disclosure of these records." SAMHSA designed the abbreviated language to fit in standard free-text space within healthcare electronic systems, which typically contain a maximum of 80 characters of free text space. SAMHSA also encourages Part 2 programs and lawful holders using the abbreviated notice to discuss disclosure requirements with those to whom they are disclosing the patient identifying information. These discussions are intended to alleviate any concerns that the abbreviated notice does not sufficiently convey Part 2 requirements.

SAMHSA also encourages Part 2 programs and lawful holders to discuss disclosure requirements with those to whom they are disclosing the patient identifying information.

The new, abbreviated notice option does not substantively change Part 2 regulations to be more consistent with HIPAA. However, the additional notice option does more closely align Part 2 goals with HIPAA's overarching goals of increasing the use of electronic health records and interoperability between health systems.

Additional disclosures permitted with written consent

Part 2 regulations limit the patient identifying information that lawful holders can re-disclose to their downstream entities (i.e., contractors, subcontractors, and legal representatives). These limits are meant to minimize the sharing of sensitive SUD information disclosed pursuant to a patient's written consent and to create additional protections for patients seeking treatment. The final rule clarifies that 42 CFR § 2.33 allows lawful holders to re-disclose such information to the downstream entities they use for payment and healthcare operations purposes. SAMHSA clarifies in 42 CFR § 2.33(b) that the re-disclosed information must be limited to the minimum amount necessary for the particular payment and healthcare operations stipulated in their contract or comparable legal instrument with these entities.

Further, the purpose of that disclosure must align with the purpose specified in the patient's consent. For example, as a lawful holder, a third-party payer may re-disclose information to its downstream contractors and legal representatives for payment purposes without obtaining additional patient consent. However, the patient must have consented to disclosure of their Part 2 records for payment purposes in their original patient consent form. The final rule also requires lawful holders to include written contractual language that requires these downstream entities to comply with Part 2 regulations. If no contract exists, a comparable legal instrument can be

used for these purposes. SAMHSA requires lawful holders to bring their contracts and legal instruments into compliance with these requirements by February 2, 2020.

SAMHSA also included an illustrative but non-exhaustive list of 17 disclosures that are permitted without additional patient consent in the preamble of the final rule. The list exemplifies situations that the agency considers to fall under the category of "payment and healthcare operations." It also provides concrete examples of how Part 2 disclosures differ from HIPAA Privacy Rule disclosures.

With these changes, SAMHSA attempts to better align the Part 2 re-disclosure rules with HIPAA's permitted PHI disclosures for payment and healthcare operations.[8] The HIPAA Privacy Rule permits such re-disclosures without first obtaining an individual's authorization.[9] SAMHSA, however, emphasizes that Part 2 does not mirror HIPAA's permitted PHI disclosures, and that the Part 2 regulations should be read more narrowly. For example, the HIPAA Privacy Rule includes case management and care coordination activities under its definition of "healthcare operations." However, the final rule specifically states that disclosures to contractors, subcontractors, and legal representatives for SUD patient diagnosis, treatment, or referral for treatment are not permitted. SAMHSA acknowledged public concerns about excluding case management, care coordination, and other treatment-related activities from its permitted re-disclosures. The agency stated that further alignment between Part 2 and HIPAA disclosure requirements will be discussed at the required stakeholder meeting for future rulemaking.

Disclosures for audits and evaluations

Part 2 programs under 42 CFR § 2.53 are permitted to re-disclose patient-identifying information to federal, state, or local government agencies that are conducting an audit or evaluation of the program. These reviews include quality improvement and program integrity audits and evaluations. The final rule clarifies that patient-identifying information may be disclosed to entities performing audits and evaluations on behalf of government agencies that provide financial assistance to, or regulate the activities of, lawful holders and Part 2 programs. Third-party payers or quality improvement organizations can also re-disclose information to downstream entities performing audits on their behalf. The auditing or evaluating entity may receive this patient identifying information directly from the lawful holder. Additionally, SAMHSA clarifies that further disclosures can be made to contractors, subcontractors, and legal representatives of entities conducting a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or an administrative remedy.

The final rule's audit and evaluation clarifications were made to assist Part 2 programs and lawful holders in complying with other federal, state, and local regulations. Although the Part 2 regulations do not mirror HIPAA requirements, SAMHSA clarifications further align Part 2 regulations with the HIPAA Privacy Rule's permitted disclosures to health oversight agencies. The Privacy Rule allows for disclosure of PHI to a health oversight agency for oversight activities authorized by law.[10] The final rule emphasizes, however, that the requirement is still narrow in that the disclosed information can only be used for the audit or evaluation's purpose.

The final rule does not include a list of permitted disclosures for audit and evaluation purposes, as requested by public commenters. It did, however, state that SAMHSA would consider creating a list of permitted disclosures in future rulemaking, after receiving further stakeholder input.

Conclusion

SAMHSA has made strides toward achieving interoperability with other privacy and confidentiality regulations such as the HIPAA Privacy Rule. However, compliance officers and those healthcare entities handling the particular patient identifying information affected should be aware of the separate regulations as they pertain to SUD programs. Given the differences, disclosure procedures, contracting, and education and training of staff on those differences should be on future agendas for discussion. Compliance officers who oversee Part 2 participating programs should therefore carefully review their compliance programs and, together with Legal, assess policies and procedures, contracts, and needed education and training to assure compliance with both sets of regulations. They should also stay on the lookout for future changes to SUD program requirements.

1. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment: "The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs" June 2004. Available at https://bit.ly/2w7NK6R
2. 42 CFR 2. (1987) (Confidentiality of Alcohol and Drug Abuse Patient Records)
3. 42 CFR 2. (January 18, 2017) (Confidentiality of Substance Use Disorder Patient Records)
4. 42 CFR § 2.11. (Definitions)
5. Public Law No. 114-255 "21st Century Cures Act" December 13, 2016. Available at https://bit.ly/2Mh1JSr
6. 45 CFR §160, Subpart A and §164, Subpart E (The Privacy Rule).
7. 42 USC 290dd-2. (Confidentiality of records)
8. 45 CFR § 164.502(a)(1)(ii). (Uses and disclosures of protected health information)
9. 45 CFR § 164.506(c)(4). (Implementation specifications: Treatment, payment, or health care operations)
10. 45 CFR § 164.512(d). (Uses and disclosures for health oversight activities)