A Review of Part 2: Consider a More Flexible Compliance Program in the Wake of the Revised Rules

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With the heightened demand for Substance Use Disorder (SUD) treatment as a result of the opioid crisis and the advancement of integrated models of health care in recent years, federal regulators have repeatedly amended the antiquated Confidentiality of Substance Use Disorder Patient Records regulations codified at 42 C.F.R. part 2 (Part 2) in an attempt to modernize the federal regulations. Nonetheless, even taking into account these recent modifications, when compared to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, the restrictions on use and disclosure of Part 2 records were, until very recently, incredibly stringent, making operationalizing a Part 2 compliance program a challenging feat for most SUD treatment providers subject to the federal regulations. Particularly in view of the fact that a large percentage of individuals with SUD have concomitant mental health or other chronic medical conditions that must be coordinated with the SUD care they receive. Consequently, in contrast to the HIPAA Privacy Rule's more permissive framework, Part 2 has often been perceived as a significant source of confusion and complexity in the development of health care systems' compliance programs and has burdened or interfered with efforts to effectively coordinate care between general medical providers, mental health clinicians, and SUD treatment providers.

On February 8, 2024, the U.S. Department of Health and Human Services (HHS) through the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights (OCR) announced a long-awaited final rule (the "2024 Final Rule") modifying Part 2 with the goal of further aligning Part 2 with the HIPAA Privacy Rule and easing the burden of compliance on regulated persons and entities.[1] However, the question remains whether the 2024 Final Rule finally strikes the appropriate balance between

safeguarding highly sensitive SUD information with the need to remove barriers impeding the exchange of SUD information and SUD patients' participation in emerging integrated and coordinated care models. Only time will tell. In the meantime, it is valuable for Part 2 "Programs" and "Lawful Holders" (as defined in Part 2) to review existing policies and procedures to take advantage of the increased flexibility the 2024 Final Rule offers (while also taking into consideration any new applicable requirements).

Overview and History of Part 2

Part 2 was first promulgated in 1975 in response to concerns about the potential use of SUD information in circumstances unrelated to an individual's SUD treatment, such as child custody hearings; criminal proceedings; and life insurance, housing, and employment decisions.[2] At the time, there was a great concern that the unauthorized disclosure of SUD information could, at times, lead to negative consequences for the patient in the aforementioned situations as well as others. Therefore, the impetus of the law was to safeguard patients with a history of SUD treatment from being more vulnerable to discrimination as a result of the availability of their treatment records than those individuals who chose not to seek treatment for SUD.[3] The former Part 2 regulations were very restrictive and, with very limited exceptions (i.e., bona fide medical emergency; for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order), required prior written patient consent for disclosure, even for other medical treatment.

Part 2 protects any "information, whether recorded or not, created by, received, or acquired by a Part 2 Program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts)."[4] This information is known as "Part 2 records."

Part 2 applies to individuals, entities (other than general medical facilities), or an identified unit within a general medical facility that: (1) holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment;[5] and (2) is "federally-assisted," which is broadly defined in the federal regulations and includes, but is not limited to the following circumstances: (a) providing services under a license, certification, registration, or other authorization granted by any federal department or agency (e.g., participating provider in the Medicare program); (b) the individual, entity, or unit is supported by funds provided by any federal department or agency (e.g., a recipient of federal financial assistance in any form, including financial assistance not directly covering the SUD diagnosis, treatment, or referral for treatment); or (c) the treatment services are conducted, in whole or in part, by a federal department or agency (whether directly, by contract, or otherwise).[6] Such individuals, entities, or units are known as "Part 2 Programs." In addition, Part 2 applies to "Lawful Holders," which are persons who are bound by the restrictions in Part 2 as a result of receiving Part 2 records from a Part 2 Program, either via patient consent or one of the enumerated exceptions in the federal regulations.[7]

Prior Efforts at Modernizing Part 2

As reported by the 2022 United States National Survey on Drug Use and Health (NSDUH), an estimated 54.6 million people aged 12 and older needed treatment for a substance use disorder in 2022.[8] Research demonstrates that the presence of a mental health disorder may contribute to the development or worsening of an SUD,[9] and approximately 21.5 million adults in the United States have co-occurring SUD and mental health disorders.[10] Historically, the systems of care for SUD and behavioral health disorders have been siloed, as the stringent Part 2 regulations have required

strict segregation of Part 2 records from other medical records. In order for successful treatment of these comorbidities, providers need the ability to collaborate and share information effectively in a manner that was not envisioned by the original Part 2 regulations.

At the time of initial enactment of Part 2, there was little need to communicate with outside standalone SUD treatment facilities; however, the U.S. health care delivery system has made significant advancements since then. Over time, new models of integrated care, which are dependent upon information sharing, have emerged to support the coordination of patient care. Furthermore, electronic health record (EHR) systems have been broadly implemented by health care providers and there is an increasing trend of provider participation in health information exchanges (HIEs). Recognizing these advancements in technology, SAMHSA has repeatedly attempted to modify Part 2 with the objective of ensuring that SUD patients are able to benefit from new integrated care models, while maintaining appropriate privacy safeguards.[11] These amendments were aimed at aligning certain provisions of the former Part 2 regulations, which, as explained above, required prior written patient consent for most uses and disclosures of Part 2 records (including non-emergency treatment) more closely with the HIPAA Privacy Rule, which permits the use and disclosure of protected health information (PHI) without an individual's authorization for various reasons, including for treatment, payment, and healthcare operations purposes (TPO).[12]

In January 2017, SAMHSA substantively updated Part 2 for the first time since 1987 (the "2017 Final Rule").[13] These amendments were focused upon the facilitation of the exchange of Part 2 records for treatment and other legitimate health care purposes.[14] One significant change was the revision of the patient consent requirement to permit patients, when requesting disclosure of their Part 2 records to organizations that facilitate the exchange of health information, to include a "general designation" of participants who have a treating provider relationship with the patient in the "To Whom" section of the consent form (e.g., "all my treating providers, past or present"), rather than requiring patients to provide the name or title of the intended recipient, as was previously required.[15] To ensure appropriate privacy safeguards were in place, the 2017 Final Rule required that the Part 2 consent form include a statement informing patients that when they use a general designation in the ''To Whom'' section of the consent form, the patients have a right to obtain, upon request, a list of entities to which their information has been disclosed pursuant to the general designation.[16] SAMHSA anticipated that these changes would lead to more SUD patients participating in HIEs and organizations that coordinate care, such as accountable care organizations (ACOs) and coordinated care organizations (CCOs).[17]

A year later, in January 2018, SAMHSA issued a final rule further modifying Part 2 (the "2018 Final Rule").[18] Of note, this amendment revised Part 2 to permit "Lawful Holders," who receive Part 2 records pursuant to a written patient consent allowing disclosure of their Part 2 records for payment and/or health care operations, to further disclose the Part 2 records as necessary to their contractors, subcontractors, or legal representatives, in order to perform the payment and/or health care operations functions set forth on the consent form (so long as there is a written contract in place providing that the contractor, subcontractor, and legal representative is fully bound by the Part 2 requirements).[19]

Finally, in July 2020, SAMHSA issued another final rule revising Part 2 (the "2020 Final Rule").[20] Among other changes, SAMHSA added care coordination and case management as an example

of an activity for which a Part 2 "Lawful Holder" may make a make a further disclosure to its contractors, subcontractors and/or legal representatives, in support of health care payment or operations purposes.[21] SAMHSA noted that the 2020 Final Rule was intended to "serve as interim and transitional standards," until regulations conforming to requirements of Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which required the alignment of certain key aspects of Part 2 with the HIPAA Rules and the Health Information Technology for Economic and Clinical Health (HITECH) Act, could be promulgated.[22]

Despite SAMHSA's recent modifications and clarifications of Part 2 in 2017, 2018, and 2020, in an attempt to better align the federal regulations with contemporary health care models and advancements in health information technology, the overall framework of Part 2 remained the same (i.e., prior written patient consent was still generally required for all disclosures of Part 2 records). Accordingly, strict compliance with the stringent Part 2 requirements in present-day integrated care systems has continued to prove challenging for individuals and entities subject to Part 2.

The 2024 Part 2 Final Rule

On February 8, 2024, HHS issued yet another final rule aimed at further aligning Part 2 with the HIPAA Privacy Rule. The 2024 Final Rule was published in the Federal Register on February 16, 2024, and took effect on April 16, 2024.[23] The 2024 Final Rule provides greater flexibility for Part 2 Programs and Lawful Holders, particularly for those that are also HIPAA-covered entities and business associates.

The 2024 Final Rule has been in the making for quite some time. On November 28, 2022, in response to the requirement of alignment of certain aspects of Part 2 with the HIPAA Rules and HITECH set forth in section 3221 of the CARES Act (which was enacted on March 27, 2020), HHS issued a Notice of Proposed Rulemaking (NPRM) to revise Part 2, which proposed several revisions to Part 2 to better align it with HIPAA, while still recognizing the sensitive nature of SUD records. The 2024 Final Rule adopts many of the proposals set forth in the NPRM, as well as further modifications informed by public comments.

Single Patient Consent for Treatment, Payment, and Healthcare Operations

Most notably, the 2024 Final Rule creates a new path for Part 2 Programs to use and disclose Part 2 records for purposes of treatment, payment, and health care operations as permitted by HIPAA, once the patient has provided a single, written consent for all such future uses and disclosures (TPO Consent).[24] This permission remains in effect until the patient revokes the consent in writing; and each disclosure made with written patient consent must be accompanied by a required notice of Part 2 restrictions and a copy of the consent (or a clear explanation of the scope of the consent).[25] In addition, the 2024 Final Rule provides for new redisclosure permissions in reliance upon the TPO Consent: (1) HIPAA-covered entities and business associates that receive Part 2 records pursuant to a TPO Consent may redisclose the Part 2 records as permitted by HIPAA, except in certain proceedings against the patient; (2) Part 2 Programs that are not HIPAA covered entities may redisclose the Part 2 records received pursuant to a TPO Consent according to the consent; and (3) "Lawful Holders" of Part 2 records (as defined in Part 2), that are not HIPAA covered entities or business associates, may redisclose Part 2 records for payment and health care operations to their contractors, subcontractors, or legal representatives as needed to carry out the activities specified in the TPO Consent (so long as there is a written contract in place providing that the contractor, subcontractor, and legal

representative is fully bound by the Part 2 requirements).[26]

Importantly, once received by a covered entity or business associate, the Part 2 records are also PHI but still remain subject to the Part 2 prohibitions against uses and disclosures for certain proceedings against a patient without written consent or an appropriate court order.[27] The 2024 Final Rule also requires Part 2 Programs to provide patients with an accounting of disclosures for TPO purposes, only where such disclosures are made through an electronic health record, for the three years prior to the date on which the accounting is requested.[28] However, HHS is tolling the effective and compliance dates of this accounting of disclosures requirement for Part 2 Programs until the effective and compliance dates of a final rule on the HIPAA/HITECH accounting of disclosures standard, so as to ensure Part 2 Programs do not incur new compliance obligations before covered entities and business associates under HIPAA.[29]

Disclosures for Audit and Evaluation Purposes

The 2024 Final Rule further clarifies that the limits on use and disclosure of Part 2 records for audit and evaluation purposes (i.e., generally, Part 2 records disclosed for audit and evaluation purposes may be disclosed only back to the Part 2 Program or other Lawful Holder from which it was obtained) do not apply to HIPAA covered entities and business associates to the extent these activities fall within the scope of the HIPAA Privacy Rule permission for disclosures for health care operations purposes, in accordance with a patient consent that includes health care operations.[30] In addition, if a third-party auditor or evaluator that receives the Part 2 records is also a HIPAA-covered entity or business associate, the auditor or evaluator would be permitted to redisclose the records as permitted by the HIPAA Privacy Rule.[31]

Segregation of Part 2 Records No Longer Required

The 2024 Final Rule includes an express statement that the segregation or segmentation of Part 2 records received by a Part 2 Program, covered entity, or business associate pursuant to a TPO Consent is not required. These records, however, continue to retain their characteristic as Part 2 records to ensure that recipients continue to comply with the continuing prohibition on use and disclosure of the Part 2 records in investigations or proceedings against the patient, absent written patient consent or an appropriate court order.[32]

Overview of Notable New Requirements

Although this article focuses upon the new permissions offering flexibility for Part 2 Programs and Lawful Holders under the 2024 Final Rule, the revised federal regulations also include new requirements that Part 2 Programs and Lawful Holders should be aware of, including, but not limited to, the following:

a. SUD Counseling Notes. The 2024 Final Rule creates a new definition for "SUD counseling notes" that is analogous to the HIPAA definition of "psychotherapy notes." This definition encompasses a Part 2 Program provider's notes recorded (in any medium) analyzing the conversation in an SUD counseling session that the provider voluntarily maintains separately from the rest of the patient's treatment record. "SUD counseling notes" are afforded additional privacy protection and cannot be used or disclosed based upon a TPO consent. A separate patient consent for the use and disclosure of "SUD counseling notes" is required.[33]
b. Consent for Disclosure of Part 2 Records in Proceedings. The 2024 Final Rule requires a separate patient consent for use and disclosure of Part 2 records in

civil, criminal, administrative, and legislative proceedings.[34]

c. Breach Notification Requirements. The 2024 Final Rule requires Part 2 Programs to provide breach notification for breaches of Part 2 records in the same manner as breach notification is required for PHI breaches under HIPAA.[35]

d. Patient Notice Requirements. The 2024 Final Rule aligns the existing Part 2 Patient Notice requirements with the content and implementation requirements of the HIPAA Notice of Privacy Practices.[36]

Conclusion

As explained above, the 2024 Final Rule took effect on April 16, 2024, and the proposed date for persons subject to Part 2 to comply with applicable requirements is February 16, 2026 (except for the accounting of disclosures for TPO through an electronic health record, which is delayed until similar revisions to the HIPAA regulations are finalized). Therefore, individuals and entities subject to Part 2 should evaluate their existing Part 2 compliance program for ways in which they can take advantage of the new permissions and to determine whether any of the new requirements in the 2024 Final Rule apply. Covered entities and business associates subject to Part 2 should focus upon updating staff training materials and tools to reflect the new changes in the federal regulations.

Endnotes

1. *See, generally*, 89 Fed. Reg. 12472 (Feb. 16, 2024), available at *https://www.govinfo.gov/content/pkg/FR-2024-02-16/pdf/2024-02544.pdf*.
2. *See* 82 Fed. Reg. 6053 (Jan. 18, 2017), available at *https://www.govinfo.gov/content/pkg/FR-2017-01-18/pdf/2017-00719.pdf*.
3. *Id*.
4. 42 C.F.R. § 2.11.
5. 42 C.F.R. § 2.11.
6. 42 C.F.R. § 2.12.
7. 42 C.F.R. § 2.11.
8. SAMHSA, "Key Substance Use and Mental Health Indicators in the United States: November 2023 Results from the 2022 National Survey on Drug Use and Health" (Nov. 2023), at 50, available at *https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf*.
9. *Id*. at 66.
10. *Id*. at 42.
11. *See* 82 Fed. Reg. 6053 (Jan. 18, 2017), available at *https://www.govinfo.gov/content/pkg/FR-2017-01-18/pdf/2017-00719.pdf*.
12. 89 Fed. Reg. 12479 (Feb. 16, 2024), available at *https://www.govinfo.gov/content/pkg/FR-2024-02-16/pdf/2024-02544.pdf*.
13. *Id*. at 6053.
14. *Id*. at 6056.
15. *Id*. at 6081.
16. *Id*. at 6054.
17. *Id*. at 6055.
18. *See, generally*, 83 Fed. Reg. 239 (Jan. 3, 2018, available at *https://www.govinfo.gov/content/pkg/FR-2018-01-03/pdf/2017-28400.pdf*.
19. *Id*. at 241.
20. *See, generally*, 85 Fed. Reg. 42986 (July 15, 2020), available at *https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf*.
21. *Id*. at 43008.
22. *Id*. at 42987.
23. *See, generally*, 89 Fed. Reg. 12472 (Feb. 16, 2024), available at *https://www.govinfo.gov/content/pkg/FR-2024-02-16/pdf/2024-02544.pdf*.
24. *Id*. at 12560.
25. *Id*. at 12555.
26. *Id*. at 12560-61.
27. *Id*. at 12552.
28. *Id*. at 12535.
29. *Id*. at 12536.
30. *Id*. at 12588.
31. *Id*.
32. *Id*. at 12505.
33. *Id*.
34. *Id*. at 12512.
35. *Id*. at 12523.
36. *Id*. at 12527.

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