Coordinating Care

Aligning 42 CFR Part 2 with HIPAA

Addressing privacy concerns for substance use disorder patients

By David N. Crapo

In 1972, Congress enacted 42 U.S.C. § 290dd-2 ("Part 2 Statute"), which generally prohibits federally supported substance use disorder (SUD) treatment programs ("Part 2 Programs") and others lawfully in possession of SUD treatment information ("Lawful Holders") from disclosing SUD treatment information to anyone without either the patient's prior written consent or a court order. Enactment of the Part 2 Statute was triggered, in large part, by the reluctance of those suffering from SUDs to seek treatment because of (i) the stigma attached to SUDs; (ii) discrimination resulting from the disclosure of SUD information; and (iii) the potential use of SUD treatment information in criminal prosecutions. In 1975, the Substance Abuse and Mental Health Services Administration (SAMHSA) promulgated the Confidentiality of Substance Use Patient Records Regulations ("Part 2") at 42 CFR Part 2 to implement the Part 2 Statute. Reflecting the significant risks to the patient inherent in the disclosure of SUD treatment information, Part 2's restrictions are more stringent than the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which was promulgated in 2003 and more generally regulates the privacy of health care treatment records.[1]

For many reasons, people with SUDs often suffer from one or more comorbidities. Patients suffering from multiple medical conditions are best served by coordination between their health care providers. For that reason, tension has arisen between the well-intentioned—and crucial—protections embodied in Part 2 and the urgent need to coordinate the treatment of a patient's SUDs with the treatment of comorbidities. Indeed, many health care providers found Part 2 to impede care coordination. It should come as no surprise, therefore, that the inconsistencies between Part 2 and the more flexible HIPAA Privacy Rule became increasingly evident over time.

The opioid crisis and the COVID-19 emergency increased the need to facilitate the coordination between SUD treatment and the treatment of comorbidities. The Coronavirus Aid, Relief, and Economic Security (CARES) Act,[2] which was enacted on March 27, 2020, amended the Part 2 Statute to more closely align it with the HIPAA Privacy Rule. Those amendments ("Part 2 Statute Amendments") expand the ability of Part 2 Programs and Lawful Holders to disclose SUD treatment records with the patient's non-SUD health care providers for treatment, payment, and health care operations purposes. Balancing the relaxation of the disclosure restrictions, the amendments do not lift the requirement that the SUD patient must initially consent to that sharing, and Part 2 now subjects Part 2 Programs and Lawful Holders to HIPAA's Breach Notification Rule. In sum, the Part 2 Statute Amendments balance the relaxation of Part 2's disclosure restrictions to facilitate health care coordination with the continued—and crucial—need to maintain the privacy of that information.

Initially, Part 2 required either a separate patient consent for each use or disclosure of SUD treatment information or the

identification in the consent of each ***individual*** entitled to use or disclose such information. The Part 2 Statute Amendments permit the use of a general consent executed by the patient. Upon the patient's execution of a general consent, SUD treatment records "may be used or disclosed by a covered entity, a business associate of the covered entity or another business associate for...treatment, payment and healthcare operations as permitted by the HIPAA regulations."[3] Consistent with the HIPAA Privacy Rule, disclosures of SUD treatment are limited to what is minimally necessary to achieve the purpose for which disclosures are made.[4]

Redisclosure of SUD treatment information is permitted under a general consent, but only for treatment, payment, and health care operations.[5] It is, therefore likely that the more stringent Part 2 limitations no longer apply to such redisclosures. However, as with HIPAA, more stringent state laws will control the redisclosure of SUD treatment information. Also, as with HIPAA, the patient may revoke a general consent (in writing) at any time, although the revocation will not impact prior disclosures and redisclosures.[6]

DAVID N. CRAPO *is of Counsel to Gibbons P.C. at its Newark office and is a member of the firm's Financial Restructuring and Creditors' Rights Group, Health Care Team, and Data Privacy and Security Team. He has served as a patient care ombudsman in the bankruptcy cases of several behavioral health care providers.*

The Part 2 Statute Amendments address SUD patients' fears of the use of SUD treatment information against them in administrative or judicial proceedings (especially criminal prosecutions) by tightening the rules regarding the use of SUD treatment information or testimony containing such information in such proceedings. The Part 2 Statute Amendments continue the general rule under Part 2 of prohibiting the use of SUD treatment information or testimony absent prior patient consent or a court order authorizing such use.[7] Because the use of SUD information in an administrative or judicial procedure would not likely constitute a treatment, payment, or health care operations use, a specific consent by the patient would almost certainly be necessary. Additionally, such information or testimony: (i) may not be entered into evidence in any state or federal civil action or criminal prosecution; (ii) shall not form a part of the record for decision or otherwise be considered in any proceeding before a federal, state, or local agency; (iii) shall not be used by any federal, state, or local agency for a law enforcement purpose or to conduct any law enforcement investigation; and (iv) shall not be used in any application for a warrant.[8]

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The Part 2 Statute Amendments also address the fear of discrimination that discouraged those suffering from SUDs from seeking treatment. Recipients of SUD treatment information are prohibited from discriminating against the patient with respect to: (i) access to health care treatment; (ii) hiring, firing, terms of employment, or workers compensation; (iii) sale, rental, or continued rental of housing, (iv) access to federal, state, or local courts; or (v) access to government-provided social services or benefits.[9] Recipients of federal funding are singled out for special attention. They may not discriminate against individuals with respect to access to the federally-funded services they provide on the basis of SUD treatment information they have received concerning those individuals.[10] Whether the receipt of the SUD treatment information is intentional or inadvertent is immaterial to the federal funds recipients' obligations to comply with the non-discrimination prohibition of the Part 2 Statute Amendments.

As part of the alignment of Part 2 with HIPAA, the Part 2 Statute Amendments incorporate several HIPAA provisions into Part 2. The HIPAA Breach Notification Rule is one of those provisions.[11] That rule requires HIPAA-covered entities (*i.e.*, health care providers, health plans, and health care clearing houses) to report breaches of protected health information as soon as possible, but no more

than 60 days after becoming aware of the breach.[12] The rule also sets forth extensive requirements governing the content, form, and procedures relating to a breach notification, including a risk analysis that must be conducted to determine whether an authorized use or disclosure of SUD treatment information constitutes a reportable breach. The rule's requirements, therefore, apply to those Part 2 programs and Lawful Holders not already subject to them.

The Part 2 Statute Amendments permit the disclosure of SUD treatment information to public health authorities, as long as the information is de-identified in a manner consistent with HIPAA's de-identification standards.[13] For purposes of HIPAA, de-identification requires the removal of certain identifiers or the use of an actuarial method of de-identification.[14]

SUD patients are now entitled to an accounting of the disclosures of their SUD treatment information pursuant to a general consent for treatment, payment, or health care operations.[15]

Violations of Part 2 as amended are now subject to the same penalty structure applicable to HIPAA violations.[16] HIPAA provides a tiered approach to the penalties grounded in the culpability of the violator.[17] The four tiers and their respective current penalty amounts are:

- **Tier 1:** The violator lacked knowledge of the violation, could not have realistically avoided it, and had taken a reasonable amount of care to comply with HIPAA Rules. For violations in this tier, the minimum fine is $120 per violation up to a maximum fine of $30,113 per violation, with a maximum fine of $30,113 per year for each type of violation.
- **Tier 2:** A violation of which the covered entity should have been aware but could not have avoided even with a reasonable amount of care, falling short of willful neglect of the Part 2 and HIPAA Rules. For violations in this tier, the minimum fine is $1,205 per violation up to a maximum fine of $60,226 per violation, with a maximum fine of $120,452 per year for each type of violation.
- **Tier 3:** A violation suffered as a direct result of "willful neglect" of the Part 2 and HIPAA Rules, in cases where an attempt has been made to correct the violation. For violations in this tier, the minimum fine is $12,045 per violation up to a maximum fine of $60,226 per violation, with a maximum fine of $301,130 per year for each type of violation.
- **Tier 4:** A violation of Part 2 and HIPAA Rules constituting willful neglect, where no attempt has been made to correct the violation within 30 days of discovery. For violations in this tier, the minimum fine is $60,226 per violation up to a maximum fine of $1,806,775 per violation, with a maximum fine of $1,806,775 per year for each type of violation.

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Following the enactment of the Part 2 Statute Amendments, SAMHSA issued a rule ("Transitional Rule") amending Part 2[18] to facilitate the coordination of health care for SUD patients. The Transitional Rule became effective on Aug. 20, 2020. It sets interim standards to be used pending the issuance of a final rule implementing the Part 2 Statute Amendments. Its purpose is not to implement the Part 2 Statute Amendments.

One focus of the Transitional Rule is to facilitate the coordination between Part 2 Programs and non-Part 2 health care providers. One obstacle to such coordination was the potential that the inclusion of SUD treatment records in a medical file could convert a non-Part 2 provider's records into Part 2 records subject to Part 2 Restrictions. The Transitional Rule provides that treatment records created by a non-Part 2 provider based on the provider's own patient encounter(s) are explicitly not covered by Part 2, even if they have received the information orally from a Part 2 Program or Lawful Holder.[19] However, if a non-Part 2 provider receives any written SUD treatment records from a Part 2 Program and incorporates those records into non-Part 2 records, the non-Part 2 records will be subject to Part 2's restrictions.[20] Consequently, written records received from Part 2 Programs be segregated from non-Part 2 records to ensure that new records created by non-Part 2 providers will not become subject to Part 2.[21]

Consistent with the policies underlying the Part 2 Regulations, only limited exceptions were permitted to the general prohibition against disclosure of SUD treatment information. The Transitional Rule relaxed some of those exceptions. In response to the COVID-19 emergency, for example, the medical emergency

exception was amended to permit disclosure of SUD treatment information without prior patient consent if: (i) a federal or state authority declares a state of emergency arising out of a natural or major disaster; (ii) the operations of the Part 2 Program are suspended; and (iii) the Part 2 Program cannot obtain informed patient consent.[22] This expanded disclosure authorization terminates, however, once the Part 2 Program again becomes operational.[23]

The Transitional Rule aligns Part 2's research exception more closely with the HIPAA Privacy Rule and the Common Rule for research on human subjects. Part 2 Programs and Lawful Holders may disclose patient-identifying SUD treatment information to qualified research personnel if: (i) the researcher is subject to and documents its compliance with privacy protections for human research subjects contained in the Common Rule (at 45 CFR §§ 46.111, 46.116) or the HIPAA Privacy Rule (at 45 CFR 164.512(i)); or (ii) if the researcher has not documented compliance with either HIPAA or the Common Rule, the disclosure complies with the provisions of § 512(i) of HIPAA Privacy Rule.[24] However, only aggregated or de-identified data may be used in research reports.[25] Researchers must also agree to resist judicial proceedings attempting to obtain access to the SUD treatment information.[26]

The Transitional Rule amends sub-sections (c), (f), and (g) of § 2.53 of Part 2, which implements the audit/evaluation exception restrictions, to include audits concerning: (i) changing policies to improve patient outcomes across Part 2 Programs; and (ii) determining the need to adjust payment policies. Only de-identified data should be used for an audit or evaluation. Patient-identifying data may be disclosed to federal, state, or local government agencies in connection with an audit required by law if the audit cannot be carried out without de-identified data. SAMHSA urges parties to use de-identified data for such disclosures but recognizes that doing so may not be cost-effective or may be too cumbersome.

In response to the opioid crisis, section 2.34 of Part 2 now permits Central Registries to disclose SUD treatment information to all providers, not only opioid use treatment providers, including whether a patient is already receiving opioid use treatment. This amendment prevents duplicative enrollment in such treatment programs and informs treatment providers' decisions concerning prescription and plans of care. Also, in response to the opioid crisis, the Transitional Rule adds § 2.36 to Part 2, authorizing opioid treatment providers and other Lawful Holders to enroll in and, with the patient's consent, disclose prescription information to state Prescription Drug Monitoring Programs.

The Transitional Rule amends § 2.31(a)(4) of Part 2 to move it toward the general consent authorized by the Part 2 Statute Amendments. The amendment generally eliminates the requirement that a patient's consent to disclosure identify the individual or individuals to whom SUD treatment is being disclosed. In most cases, a valid consent need identify only either the individuals or the entities to which the disclosure is being made. The amendment provides patients with options on how SUD treatment information is disclosed and facilitates the coordination of care. The amendment does not, however, completely eliminate the requirement that each individual to whom SUD treatment information is being disclosed be identified in the consent. Amended § 2.31(a)(4) retains a limited requirement concerning the identification of individuals receiving such information in connection with disclosures for research purposes or to health information exchanges. It remains to be seen whether the anticipated final rule eliminates this limited requirement.

The Transitional Rule amends §2.13 of Part 2 to provide the patient with a right of accounting of the disclosures of SUD treatment information pursuant to a general consent during the two years immediately preceding the request for an accounting, which is not as broad as the accounting right provided by HIPAA Privacy Rule, which has been incorporated into the Part 2 Statute. In response to certain formatting limitations in electronic health records, § 2.32 of Part 2 has been amended to approve the use of a shortened version of the notice to the recipient of SUD treatment information that re-disclosure prohibited. SAMHSA encourages the use of the longer notice where possible. The Transitional Rule amends § 2.33(b) of Part 2, which permits disclosures for payment and health care operations to expressly include disclosures for care coordination and case management, but only if the patient consent has consented to such uses.

To encourage patients suffering from SUDs to seek treatment without fear of prosecution, by court order, § 2.17 of Part 2 generally prohibits placing undercover agents or informers in Part 2 Programs. Section 2.67(b) and (e) of Part 2 limits the use of undercover agents to investigations of the Part 2 Program itself, its employees, or agents for serious illegal conduct and cannot be used to investigate patients. Amended § 2.67(d)(2) expands the duration of the agent's placement to 12 months, but requires a new court order for an agent to remain in place beyond the 12-month period.

Part 2 generally requires a Part 2 Program to communicate with and receive communications only via a Part 2-authorized medium. Personal devices and cell phone accounts used in such communications must be sanitized of any SUD

treatment information. Before the promulgation of the Transitional Rule, it was unclear whether this required the sanitization of the whole device. In guidance on the Transitional Rule, SAMHSA has stated that media and accounts may be sanitized by immediately deleting the SUD treatment information.[27] Any response to a patient should be on an authorized medium, unless response by a personal account is in the patient's best interest.

As noted above, the Transitional Rule does not implement the Part 2 Statute Amendment. It does, however, align Part 2 more closely to HIPAA and makes significant progress toward the availability of a general consent. A final rule fully implementing the Part 2 Statute Amendments was supposed to have been promulgated by mid-2021. Promulgation has been delayed several times, and the final rule has still not been issued for comment, let alone promulgated. Hence, Part 2 Programs, Lawful Holders, and their counsel will be governed by the Transitional Rule to the extent it is consistent with the Part 2 Statute Amendments for the foreseeable future. ■

Endnotes

1. *See* 45 CFR §§ 164.500, et seq.
2. Pub. L. No. 116-136, congress.gov/bill/116thcongress/house-bill/748/text
3. 42 U.S.C. § 290dd-2(b)(1)(B)
4. *Id.*
5. 42 U.S.C. § 290dd-2(b)(1)(B)
6. 42 U.S.C. § 290dd-2(b)(1)(C)
7. 42 U.S.C. § 290dd-2(c)
8. 42 U.S.C. § 290dd-2(c)(1)-(4)
9. 42 U.S.C. § 290dd-2(i)(1)
10. 42 U.S.C. § 290dd-2(i)(2)
11. 42 U.S.C. § 290dd-2(j)
12. 45 CFR 164.400, et seq.
13. 42 U.S.C. § 290dd-2(i)(2)
14. *See* 45 CFR § 164.514(b)(2)(D)
15. 42 U.S.C. § 290-dd-2(b)(1)(D)
16. 42 U.S.C. § 290dd-2(f)
17. 45 CFR § 160.404
18. 42 CFR §§ 2.1, et seq.
19. 42 CFR § 2.12(d)(2)(ii)
20. *Id.*
21. *Id.*
22. 42 CFR § 2.51(a)(2)
23. *Id.*
24. 42 CFR § 2.52(a)(1) and (2)
25. 42 CFR § 2.52(b)(3)
26. 42 CFR § 2.52(b)(1)
27. *See* Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule accessed on March 15, 2022 at samhsa.gov/newsroom/press-announcements/202007131330.