

# Treatment Record Privacy Laws

August 2020

## BACKGROUND

In the early 1970's, as part of its efforts to increase treatment for substance use disorder and reduce the stigma surrounding such treatment, the federal government enacted the Drug Abuse Office and Treatment Act of 1972.<sup>1</sup> That Act included a statutory provision for the confidentiality of patient records, now codified at 42 U.S.C. § 290dd-2.<sup>2,3</sup> This section provides the legal basis for regulations first adopted in 1975 that supplement and expand on the confidentiality provisions of 42 U.S.C. § 290dd-2. These regulations, known colloquially as "42 C.F.R. Part 2" or just "Part 2" (referred to herein as 42 C.F.R. Part 2), provide increased protection for the records of patients receiving treatment for substance use disorder.<sup>4</sup> Subsequent amendments over the years to both 42 U.S.C. § 290dd-2 and 42 C.F.R. Part 2 served to modernize, clarify, and expand upon the protections granted by the original provisions. This article addresses the two most recent sets of amendments created by: (1) the passage of the Coronavirus Aid, Relief, and Economic Security (CARES) Act on March 27, 2020; and (2) the adoption of revisions to 42 C.F.R. Part 2, effective August 14, 2020, by the Substance Abuse and Mental Health Services Administration (SAMHSA).<sup>5</sup>



## CARES ACT CHANGES TO 42 U.S.C. § 290dd-2

The purpose of both 42 U.S.C. § 290dd-2 and 42 C.F.R. Part 2 is to protect the privacy of individuals receiving treatment from Part 2 programs<sup>6</sup> for substance use disorder by restricting the disclosure and redisclosure of their substance use disorder treatment records. Compared to the Health Insurance Portability and Accountability Act (HIPAA), which governs the privacy and security of health information generally,<sup>7</sup> both 42 U.S.C. § 290dd-2 and 42 C.F.R. Part 2 impose higher restrictions on the sharing of substance use disorder treatment records, particularly as to consent-to-disclosure requirements. The recent amendments to 42 U.S.C. § 290dd-2 under the CARES Act, however, bring the consent provisions in the statute more in line with

HIPAA and ease some of the burden on both patients and providers in sharing patient treatment information.

### Consent Provisions

Under the pre-CARES Act language of the statute, the consent provisions of 42 U.S.C. §290dd-2 provided as follows:

The content of any [substance use disorder treatment record] may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under [42 C.F.R. Part 2].<sup>8</sup>

In practical terms, this meant that the provisions of 42 C.F.R. Part 2 governed the consent requirements for the disclosure and redisclosure of patient treatment information.

Under the language of the statute as amended by the CARES Act, patient substance use disorder treatment records may be disclosed as follows:

- In accordance with the prior written consent of the patient.
- Once prior written consent has been obtained, the records may be used or disclosed by a covered

business entity, business associate, or a Part 2 program for purposes of treatment, payment, and health care operations as permitted by HIPAA regulations and, further, may be redisclosed in accordance with HIPAA.<sup>9</sup>

- Patient consent may be given once for all future uses or disclosures for purposes of treatment, payment, and health care operations, until the patient revokes such consent.<sup>10</sup>

Unlike 42 C.F.R. Part 2, pursuant to which consent under 42 U.S.C. § 290dd-2 was previously tied, HIPAA regulations do not require patient consent each time a patient's health information is disclosed or redisclosed for treatment, payment, and health care operations.<sup>11</sup> Thus, the post-CARES Act version of 42 USC § 290dd-2 makes the disclosure and redisclosure of patient information easier.

All disclosures under the above provisions are subject to § 17935(a) of the Health Information Technology and Clinical Health (HITECH) Act, which allows a patient to request restrictions on the disclosure of their information.<sup>12</sup> A HIPAA-covered entity must comply with a patient's request if the disclosure is to a health plan for purposes of carrying out payment or health care operations (but not for carrying out treatment) and the health information pertains solely to a health care item or service for which the provider was paid out of pocket in full.<sup>13</sup>

In addition, the CARES Act amends the disclosure-without-consent provisions of § 290dd-2 to now allow the disclosure of substance abuse treatment records to a public health authority without the consent of the patient so long as the information is de-identified.<sup>14</sup>



### Criminal, civil, or administrative contexts

One of the key features of the protection of patient substance use disorder treatment information in 42 U.S.C. § 290dd-2 is the prohibition against the use of such information in a criminal proceeding, including using such information to initiate or substantiate criminal charges or to conduct an investigation of the patient

without a court order. The amended language of the statute increases these protections beyond criminal proceedings, expanding them to include civil, administrative, and legislative proceedings.<sup>15</sup> The new language provides that, minus a court order or consent of the patient, treatment information may not be used or disclosed, and no individual may testify as to the contents of such records, in any civil, criminal, administrative, or legislative proceeding.<sup>16</sup> Included in the new language are several activities that are specifically prohibited, including:

- Barring the entry into evidence of such record or testimony in any criminal prosecution or civil action before a Federal or State court;
- Prohibiting the entry of such record or testimony into the record for decision in any proceeding before a Federal, State, or local agency;
- Prohibiting the use of such record or testimony for a law enforcement purpose or to conduct any law enforcement investigation; and
- Barring the use of such information in any application for a warrant.<sup>17</sup>

### Antidiscrimination

The last of the major changes to 42 U.S.C. § 290dd-2 in the CARES Act is the addition of antidiscrimination provisions. This subsection provides that no one can discriminate against an individual, either intentionally or unintentionally, because of information received pursuant to a disclosure of the individual's substance use disorder treatment records or information contained in those records.<sup>18</sup> The statute specifically states that discrimination is prohibited in:

- The admission, access to, or treatment for health care;
- Hiring, firing, or terms of employment, or receipt of worker's compensation;
- The sale, rental, or continued rental of housing;
- Access to Federal, State, or local courts; or
- Access to, approval of, or maintenance of social services and benefits provided or funded by Federal, State, or local governments.<sup>19</sup>

Additionally, recipients of Federal funds are prohibited from discriminating against an individual by denying access to the services provided by the entity with such funds.<sup>20</sup>

### **CHANGES TO 42 C.F.R. PART 2 RECENTLY ADOPTED BY SAMHSA**

Like 42 U.S.C. § 290dd-2, 42 C.F.R. Part 2 has been through many iterations over the years. The latest amendments adopted by SAMHSA primarily clarify certain provisions and ease some of the restrictions on disclosure of patient

records.<sup>21</sup> For example, the amendments to §§ 2.11 and 2.12 clarify that patient records held by a non-Part 2 provider are not subject to the provisions of 42 C.F.R. Part 2 merely because those records mention that the patient has a substance use disorder, as long as certain requirements are met.<sup>22</sup> Further, § 2.32 regarding redisclosure now provides that only Part 2 records held by a non-Part 2 provider are subject to the provisions of 42 C.F.R. Part 2, and the mere act of placing Part 2 information in a patient's health record does not subject the entire record to the restrictions of 42 C.F.R. Part 2.<sup>23</sup>



### Consent Provisions

One of the biggest changes to 42 C.F.R. Part 2 under the amended rule is that patients are no longer required to name a specific individual within an organization to whom records may be disclosed and may simply consent to release of their records to an organization itself.<sup>24</sup> This is particularly useful if the patient is applying for Social Security or Medicare/Medicaid benefits and does not know the name of the individual within the organization to whom their records would need to be disclosed.<sup>25</sup>

In addition, Part 2 now includes a list of examples under § 2.33 that are considered to be permissible payment and health care operations activities for which disclosure is permitted with the written consent of the patient.<sup>26</sup> Previously, the preamble to the rule contained these activities; however, due to confusion over whether the information in the preamble is authoritative or not, SAMHSA moved the examples to the actual text of the rule.<sup>27</sup>

### Other Disclosures

In an effort to prevent duplicate enrollments, the amendments to Part 2 allow providers who do not qualify as a "Part 2 program" but who are treating a patient for substance use disorder to query a central registry to determine if their patient is already under treatment with another provider for substance use disorder.<sup>28</sup>

The amended rule also allows disclosure of patient

treatment information without patient consent in medical emergencies, which now includes natural disasters, and for the purpose of research to a HIPAA-covered entity or business associate if the disclosure is consistent with HIPAA. Additionally, revisions to § 2.53 clarify specific circumstances that fall within the scope of permitted disclosures for the purpose of audit and/or evaluation of the Part 2 program.<sup>29</sup>

The amended final rule also clarifies that Part 2 programs can report to the state prescription drug monitoring program any Schedule II – V controlled substance prescribed or dispensed to a patient if: (1) the state requires the submission of such information by law; and (2) the patient consents to the disclosure.<sup>30</sup>

### IMPLICATIONS FOR PATIENTS AND PROVIDERS

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Many of the changes made to 42 U.S.C. § 290dd-2 (via the CARES Act) and 42 C.F.R. Part 2 (via SAMHSA's adoption of new rules) do not overlap. However, there is now a schism between the consent-to-disclose provisions of the statute and 42 C.F.R. Part 2. For those readers without a legal background, it is important to know that, under the legal principles of hierarchy of authority, the language of a statute supersedes the language of a regulation, meaning that where there is a conflict between a statute and a regulation, the statute controls. Pursuant to the CARES Act, the Secretary of Health and Human Services is required to amend 42 C.F.R. Part 2 so that it comports with the revisions to 42 U.S.C. § 290dd-2.<sup>31</sup> Until then, patients and providers may follow either the more restrictive consent-to-disclose requirements of 42 C.F.R. Part 2 or the looser provisions of 42 U.S.C. § 290dd-2.

### ENDNOTES

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1. Drug Abuse Office and Treatment Act of 1972, Pub. L. No. 92-255, 86 Stat. 65, (1972). <https://uscode.house.gov/statutes/pl/92/255.pdf>
2. *Id.* at 79.
3. 42 C.F.R. §§ 2.1 to 2.67 (2020).
4. *Id.*
5. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, <https://www.congress.gov/bill/116th-congress/house-bill/748/text>; Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42,986 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2), <https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf>.
6. A Part 2 program is defined as a program that is federally assisted. "Program" means an individual or entity, an identified unit within a general medical facility, or medical personnel or other staff in a general medical facility that holds themselves/itself out as providing, and does provide, substance use disorder

diagnosis, treatment, or referral for treatment. 42 C.F.R. § 2.11 (2020).

7. U.S. Dept. of Health and Human Svcs., Off. For Civ. Rights: HIPAA Administrative Simplification, Regulation Text (2013),

<https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf>.

8. 42 U.S.C. § 290dd-2 (2019).

9. 42 U.S.C. § 290dd-2(k) provides that covered business entity, business associate, payment, and health care operations have the meanings given them under HIPAA and can be found at 45 C.F.R. § 160.103 (2013).

10. 42 U.S.C. § 290dd-2(b)(1) (2020).

11. 45 C.F.R. Part 164 (2020).

12. 42 U.S.C. § 17935(a) (2020).

13. *Id.*

14. 42 U.S.C. § 290dd-2(b)(2)(D) (2020).

15. 42 U.S.C. § 290dd-2(c) (2020).

16. *Id.*

17. *Id.*

18. 42 U.S.C. § 290dd-2(i) (2020).

19. *Id.*

22. *Id.*

21. *See*, Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42,986 (July 15, 2020) (to be codified at 42 C.F.R. pt. 2), <https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf>.

22. *Id.*

23. *Id.*

24. U.S. Dept. of Health and Human Svcs., <https://www.hhs.gov/about/news/2019/08/22/hhs-42-cfr-part-2-proposed-rule-fact-sheet.html> (last visited Aug. 4, 2020).

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, <https://www.congress.gov/bill/116th-congress/house-bill/748/text>.

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