

Coppersmith Briefs

The CARES Act: Sweeping Changes to Substance Use Disorder Privacy Law (42 USC 290dd-2)

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On March 27, 2020, President Trump signed into law the [Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\)](#). The CARES Act changes how health care providers, health plans, health care clearinghouses and their business associates may share sensitive substance use disorder treatment records protected by [42 USC 290dd-2](#) and its implementing regulations located at [42 CFR Part 2](#) (collectively, “Part 2”). The CARES Act partially aligns Part 2’s stringent restrictions on disclosures of Part 2-protected information with HIPAA’s permitted use of information for treatment, payment and health care operations purposes. The CARES Act also adopts HIPAA’s breach notification, enforcement and penalty structure for Part 2 breaches and violations, and directs the Secretary of the Department of Health and Human Services (HHS) to make any necessary revisions to the Part 2 regulations to implement and enforce these changes. **These changes apply to uses and disclosures of Part 2 protected information that occur on or after March 27, 2021.** However, it is unclear whether any failure on the part of HHS to issue implementing regulations will toll the deadline.

A little background:

By way of background, Part 2 imposes more stringent privacy protections than HIPAA on the use and disclosure of information that identifies a patient either directly or indirectly as having (or having had) a substance use disorder, if that information originates from a federally-assisted substance use disorder treatment provider (called a Part 2 program). Part 2 programs include medication-assisted treatment (MAT) facilities, chemical dependency units within general hospitals, as well as most addiction medicine specialists, substance abuse counselors and substance use navigators that work in general medical facilities. The Part 2 privacy protections follow the protected Part 2 information under certain circumstances, thus requiring health plans and other non-Part 2 programs to follow Part 2’s more stringent privacy protections with respect to the Part 2 information they receive.

Unlike HIPAA, Part 2 requires use of a special type of written consent to use and disclose Part 2 information for non-emergency treatment, payment and health care operations (TPO) purposes, unless one of the limited Part 2

exceptions apply. **The CARES Act did not change the requirement that a patient consent to the use and disclosure of his or her Part 2 information for TPO purposes.** However, it makes big changes to how that information may be used and disclosed after that consent is given.

A summary of the key provisions of Section 3221 of the CARES Act:

- **Disclosures to Covered Entities Consistent with HIPAA (Sec. 3221(b)):** After a patient's written consent for the use or disclosure of Part 2 information is obtained, a HIPAA covered entity, HIPAA business associate, or a Part 2 program may use or disclose the Part 2 information for TPO purposes as permitted by HIPAA. And any of the Part 2 information disclosed pursuant to the consent may then be redisclosed by the recipient in accordance with HIPAA. This is a momentous and important change from the status quo. However, there are four important caveats:
 1. All disclosures must comply with [42 USC 17935\(c\)](#). Section 17935(c) is the provision of the Health Information Technology for Economic and Clinical Health (HITECH) Act that requires accounting of TPO disclosures made through an electronic health record. HHS has yet to finalize any rules implementing this particular requirement of the HITECH Act. We anticipate that, like HITECH, this new provision in the CARES Act will not be enforced without implementing regulations.
 2. These new provisions apply only if a patient consents to such future uses or disclosures for TPO purposes.
 3. The CARES Act does not invalidate the existing consent form requirements in [42 CFR 2.31](#). Thus, these requirements will continue to apply until HHS finalizes new regulations.
 4. A patient may revoke the TPO consent in writing.
- **Self-Pay Restriction (Sec. 3221(b)(1)(D)):** All disclosures of Part 2 information pursuant to a patient's consent are subject to the provision of the HITECH Act (already implemented in the HIPAA regulations) that requires HIPAA covered entities to comply with a patient's request to restrict disclosures to a health plan, if the information pertains solely to a health care item or service the patient paid for fully out of pocket. See [42 USC 17935\(a\)](#).
- **Disclosure of De-Identified Health Information to Public Health Authorities (Sec. 3221(c)):** The CARES Act expressly authorizes disclosures to a public health authority, so long as the content is de-identified in accordance with the HIPAA standard, [45 CFR 164.514\(b\)](#).

- **Definitional Alignment with HIPAA (Sec. 3221(d)):** The CARES Act adopts HIPAA’s definitions of breach, business associate, covered entity, health care operations, payment, public health authority, treatment and unsecured protected health information.
- **Use of Records in Criminal, Civil, or Administrative Contexts (Sec. 3221(e)):** The CARES Act expands the existing prohibition against using Part 2 information in law enforcement investigations and court/administrative proceedings, by giving illustrative examples of how the Part 2 information cannot be used in such contexts. It also expressly provides that the patient may consent to waive these protections.
- **HIPAA Penalties and Enforcement (Sec. 3221(f)):** The CARES Act shifts the primary enforcement responsibility away from the Department of Justice (DOJ) to HHS. Part 2 violations will be subject to the same penalties currently in place for HIPAA violations, see [42 USC 1320d-5](#) and [42 USC 1320d-6](#). That means that enforcement will no longer be criminal only and will be conducted by a department that is more experienced in enforcing federal privacy laws, which will substantially increase the likelihood of enforcement actions.
- **Antidiscrimination (Sec. 3221(g)):** The CARES Act expressly prohibits any entity from using Part 2 information to discriminate against an individual with respect to that individual’s treatment, employment, worker’s compensation, housing, court access, or social services or benefits. Recipients of federal funds also cannot discriminate against an individual in affording access to services provided with such funds.
- **Breach Notification (Sec. 3221(h)):** The HIPAA breach notification requirements in [42 USC 17932](#) will apply to a Part 2 program and, in the case of a breach of Part 2 information, to the same extent and in the same manner as such provisions apply to a HIPAA covered entity in the case of a HIPAA breach. This is a significant change to the status quo because it will require reporting of unauthorized uses and disclosures of Part 2 information.
- **Regulations (Sec. 3221(i)(1)):** HHS must issue new regulations to implement these changes. HHS must do so fairly quickly if the changes made by the CARES Act are to be implemented and enforced by March 27, 2021. This provision of the CARES Act expressly states that its “amendments shall apply with respect to uses and disclosures of information occurring on or after the date that is 12 months after the date of enactment of this Act.” It is unclear whether any HHS delay in making the necessary rule changes will toll this date.

The logo for Coppersmith Brockelman Lawyers features the firm's name in a white, sans-serif font against a dark blue background with a city skyline. The text is arranged as follows: 'COPPERSMITH' on the top line, 'BROCKELMAN' on the second line, and 'LAWYERS' on the third line, centered below a thin white horizontal line.

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- **Notice of Privacy Practice (NPP) (Sec. 3221(i)(2)):** Within 1 year of enactment, HHS must update [45 CFR 164.520](#) to require HIPAA covered entities to include specific information in their NPPs if they are holding Part 2 information.

Melissa Soliz focuses on HIPAA and 42 C.F.R. Part 2 compliance, health information exchange and networks (including compliance with the new information blocking rule), compliance with opioid treatment laws and regulations, data breaches and OCR investigations, as well as clinical research compliance and contracting.

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