Coppersmith Briefs

Regulatory Changes to Substance Use Disorder Privacy Law

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On July 15, 2020, the Substance Abuse Mental Health Services Administration (SAMHSA) published the final rule changes to 42 CFR Part 2 (Part 2). **These changes are effective August 14, 2020**.

Part 2 governs the confidentiality of substance use disorder (SUD) patient records. It 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 SUD, if that information originates from a federally-assisted SUD provider (called a Part 2 program). The Part 2 privacy protections follow the protected Part 2 information under certain circumstances, thus requiring non-Part 2 program providers, health plans and others to follow Part 2's more stringent privacy protections with respect to the Part 2 information they receive.

SAMHSA has revised Part 2 to better facilitate coordination of care in response to the opioid epidemic while maintaining its confidentiality protections against unauthorized disclosure and use. This final rule change does **not** implement the changes brought about Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). (Please see Coppersmith Briefs, The CARES Act: Sweeping Changes to Substance Use Disorder Privacy Law (42 USC 290dd-2) for a summary of the CARES Act changes.) SAMHSA will propose additional regulatory changes to implement the CARES Act by March 27, 2021—the deadline required by the CARES Act. SAMHSA provides important clarification to the community that the "statutory timeline in § 3221 prevents the part 2-related provisions of the CARES Act from taking effect before March 27, 2021."

In the interim, this final rule makes the following changes to Part 2:

- **Limiting when Part 2's Disclosure Restrictions Apply to Non-Part 2 Program Providers.** Part 2's downstream redisclosure restrictions on non-Part 2 program treating providers now only apply to the "records" of Part 2 programs that non-Part 2 program treating providers receive pursuant to the patient's written consent and that are accompanied by the prohibition on redisclosure notice. The redisclosure restrictions no longer apply to the recording of SUD information (oral or non-oral) that a non-Part 2 program treating provider may include in the patient's general (non-Part 2) medical record.

  SAMHSA is drawing a distinction between the actual Part 2 program "record" and SUD "information." SAMHSA's intent is to restrain the scope of Part 2's applicability so that treatment records created by

non-Part 2 program treating providers—even if they incorporate a patient's SUD information from a Part 2 program—are explicitly not covered by Part 2. This is an important and fundamental change to the applicability of the Part 2 regulations to non-Part 2 program providers who provide direct patient treatment. However, SAMHSA emphasizes that:

- The Part 2 program must still get the patient's written consent to disclose any information from the Part 2 records (including oral and non-oral disclosures) to non-Part 2 program providers. The change SAMHSA has made affects Part 2 applicability to non-Part 2 program treating providers only.

- Non-Part 2 program treating providers must still protect any actual Part 2 program records that they hold under Part 2's stringent redisclosures restrictions.

- This change "will not immunize the misconduct of a non-part 2 provider who engages in the wholesale transcription of a received SUD patient record, without her own direct patient encounter and without clinical purpose." The intent behind SAMHSA's changes to the applicability provision (and definition of records) is "to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2."

- This final rule change does not address Part 2's downstream applicability to health plans. Part 2 continues to apply to "[t]hird-party payers with regard to records disclosed to them by part 2 programs," and the definition of records continues to be, "any information . . . [of] a part 2 program relating to a patient (*e.g.*, diagnosis . . . billing information)." *See* 42 C.F.R. §§ 2.11, 2.12(d)(2)(i)(A).

This change in applicability has also resulted in a change to the full length prohibition on redisclosure notice. The abbreviated version has not changed.

- **Permitting Patients to Consent to Disclosures to Any Named Entity, Regardless of Whether the Named Entity Has a Treating Provider Relationship with the Patient.** In its 2017 final rule, SAMHSA changed the Part 2 consent form requirements to require that the patient name the person who will receive the patient's Part 2 information, unless the receiving entity was a health plan, had a treating provider relationship with the patient, or was an intermediary entity who facilitated the exchange of the Part 2 information to such persons/entities. This restriction prevented patients from authorizing disclosures of their Part 2 information to entities—like the social security administration and community based organizations—that lack this treating provider relationship, but are critical to patients receiving important services. This restriction has been lifted. A patient may now consent to disclosure of the

patient's Part 2 information to any entity named on the consent form, without naming a specific person as the recipient for the disclosure.

- **Removing the Patient Consent Requirement for Contractors who Perform Care Coordination/Case Management Functions under a Part-2 Compliant Agreement.** In the 2017 and 2018 rule changes, SAMHSA declined requests that it permit patient consented disclosures for "health care operations" purposes to include care coordination and case management activities. This decision caused Part 2 programs and non-Part 2 programs alike to not use vendors (or at least limited their use of vendors) to provide important care coordination and case management services to those patients often most in need of these services—patients suffering or recovering from SUDs. In this 2020 final rule, SAMHSA has reversed its earlier decision and now includes care coordination/case management services in the list of illustrative activities that can be done by contractors of Part 2 programs (under a Qualified Service Organization Agreement) or non-Part 2 programs (that are holding the Part 2 records pursuant to a patient's consent that allows the non-Part 2 program to use the Part 2 program records for payment or health care operations activities).

- **Permitting Patients to Consent to Non-Part 2 Program Provider Access to Central Registries.** Part 2 now permits central registries to respond to requests from non-Part 2 program providers who have a treating provider relationship with the patient to ensure appropriate coordinated care (that is, to inform prescriber decision making). SAMHSA recognizes that non-Part 2 program provider access to central registries is needed to fully inform decision making regarding appropriate prescription drugs for patients. However, the patient consent requirement for these disclosures remain. SAMHSA thus anticipates that Part 2 programs will update their consent forms to include new language regarding information shared with non-Part 2 program providers or create a new consent form for this purpose. SAMHSA also expects non-Part 2 program providers to demonstrate their treating provider relationship prior to making a query to a central registry.

- **Permitting Patients to Consent to Prescription Data Monitoring Programs (PDMPs).** SAMHSA has also finalized the proposed rule change that will allow Part 2 programs to participate in state mandated (required) PDMP reporting. This change might not apply if state law does not require certain Part 2 programs to report to the PDMP (*e.g.*, state PDMP laws with exceptions for opioid treatment programs (OTPs)). Moreover, patient consent for disclosures to the PDMP is still required. SAMHSA expects Part 2 programs to update their consents forms or create new ones to allow for these disclosures. With respect to satisfying the "to whom" consent form requirement (that is, who is authorized to receive the information disclosed to the PDMP), SAMHSA suggests that capturing the patient's consent to disclose to the PDMP is good enough because SAMHSA writes: "[w]e do not expect the proposed changes to require additional consent for redisclosure to each registered PDMP end-user."

- **Adding Natural Disasters to the Medical Emergency Exception.** The final rule permits Part 2 programs to disclose Part 2 information to medical personnel without the patient's consent during a temporary state of emergency declared by a state or federal authority as the result of a natural/major disaster (*e.g.*, hurricane, wildfire), during which the Part 2 program is closed and not able to provide services or obtain the patient's written consent due to the emergency. In such circumstances, Part 2 programs are still required to document the name of the medical personnel to whom the disclosure was made (and their facility affiliation), the name of the individual making the disclosure, the date/time of the disclosure, and the nature of the medical emergency. SAMHSA further emphasizes that "consent should still be obtained if at all feasible," and this exception is "rescinded when the part 2 program resumes operation." This exception does not extend to public health emergencies, such as the opioid epidemic or COVID-19 pandemic.

- **Expanding the Research Exception.** The final rule changes Part 2 research exception in two significant ways. First, it permits the disclosure of Part 2 information by a Part 2 program, HIPAA covered entity or HIPAA business associate pursuant to the HIPAA research requirements at 45 C.F.R. § 164.512(i). It also continues to permit such disclosures if a person with director/CEO level authority determines that the recipient of the Part 2 information is a HIPAA covered entity or HIPAA business associate who has obtained the patient's HIPAA authorization or waiver of that requirement under 45 C.F.R. § 164.512(i), or is subject to the Common Rule (45 C.F.R. Part 46) and has obtained the patient's informed consent, waiver of consent, or the research qualifies for an exemption to the Common Rule. Second, the final rule extends the director/CEO's decision making authority to include recipients who are determined to be subject to the FDA human subjects regulations (21 C.F.R. Parts 50 and 56) and have obtained the patient's informed consent or waiver of consent.

- **Adding Clarifying Language Regarding the Scope of the Audit and Evaluation Exception.** The final rule also adds much needed clarifying language to explain the scope of the audit and evaluation exception. Under the final rule changes, it is clear that this exception includes activities by governmental agencies and third party payers (and their contractors) that need access to Part 2 information for purposes of making policy/procedural changes to improve patient care and outcomes across Part 2 programs, to target limited resources more effectively, and to adjust payment policies to enhance care or coverage for SUD patients. It also applies to agency and third party payer activities related to reviews of appropriateness of medical care, medical necessity, and utilization of services. SAMHSA further clarified that auditors may include any entity that has direct administrative control over the Part 2 program and quality assurance entities, like accreditation bodies.

- **Expanding the Audit and Evaluation Exception to Allow for Mandated Disclosures to Governmental Agencies without Requiring the Agency (or its Contractors) to Enter into a Written Agreement with the Disclosing Entity.** The final rule now permits Part 2 programs and non-Part 2 programs to disclose Part 2 information to federal, state or local governmental agencies (and their

contractors) during an audit or evaluation mandated by law, if the audit or evaluation cannot be carried out using de-identified information, without requiring the agency (or contractor) to enter into a written agreement requiring compliance with Part 2.

- **Extending the Time Undercover Agents/Informants can be Placed in a Part 2 Program.** Court-ordered placement of undercover agents or informants has been extended to up to 12 months, with the option of a court-ordered extension, in order to assist law enforcement efforts in uncovering bad actor providers within Part 2 programs.

- **Providing Further Details on How Personal Devices may be Sanitized under Part 2's Record Disposition Requirement.** The 2017 changes to Part 2's record disposition requirements have resulted in Part 2 programs confiscating or destroying Part 2 program personnel's personal devices in order to meet Part 2's sanitization requirements for records disposition. Under this 2020 final rule, in instances where Part 2 program personnel receive an incidental patient message to the personnel's personal device, deleting that message is sufficient to meet Part 2's disposition requirements.

For additional information, please check out these resources:

- Final Rule, 85 Fed. Reg. 42986 (July 15, 2020)
- Proposed Rule, 84 Fed. Reg. 44568 (Aug. 26, 2019)
- 42 C.F.R. Part 2
- 42 U.S.C. § 290dd-2
- Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule (July 13, 2020)
- HHS 42 CFR Part 2 Proposed Rule Fact Sheet (Aug. 22, 2019)
- SAMHSA, Substance Abuse Confidentiality Regulations, FAQs
- Focus:PHI, The Centers for Excellence for Protected Health Information

Melissa Soliz's regulatory health law practices focuses on compliance with health information confidentiality and access laws (including HIPAA, 42 U.S.C. § 290dd-2 and 42 C.F.R. Part 2, the ONC Information Blocking Rule, the CMS Interoperability and Patient Access Rule, and state laws), as well as compliance with opioid treatment laws and regulations, health information exchange (HIE), behavioral health/substance use disorder law issues, data breaches and OCR investigations, as well as clinical research compliance and contracting.

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