Demystifying 42 CFR Part 2:

Legal and Ethical Use of SUD Records

Sharing and integrating substance use disorder (SUD) records safely and responsibly can help governments and their partners facilitate early identification and intervention, allocate resources effectively and implement targeted prevention programs. However, sharing SUD data is not without risks and this data is subject to a set of stringent regulations in 42 CFR Part 2 (commonly referred to as "Part 2"). Many local and state governments find Part 2 intimidating, often mistakenly believing that it completely prohibits the sharing of substance use disorder patient records. This brief aims to demystify Part 2, a critical regulation governing the confidentiality of these records, by providing a broad overview of its core components. This brief is not intended to be exhaustive and does not cover every instance in which Part 2 data can be shared. This brief only covers federal law and does not address more restrictive state law.

WHAT?

42 CFR Part 2 protects the confidentiality of any record that could "identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person." **42 CFR §2.12 (a) (1)**.

WHY?

The intent of 42 CFR Part 2 regulations is "to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable by reason of the availability of their record than an individual with a substance use disorder who does not seek treatment." **42 CFR §2.2(b)(2)**.

WHO?

42 CFR Part 2 applies to any "federally assisted" program that provides substance use or alcohol treatment, diagnoses, or referrals to treatment. **42 CFR § 2.12**.

The bar is low to be considered a "federally assisted" program—a program need only receive some type of benefit from the U.S. government (i.e. grant money, accepting Medicaid, receiving non-profit status from IRS, etc.). Therefore, most drug and alcohol treatment programs are "federally assisted." Additionally, even private clinics that do not meet any of these requirements may be subject to state law requirements that require them to follow 42 CFR Part 2.

Continued on next page

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COMMON EXCEPTIONS TO CONSENT REQUIREMENT

In general, Part 2 Programs are prohibited from disclosing any information that would identify a person as having or having had a SUD unless that person provides written consent. However, there are some notable exceptions to the consent requirement that are pertinent to data sharing and integration:

Research

SUD data can be disclosed to researchers without consent for "scientific research" if certain conditions are met. 42 CFR § 2.52(b). Importantly, if researchers are requesting linkages to data sets from data repositories, 1) the request must be approved by an IRB to "to ensure that patient privacy is considered and the need for identifiable data is justified;" 2) no data can be disclosed to law enforcement; and 3) data linkages cannot be redisclosed, except as permitted by law. 42 CFR § 2.52(c)(1). Finally, after the data is provided, the linked data must be deleted or destroyed and researchers who receive patient identifying information are prohibited from redisclosing the patient-identifying information to anyone except back to the program. 42 CFR § 2.52(c)(2).

Audits and Evaluations

42 CFR Part 2 permits disclosures of identifiable information without consent to conduct audits and evaluation activities. The audit or evaluation must be conducted on or behalf of a governmental body, an entity that has direct administrative control over the Part 2 program, a quality improvement organization or any organization providing financial assistance to the program. 42 CFR § 2.53(a)(1). Furthermore, the regulations impose certain additional restrictions by requiring that the party conducting the audit or evaluation agree in writing that it will redisclose patient identifying information only (1) back to the program, or (2) pursuant to a court order to investigate or prosecute the program (not a patient), or (3) to a government agency that is overseeing a Medicare or Medicaid audit or evaluation. 42 CFR § 2.53(c)-(d).

Vital Statistics Reporting

Part 2 permits the disclosure of identifiable information about cause of death if required by laws that require the collection of death or other vital statistics. The release must be consistent with a law that requires collection of the information. 42 CFR § 2.15(b)(1).

Qualified Service Organization Agreements (QSOAs)

The regulations allow Part 2 programs to share communications with a qualified service organization (QSO) for the QSO to provide services to or on behalf of the program. 42 CFR § 2.12(c)(4).

Continued on next page

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EXCEPTIONS ALLOWED BY THE AMENDED RULES

Additionally, the U.S. Department of Health & Human Services modified these regulations in February 2024, by implementing the confidentiality provisions of section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act which required DHHS to better align 42 CFR Part 2 with certain aspects of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Rules. These modified regulations include new exceptions to the consent requirement that could be relevant to data sharing and integration.

Disclosures to Public Health Authorities

The updated rules provide that de-identified patient information can be disclosed to public health authorities for public health purposes. **42 CFR § 2.54(a)-(b)**. The earlier Part 2 rule did not permit de-identified information to be shared with public health authorities.

Disclosure once consent is received for treatment, payment and health care operations (TPO)

The new rules allow a single consent for all treatment, payment, and health care operations (TPO). Previously, providers needed to get consent every time for TPO. Importantly, when SUD data is disclosed for TPO to a covered entity or business associate, a recipient "may further disclose those records in accordance with the HIPAA regulations, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient." **42 CFR § 2.33(b)(1)**.

ADDITIONAL RESOURCES

Substance Abuse and Mental Health Services (SAMHSA). (May 2018). ***Disclosure Of Substance Use Disorder Patient Records: Does Part 2 Apply To Me?*** The Office of National Coordinator for Health Information Technology.

Network for Public Health Law. (2024). ***Summary of 42 CFR Part 2: Confidentiality of Substance Use Disorder Patient Records Final Rule***.

Network for Public Health Law. (2020). ***Snapshot of SAMHSA Confidentiality of Substance Use Disorder Patient Records Regulation: 42 CFR Part 2***.

U.S. Department of Health and Human Services. (2024). *Fact Sheet: 42 CFR Part 2 Final Rule*. Retrieved from, ***https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#ftn1***

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