Central Registries and Confidentiality of SUD Records, 42 CFR Part 2

Data Privacy Considerations for OTPs and State Authorities

Central registries for opioid treatment programs (OTPs) manage limited patient information to help identify whether a patient is already enrolled in another OTP and to support coordinated care. Learn how central registries can manage patient data while complying with the federal confidentiality protections in 42 CFR Part 2.

What you need to know

Federal law permits limited disclosures and uses of patients' treatment records by OTPs and central registries. OTPs must obtain patients' written consent before sharing information with a central registry. Consent forms should be easy for patients to understand and should accurately describe any intended disclosures, uses, or redisclosures by the central registry.

What is a central registry for opioid treatment programs (OTPs)?

A central registry is an organization that manages records about OTP patients for the purpose of preventing an individual from enrolling in multiple OTPs at the same time.[1] With patient consent, OTPs may share information with a central registry when a patient is admitted, transferred, discharged, or changes medication type or dosage.[2] A central registry may share limited patient records with other OTPs to prevent multiple enrollments, and may also share information with a patient's treating providers outside the OTP to ensure appropriate coordinated care and inform prescriber decision-making.[3] Central registries are permitted but not required by federal law; not all states have a central registry.[4]

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42 CFR Part 2 Requirements for Central Registry Operations

LOTPs are subject to the federal confidentiality law and regulations for substance use disorder (SUD) records, 42 USC § 290dd-2 and 42 CFR Part 2 (Part 2).[5] This federal law only permits OTPs to share patient information with a central registry if authorized by the patient's written consent.[6] Central registries' use and disclosure of Part 2 records received from OTPs is similarly limited by Part 2.[7] Other laws, including HIPAA and state law, may also apply.[8]

(1) Permitted Disclosures by OTPs to Central Registries

OTPs may only disclose three categories of information to central registries: (i) patient-identifying information; (ii) type and dosage of the medication; and (iii) relevant dates.[9] The table below gives some illustrative examples of data elements in each category:

Part 2 Category	Examples
Patient-identifying information	Name, date of birth, mother's maiden name, other information used to identify the individual (e.g., address)
Medication type and dosage	Methadone, buprenorphine, amount dispensed or administered (e.g., 120mg)
Relevant dates	Admission date, date of dosage change, date of last medication dispensed ("take-home doses"), transfer date, discharge date

As with all disclosures of Part 2 records, disclosures to the central registry must be accompanied by Part 2's notice and a copy of the patient's written consent form, or a description of the scope of the consent.[10]

(2) Permitted Uses and Redisclosures by Central Registries

Central registries may only use and redisclose Part 2 records for two purposes: (i) to prevent multiple enrollments; and (ii) to support appropriate coordinated care with other treating providers in certain circumstances.[11]

When an OTP queries a central registry about a prospective new patient, the central registry may disclose the name, address, and telephone number of an OTP where the patient is already enrolled.[12] The central registry also may disclose the name, address, and telephone number of the inquiring OTP to the OTP where the patient is already enrolled.[13] The OTPs may then communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollments.[14]

- **Case Study: Permissible Central Registry Uses and Disclosures to Prevent Multiple Enrollments**
  - Mary is applying for treatment at Blue River OTP. She signs a consent authorizing the OTP to query the central registry. The OTP shares Mary's full name, date of birth, and mother's maiden name with the central registry. The central registry returns a report that Mary is already enrolled in Green Valley OTP in a nearby county. Blue River OTP calls Green Valley OTP and confirms that this was an administrative error: Mary was already discharged from treatment, and is therefore eligible to be enrolled in Blue River.

When responding to a treating provider's query for the purpose of prescriber decision-making, a central registry may disclose the name, address, and telephone number of the OTP where the patient is enrolled, the type and dosage of any medication being administered or prescribed to the patient, and relevant dates of medication administration or prescription.[15] The central registry and treating provider may communicate as necessary to verify no error has been made, and to prevent or eliminate multiple enrollments or improper prescribing.[16]

- **Case Study: Permissible Central Registry Uses and Disclosures to Inform Prescriber Decision-making**
  - Mary enters treatment at Blue River OTP and signs a consent form authorizing Blue River to share information with the central registry. Late one night, Mary takes the ambulance to the emergency department at a local hospital. A doctor at the emergency department wants to verify Mary's medication type and dosage, but the OTP is currently closed. The doctor queries the central registry, which shares the name of Mary's OTP as well as her current medication, dosage, and the date it was last administered.

Central registries may also use patient information if authorized by a special court order that meets the specific procedural and substantive requirements in 42 CFR Part 2, Subpart E. Absent a special court order, Part 2 prohibits any other uses or redisclosures by central registries – even to other state agencies, public health departments, or state or federal law enforcement.[17]

(3) Additional Considerations for Consent Forms and Central Registries

Consent forms should be understandable to patients and should accurately describe the central registry, the information to be disclosed, and the purpose of the disclosure, as well as the other required elements of Part 2 consent.[18]

A key operational question is whether the consent forms validly authorize the disclosure of OTP data to the central registry, and the central registry's use and re-disclosure of that data. Not only is this important for OTPs' compliance with Part 2, but it also implicates the central registry's lawful operations and compliance. Remember: central registries can

only use and disclose information as permitted by Part 2 and as authorized by the patients' written consent. Even a use or disclosure otherwise permissible under Part 2 is not allowed if it is not authorized by the patient's signed consent form.

- **Case Study: Deficient Consent**
  - State A creates a consent form for OTPs reporting to State A's central registry. The consent form asks patients to authorize disclosures of the following information: patient name, date of birth, and mother's maiden name. The consent form does not mention disclosures about patient status or information about medication type and dosage. The consent form does not state a purpose of the disclosure, does not identify the central registry, and does not include an expiration date. An OTP cannot legally share any information pursuant to this consent form, because it is legally deficient under Part 2.[19]

For More information

Resources: This resource is one of many that are available within the CoE-PHI's resource library, which can be found at coephi.org.

Training/Technical Assistance: You can request brief, individualized technical assistance and join our mailing list for updates, including news about the publication of new resources and training opportunities on our website.

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References

1. *42 CFR § 2.11 (defining "central registry" and "member program").*
2. *See 42 CFR § 2.34(a)(1).*
3. *See 42 CFR § 2.34(b); see Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42,986, 43,013 (July 15, 2020) (to be codified at 42 CFR Part 2) (amending the regulations to permit the use of central registry information to coordinate care with other treating providers), https://www.federalregister.gov/d/2020-14675/p-374.*
4. *Central registries help OTPs satisfy their obligations under federal law to document "a good faith effort to determine whether the patient is enrolled in any other OTP." 42 CFR § 8.12(g)(2). Other means of satisfying this requirement are also available, such as by directly contacting other local OTPs or accessing patient records through a shared electronic health record or health information exchange. If you are unsure whether your state operates a central registry, contact your State Opioid Treatment Authority; contact information is available at https://findtreatment.gov/state-agencies.*
5. *The federal confidentiality protections for SUD treatment records apply to patient-identifying information from "Part 2 programs," which include federally assisted SUD treatment programs like OTPs. See 42 USC § 290dd-2(a); 42 CFR § 2.11 (defining "Part 2 program").*
6. *42 CFR § 2.34; see also id. at § 2.33(a)(1) (requiring consent for disclosures to central registries to meet the requirements of § 2.34).*
7. *42 CFR § 2.34(b); see also id. at §§ 2.11 (defining "lawful holder"), 2.12(d)(2)(i)(C) (describing legal obligations of lawful holders).*
8. *HIPAA, or the Health Insurance Portability and Accountability Act, applies to covered entities and business associates. 45 CFR § 160.103. In some cases, a central registry may be a HIPAA business associate if it is engaged by a covered entity or covered entities. See 45 CFR § 160.103 (defining "business associate"); see also U.S. Dep't of Health & Human Services, Business Associates, https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html. State health or consumer privacy laws may also apply; these laws are changing frequently, so it is important to consult with local counsel in your state.*
9. *42 CFR § 2.34(a)(2).*
10. *See 42 CFR § 2.32.*
11. *42 CFR § 2.34(b).*
12. *See 42 CFR § 2.34(c)(1).*
13. *42 CFR § 2.34(c)(2).*
14. *42 CFR § 2.34(c)(2), (e).*
15. *See 42 CFR § 2.34(d)(1)-(3).*
16. *42 CFR § 2.34(d)(3).*
17. *42 CFR § 2.34(b); see also 42 CFR Part 2, subpart E (describing the requirements for Part 2 court orders). For more information about court orders, see Jacqueline Seitz, "Civil Court Orders Authorizing Disclosure of Part 2 Records," Center of Excellence for Protected Health Information, https://coephi.org/resource/civil-court-orders-authorizing-disclosure-of-sud-treatment-records-protected-by-42-cfr-part-2/ and Jacqueline Seitz & Ashleigh Giovannini, "Criminal Court Orders Authorizing Disclosure of Part 2 Records," Center of Excellence for Protected Health Information, https://coephi.org/resource/criminal-court-orders-authorizing-disclosure-of-part-2-records/.*
18. *See 42 CFR § 2.34; see also id. at § 2.31.*
19. *See 42 CFR § 2.34(a)(3) (requiring consent to include the name and address of the central registry and otherwise to meet the requirements of Section 2.31). Section 2.31 requires consents to include a description of the purpose of the requested use or disclosure and an expiration date or event, among other required elements. Id. at § 2.31(a)(5), (7).*