Permitted Disclosures of Part 2 Records to State and Local Government Agencies for Oversight and Evaluation

42 CFR Part 2 ("Part 2") protects the confidentiality of substance use disorder (SUD) treatment records. Under Part 2, federally assisted substance use disorder (SUD) treatment programs are prohibited from disclosing patient-identifying information without the patient's **written consent**, unless a specific exception applies. Please see CoE-PHI's related resource: **Template Consent for Uses and Disclosures of Part 2 Records**, which provides a framework that Part 2 programs and others may adapt when developing a consent form to authorize uses and disclosures of Part 2-protected records.

While the law generally requires patient consent before disclosure, there are circumstances where disclosures to state and local government agencies are allowed without patient consent for oversight and evaluation. This resource outlines three exceptions where consent is not required under Part 2.

The first two exceptions: (1) **audit and evaluation** and (2) **deceased patients**, including overdose fatality review board disclosures, permit identifiable information to be shared without consent. The third exception, **for disclosures to public health**, only permits de-identified information to be shared without consent. Sharing identifiable information for **public health reporting purposes** requires **patient consent**.

There are additional exceptions when consent is not required that may also be relevant to local and state government agencies. While not discussed in detail in this resource, these exceptions include: reporting crime on program premises (42 CFR § 2.12(c)(5)), reports of suspected child abuse and neglect (42 CFR § 2.12(c)(6)), court orders (42 CFR § 2.64 and 2.65), and research (42 CFR § 2.52).

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1. Audit and Evaluation Disclosures (42 CFR § 2.53)

Part 2 programs and lawful holders of Part 2 records may disclose identifiable Part 2 records[1] during the course of an audit or evaluation if it is performed on behalf of[2]:

- Federal, state and local government agencies that provide financial assistance or are authorized by law to regulate activities of a Part 2 program or **lawful holder**, or
- An entity that provides financial assistance to a Part 2 program or lawful holder (such as a 3rd party payor), or
- An entity with direct administrative control over a Part 2 program or lawful holder.

Part 2 states that activities can include but are not limited to: (1) activities undertaken by a government agency or third-party payor or health plan to improve care and outcomes, manage resources to care for patients effectively, or adjust payment policies to enhance care or coverage; or (2) review the appropriateness of medical care and service utilization.[3]

Additionally, the regulations permit disclosures to any person for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation[4] as well as disclosures to government agencies and their contractors and representatives that are conducting an audit or evaluation mandated by statute or regulation.[5]

Example: SAMHSA provided several examples of the types of activities that may fall under the audit and evaluation exception. SAMHSA has also made it clear that this exception extends to identifiable information and has not specified how frequently or infrequently audits and evaluations can be performed.[6] Examples in the 2018 and 2020 preambles to the Part 2 updates include:

- An Accountable Care Organization (ACO) or similar CMS-regulated health care model that wanted to evaluate the impact of integrated care on several participating behavioral health care programs' quality of care.[7]
- A state that wished to do an audit to see how many individuals who leave state-supported correctional facilities subsequently receive substance use disorder treatment.[8]
- A state Medicaid Agency or state or local health department may need to

[1] SUD counseling notes have more limited disclosure permissions in an audit or evaluation conducted under Section 2.53. 42 CFR § 2.31(b).
[2] 42 CFR § 2.53(a)(1)(i)-(iii).
[3] 42 CFR § 2.53(c)(1)-(2).
[4] 42 CFR § 2.53(e).
[5] 42 CFR § 2.53(g).
[6] Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 43027 (July 15, 2020).
[7] Confidentiality of Substance Use Disorder Patient Records, 83 Fed. Reg. 246 (January 3, 2018).
[8] *Id.*

know about specific challenges faced by patients receiving opioid therapy treatment, such as co-occurring medical or psychiatric conditions, or social and economic factors that impede treatment or recovery. An agency may need this information to recommend or mandate improved medical care approaches; to target limited resources more effectively to care for patients; or to adjust specific Medicaid or other program policies or processes related to payment or coverage to facilitate adequate coverage and payment.[9]

- Government agencies may need to know how many patients test positive for a new and harmful illicit drug, and how part 2 programs are actually treating those patients, as an input to agency decisions aimed at improving quality of care. For example, agencies may wish to modify requirements for part 2 programs, educate or provide additional oversight of part 2 providers, and/or update corresponding payment or coverage policies.[10]

Records: Records with patient identifiable information may be viewed on the premises or copied, removed, downloaded, or forwarded.

- In both instances, the record reviewer must agree to comply with limitations on uses and disclosures, namely the reviewer can only disclose the information back to the Part 2 provider or lawful holder or use it to carry out audit and evaluation activities, or to investigate or prosecute criminal activities in accordance with a Part 2 compliant court order under Section 2.66.[11]
- If records are copied, removed, downloaded, or forwarded, the entity conducting the audit or evaluation must also agree in writing to maintain and destroy the patient identifying information consistent with the Part 2 program's policies, retain records in accordance with law and comply with the limitations on disclosure described above.[12]

Practice Tip: Verify the scope and authority of any audit or evaluation request. Ensure the reviewer understands redisclosure restrictions and if copying, removing, or downloading records, agrees in writing to abide by the requirements of Part 2 and any other applicable law.

2. Deceased Patients & Overdose Fatality Review (OFR) (42 CFR § 2.15(b))

Part 2 **extends privacy protections to deceased patients** indefinitely but does permit disclosures without consent in certain limited circumstances. This includes disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.[13] Under certain circumstances this exception may extend to overdose fatality review teams or programs.

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[9] Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 43022 (July 15, 2020).
[10] *Id.*
[11] 42 CFR § 2.53(f).
[12] 42 CFR § 2.53(b).
[13] 42 CFR § 2.15(b)(1).

Key Conditions:

- Disclosure must be related to the cause of death of the patient.
- There must be a state law that requires the collection of death or other vital statistics, or that permits inquiry into the cause of death.
- If either of these conditions are not met, then consent from the deceased patient's personal representative must be obtained.

Example: A local health department's OFR team requests records of a decedent who received SUD treatment. If state law authorizes the board to inquire into the cause of death, the records may be shared.

Practice Tip: Ensure your organization understands what state law the requestor is relying on that permits disclosure of the records without consent.

3. Public Health Disclosures (42 CFR § 2.54)

Part 2 allows disclosures of SUD records to public health authorities, as defined by the Health Insurance Portability and Accountability Act at 45 CFR § 164.501, without consent only if the data is de-identified, or with consent if it includes identifiable information. Although HIPAA permits regulated entities to share identifiable information with public health authorities, SAMHSA did not believe it had authority under the CARES act to extend this exception to identifiable data.[14] **As such, Part 2 is explicit that the permitted disclosures without consent are limited to de-identified data and a patient must sign a specific consent authorizing disclosures to public health.**[15]

The de-identified patient information must meet the HIPAA standard for de-identification.[16] The first is the "safe harbor" method, where you can remove 18 enumerated identifiers that are listed in Part 2, and second is the "expert determination" method, where someone with appropriate statistical and scientific knowledge and experience of rendering information not individually identifiable applies those methods and determines there the risk of reidentification is very small. Under either method, there should be no reasonable basis to believe the information could be used to identify a patient.[17]

Practice Tip: Document how data meets the HIPAA de-identification standards. When in doubt, obtain consent or consult legal counsel and/or a qualified expert to assist in the process.

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[14] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12569 (February 16, 2024).
[15] Confidentiality of Substance Use Disorder (SUD Patient Records), 89 Fed. Reg. 12544 (February 16, 2024).
[16] 42 CFR § 2.54(b).
[17] *Id.*

Conclusion

Even in circumstances when Part 2 allows disclosures without consent, state laws may impose stricter requirements. Always review applicable state law and your organization's internal policies before releasing any records.

For More Information

Resources:

This resource is one of many that are available within the Center of Excellence for Protected Health Information's resource library, which can be found at **coephi.org**.

Request 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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