



## Privacy Considerations for Medication Assisted Treatment in Jails and Prisons

### WHAT YOU NEED TO KNOW

Jails and prisons around the country are implementing programs to provide medication for opioid use disorder (MOUD) for substance use disorder (SUD). In designing their MOUD programs, jails and prisons need to determine whether the federal privacy and security requirements for substance use disorder (SUD) treatment records, 42 CFR Part 2 (Part 2), will apply to their operations.<sup>1</sup> If so, they must identify the required privacy and security protections for Part 2-protected records.

Maintaining the confidentiality of patients' SUD treatment records is not only required by law, but also is a crucial element of quality SUD treatment and positive patient treatment outcomes. Privacy protections ensure that patients receiving SUD treatment are not made *more vulnerable* to negative outcomes than had they not sought treatment.<sup>2</sup> These protections are particularly salient in jails and prisons.

### DETERMINING WHETHER PART 2 APPLIES IN JAILS AND PRISONS

Part 2 applicability depends on the specific structure of a jail or prison's SUD treatment program, including who is providing MOUD and how the services are organized. Below, we describe two possible program designs and how Part 2 might apply:

#### ① **JAILS AND PRISONS OFFERING MOUD DIRECTLY:** IDENTIFYING WHETHER THERE IS A "PART 2 PROGRAM" ON-SITE

A jail or prison that provides MOUD directly to patients (as opposed to through a contractor) will need to comply with Part 2's privacy and security requirements *if the MOUD program meets the definition of a "Part 2 program."*<sup>3</sup> In order to be considered a "Part 2 program," a provider or unit must –

- Be *federally assisted and*
- meet the regulatory definition of a *program.*<sup>4</sup>

## (a) Is the jail or prison **FEDERALLY ASSISTED**?

Any jail or prison providing **methadone** or **buprenorphine** for opioid use disorder (OUD) is *federally assisted* (although will not necessarily meet the definition of a *program*; see section (b) below).<sup>5</sup> A jail or prison offering only **naltrexone** (or medication for addiction treatment (MAT) other than methadone or buprenorphine) may still be considered “federally assisted” if it is part of a state or local government unit that receives federal funds eligible to be spent on the SUD treatment program.<sup>6</sup> A jail or prison may also be “federally assisted” if it contracts with a federal agency, such as Immigration and Customs Enforcement (ICE) or the U.S. Marshals Services (USMS), and the federal contract includes funding for the SUD treatment program.<sup>7</sup> Other sources of federal assistance also may apply.<sup>8</sup>

If the jail or prison is federally assisted, keep reading to see if it meets the definition of a *program*.

## (b) Does the jail or prison have a **PROGRAM**?

**A jail or prison program offering MOUD directly to patients would meet Part 2’s definition of a “program” if its MOUD program meets any of the following definitions:**

- **Program type 1:** an individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment. *Most jail or prisons likely would not have this type of program.*
- **Program type 2:** an identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment;

### Examples of program type 2:

A jail or prison **on-site OTP is very likely a “program” if the OTP is an *identified unit*** within the correctional health services’ general medical facility and *holds itself* out as providing SUD services. An example of “holding itself out” would be by conducting any activity that would lead one to reasonably conclude that the OTP offers SUD diagnosis or treatment.<sup>9</sup> As discussed above, a jail or prison with an on-site OTP is “federally assisted.” Therefore, the jail or prison’s OTP would be a “Part 2 program.” All OTP records would need to be protected and secured as required by Part 2.

- **Program type 3:** medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.<sup>10</sup>

### Examples of program type 3:

**A jail or prison MOUD program also would meet the definition of a “program” if identified SUD personnel provide SUD diagnosis or treatment, and their *primary function* involves providing SUD services.**<sup>11</sup> If the jail is federally assisted (discussed above), the identified personnel would be a “Part 2 program” and would be required to protect and secure patient records in compliance with Part 2.

## Summary

If a jail or prison program offering MOUD is *federally assisted*, and its providers meet the definition of a *program*, then the jail or prison has a Part 2 program. It must follow Part 2's privacy and security requirements with respect to all patient records created and maintained by the Part 2 program.

If the jail or prison's MOUD service providers do not meet the definition of a Part 2 program – for example, because the MOUD is provided by the general medical facility and there is no identified SUD unit or identified SUD providers – then the jail or prison does *not* have a Part 2 program. However, the jail or prison still may need to apply Part 2's protections to MOUD records received from a community-based Part 2 program, as discussed below.

## ② JAILS AND PRISONS THAT PROVIDE MOUD THROUGH PARTNERSHIPS WITH COMMUNITY-BASED TREATMENT PROVIDERS: IDENTIFYING WHEN PART 2 APPLIES

A jail or prison that contracts with community-based Part 2 programs to provide MOUD will become a “lawful holder” if it receives any patient records from the program.<sup>12</sup> This situation may arise when a jail or prison requires **community-based Part 2 programs to provide the jail or prison with patient-identifying information, such as name, diagnosis and type of MOUD**. If the community-based provider is a Part 2 program, they can only share this information with the patients' written consent. **In this case, the jail or prison becomes a “lawful holder” of that information.**<sup>14</sup>

Lawful holders must follow Part 2's privacy and security requirements, but only for the records received from the Part 2 program. Part 2's privacy and security requirements do not apply to the rest of the lawful holder's records, even if those records include substance use information.<sup>15</sup>

### Example

A prison contracts with a local OTP (a Part 2 program) to provide SUD treatment services. The prison transports patients to the OTP for diagnosis and treatment, and the OTP delivers methadone dosages weekly to the prison, to be dispensed daily by the prison's healthcare staff. **With patients' written consent, the prison receives Part 2-protected information in writing from the OTP about the methadone dose for each patient enrolled in the program. The prison becomes a “lawful holder” of this Part 2-protected information and must protect it accordingly.**<sup>16</sup>

Also note that information patients share directly with jail or prison healthcare staff is not protected by Part 2.

## Summary

A jail or prison that is not a Part 2 program can become subject to Part 2 as a lawful holder if it receives records from a Part 2 program. It would need to follow Part 2's privacy and security requirements, but only for the records received from the Part 2 program.

## PRACTICAL IMPLICATIONS

Regardless of whether the jail or prison MOUD program meets the definition of “Part 2 program” or is a “lawful holder,” it will have obligations to safeguard the privacy and security of patients’ treatment records including:

- **Obtaining patient consent** on a form that complies with Part 2 – which is stricter than HIPAA – to share information with:
  - o medical providers who fall outside the “program” (including other staff in the correctional health unit),
  - o the jail/prison administration for security and administrative purposes, or
  - o outside entities unless Part 2 permits the disclosure without consent;
- **Segmenting or separating Part 2 records** from the rest of the patient’s files and the rest of the institution’s administrative records; and
- **Creating separate policies and procedures** for the security of the Part 2 records.

**Both Part 2 programs and lawful holders will need a Part 2 compliance plan, including to coordinate care** or communicate with other community-based or jail or prison MOUD programs. For example, if a patient enters jail with an existing prescription for methadone or buprenorphine, the jail may want to contact the community-based Part 2 program to confirm the patient’s diagnosis, medication, and dosage; the jail then becomes a lawful holder of the information received from the Part 2 program and must protect it according to Part 2. Coordination with community-based providers is also crucial upon reentry. When individuals transfer between jails and prisons, similar care coordination may be necessary.

## **ADDITIONAL CONSIDERATIONS WHEN RECORDS ARE PROTECTED BY PART 2:**

- All disclosures, especially those made pursuant to consent, must **be limited to the minimum necessary** information to accomplish the need or purpose of the disclosure.<sup>17</sup> For example, it generally would not be permissible for a jail or prison to require a Part 2 program to provide confidential patient communications, such as case notes, because they would not be necessary for the purpose on the consent form, e.g., to coordinate care. A jail or prison may frequently need no information other than the individual’s diagnosis.
- **Patient privacy plays a crucial role in promoting recovery** – which benefits not only the incarcerated Individuals, their families and communities, and public safety, but also the jail and prison environment.



## 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](https://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, [here](#).



### Disclaimer

Resources, training, technical assistance, and any other information provided through the Center of Excellence for Protected Health Information do not constitute legal advice. For legal advice, including legal advice on other applicable state and federal laws, please seek out local counsel.

This resource was supported by SAMHSA of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award with 100 percent funded by SAMHSA/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by SAMHSA/HHS, or the U.S. Government

---

### References

1. See 42 USC § 290dd-2 (2021); 42 CFR Part 2 (2021).
2. See Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42987 (July 15, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf>.
3. Even if the jail or prison providing MAT does not meet the definition of a Part 2 program, it may still need to follow Part 2 with respect to records it receives from other Part 2 programs. See Section B, below.
4. See 42 CFR §§ 2.11 (definition of "program"), 2.12(b) (definition of "federally assisted").
5. "Federal Assistance" includes having a "license, certification, registration, or other authorization granted by any department or agency of the United States..." This includes an authorization to conduct maintenance treatment or withdrawal management (i.e., methadone) and registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders (i.e., buprenorphine). 42 CFR § 2.12(b)(2), § 2.12(b)(2)(ii), § 2.12(b)(2)(iii).
6. See 42 CFR § 2.12(b)(3)(ii).
7. See 42 CFR § 2.12(b)(1).
8. See generally 42 CFR § 2.12(b) for the full definition of federal assistance.
9. Official sub-regulatory guidance interprets this broadly to include internet statements, listings in registries, state licensing procedures, and information presented to patients or their families, among other activities. See U.S. Department of Health & Human Services, Substance Abuse & Mental Hygiene Services Administration, Office of the National Coordinator for Health Information Technology, Disclosure of Substance Abuse Confidentiality Regulations, FAQ #10 (rev. March 30, 2021), <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>.
10. 42 CFR § 2.11 (definition of "program").
11. While there is no official bright-line definition for "primary function," official sub-regulatory guidance provides several examples of providers that do and do not meet the standard. See U.S. Department of Health & Human Services, Substance Abuse & Mental Hygiene Services Administration, Office of the National Coordinator for Health Information Technology, Disclosure of Substance Use Disorder Patient Records at 6 (accessed November 10, 2021), <https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>.
12. Note that paying for the contracted services is not sufficient to render the jail or prison a Part 2 program.
13. Note that if a Part 2 program provides only verbal information to the jail or prison health care provider, the jail or prison health care provider will not become a "lawful holder." Verbal information conveyed with patient consent from a Part 2 program to a health provider is not protected by Part 2 if it is being conveyed for treatment purposes. 42 CFR § 2.11 (definition of "records").
14. See 42 CFR § 2.12(d).
15. See Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42986, 42995 (July 15, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-07-15/pdf/2020-14675.pdf> ("... SUD records received by [a] non-part 2 entity from a part 2 program are subject to part 2 restrictions on redisclosure of part 2 information by lawful holders, including redisclosures by non-part 2 providers. However, the records created by the non-part 2 provider in its direct patient encounter(s) would not be subject to part 2, unless the records received from the part 2 program are incorporated into such records.").
16. In other words, the prison is a "lawful holder" of these records.
17. 42 CFR § 2.13(a); 45 CFR §§ 164.502(b), 164.514(d)(5).