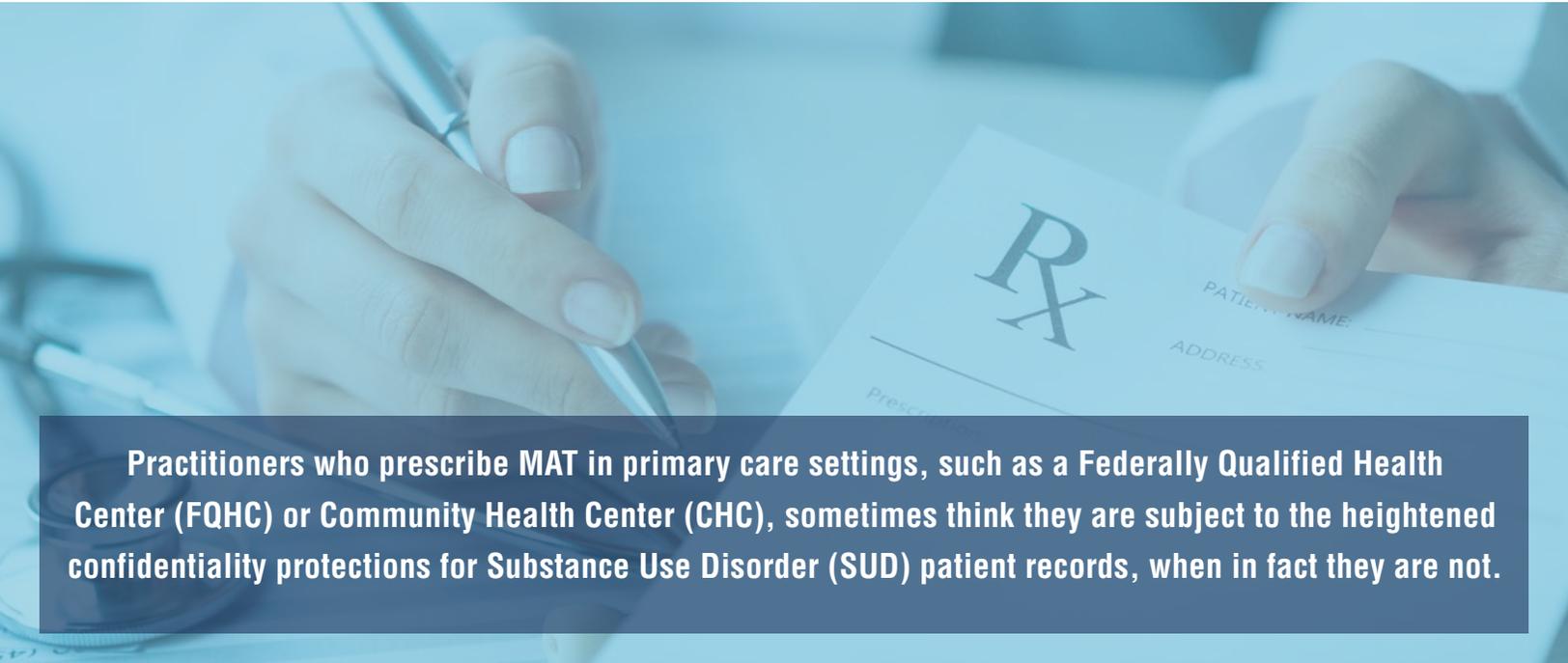


COE PHI InFocus Brief

Prescribing Medication Assisted Treatment (MAT) in a General Medical Facility

Does Part 2 Apply in Primary Care Settings?



Practitioners who prescribe MAT in primary care settings, such as a Federally Qualified Health Center (FQHC) or Community Health Center (CHC), sometimes think they are subject to the heightened confidentiality protections for Substance Use Disorder (SUD) patient records, when in fact they are not.



What You Need to Know

Practitioners who prescribe MAT while working in general medical facilities, such as community health centers (CHCs) and federally qualified health centers (FQHCs), need to follow the Part 2¹ privacy rule if:

- they work in an identified substance use disorder (SUD) unit of the general medical facility that holds itself out as providing SUD services, **or**
- their primary function consists of providing SUD services, and is identified as such.

Many, if not most, practitioners in general medical facilities do not meet these criteria, and therefore **do not** need to follow Part 2, even if they have received a **DATA-2000** waiver and prescribe buprenorphine. They should continue applying their general privacy practices in compliance with HIPAA and applicable state law when providing care.

A DATA-2000 waiver permits physicians who meet certain qualifications to treat opioid dependency with narcotic medications approved by the Food and Drug Administration (FDA)—including buprenorphine—in treatment settings other than OTPs.

NOTE: Even physicians who are not subject to Part 2 will need to protect information they receive from Part 2 programs.²



Additional Background Information

Here are 5 Common Questions That Providers Often Have....

1. Who must follow Part 2?

Part 2 applies to individuals and entities that are:

- ① federally assisted, **and**
- ② meet the definition of a “program,” 42 CFR § 2.11.

2. If a physician has a DATA-2000 waiver to prescribe buprenorphine, does Part 2 apply?

Physicians in general medical facilities, such as FQHCs and CHCs, and who receive a DATA-2000 waiver to prescribe buprenorphine, are considered federally assisted because of their waiver from the federal government.³

However, they will only be considered a “program” covered by Part 2 if:

- ① They work in the identified SUD unit of the general medical facility, which holds itself out as providing SUD services; or
- ② Their primary function is providing SUD diagnosis, treatment, or referral for treatment, and they are identified as such.

3. What does it mean that a practitioner’s “primary function” is providing SUD diagnosis, treatment, or referral for treatment?

SAMHSA and the Office of the National Coordinator (ONC) recently issued guidance clarifying the meaning of “primary function” for doctors practicing in FQHCs: *Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me?* (SAMHSA & ONC, 2018). Examples are provided below.

4. What does it mean to be “identified as” having the primary function of providing SUD services?

While there is no concrete definition, the SAMHSA/ONC guidance indicates that a provider who is “recognized as the facility’s lead SUD physician” is considered to be “identified” as a provider of SUD services.⁴

5. If a practitioner puts their name on the SAMHSA Buprenorphine Treatment Locator, does Part 2 apply?

For the reasons described above, inclusion on the **SAMHSA Buprenorphine Practitioner Locator** or any other public listing of physicians who prescribe buprenorphine does not necessarily mean that the physician must follow Part 2. Physicians practicing in FQHCs and other general medical facilities are only subject to Part 2 if the physician practices within an identified SUD unit, or the SUD services comprise the physician’s primary function and they are identified as providing such services.

SAMHSA Buprenorphine Treatment Locator. It could have the link below and say “The SAMHSA Buprenorphine Practitioner Locator helps identify nearby practitioners authorized to treat opioid dependency with buprenorphine.”
<https://www.samhsa.gov/medication-assisted-treatment/practitioner-program-data/treatment-practitioner-locator>



Case Examples from SAMHSA/ONC⁵

What are some examples of providers whose “primary function” is and is not SUD services?

Example of provider whose primary function is not SUD services

Dr. Pierce is a provider at Blue Mountain [a healthcare group that serves patients in an integrated care setting] and provides healthcare services to a diverse group of patients. Occasionally, Dr. Pierce encounters patients with an opioid dependency and provides MAT with buprenorphine. However, he does this only for a handful of patients and do not constitute his primary function at Blue Mountain.

IS DR. PIERCE COVERED? DOES PART 2 APPLY?

Dr. Pierce is federally assisted because he is registered with the DEA to prescribe controlled substances for the treatment of OUD and has received a physician waiver from SAMHSA to prescribe buprenorphine. However, Dr. Pierce practices at a general medical facility where his primary function is not providing diagnosis, treatment, or referral for treatment for a SUD. Therefore, Dr. Pierce does not meet the definition of a Part 2 Program and will follow HIPAA regulations when providing MAT services to his patients.

Example of provider whose primary function is SUD services

Dr. Tyler, an addiction specialist at Acme [a community mental health center], only treats patients with SUDs. Typically, Dr. Tyler uses controlled substances for detoxification or maintenance treatment of a patient’s SUD.

IS ACME COVERED? DOES PART 2 APPLY?

Yes. Dr. Tyler meets the definition of a Part 2 Program because Dr. Tyler works at a general medical facility where her primary function is to diagnose, treat, or refer for treatment patients with SUDs. Additionally, Dr. Tyler is considered federally assisted because she is registered with the DEA to prescribe controlled substances for detoxification or maintenance treatment of a SUD. Therefore, Dr. Tyler is considered a Part 2 Program.

 **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, [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.

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References

- 1 See also 42 U.S.C. § 290dd-2 (the authorizing statute for the regulations at 42 CFR Part 2). For more information about the federal confidentiality protections for substance use disorder patient records, visit the Center of Excellence for Protected Health Information.
- 2 Part 2 also applies to certain recipients of SUD patient records, who are termed "lawful holders" of Part 2-protected records. See Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052, 6068 (Jan. 18, 2017) ("A 'lawful holder' of patient identifying information is an individual or entity who has received such information as the result of a part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as permitted under the part 2 statute, regulations, or guidance and, therefore, is bound by 42 CFR part 2."), available at <https://www.federalregister.gov/d/2017-00719/p-364>.
- 3 See page 7 of Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me? (SAMHSA & ONC, 2018), available at <https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>.
- 4 See *id.* at 6. Note that SAMHSA has not otherwise defined or issued guidance about which types of activities may "identify" an individual provider or an entire unit within the facility as a provider of SUD services.
- 5 Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me? (SAMHSA & ONC, 2018), available at <https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>.