

## PRESCRIBING BUPRENORPHINE IN A GENERAL MEDICAL FACILITY: DOES 42 CFR PART 2 APPLY TO ME?

Physicians who prescribe buprenorphine sometimes think they are subject to the heightened confidentiality protections for substance use disorder (SUD) records, when in fact they are not.

This document explains when a physician who prescribes buprenorphine for opioid use disorder in a general medical facility, such as a federally qualified health center (FQHC) or community health clinic (CHC), becomes subject to the federal confidentiality protections for SUD patient records, 42 CFR Part 2 (referred to as “Part 2” in this document).<sup>i</sup>

### QUESTION:

**“I’m a primary care physician working in an FQHC.  
I recently received the DATA-2000 waiver to prescribe buprenorphine.  
I know that I must follow HIPAA with all my patients.  
Do I also have to follow Part 2 now that I am prescribing buprenorphine?”**

### ANSWER:

As a primary care physician working in an FQHC and prescribing buprenorphine, you do not need to follow Part 2, *unless* –

- You work in an identified SUD unit of the FQHC, *or*
- Your primary function consists of providing SUD services, and you are identified as such.

Many, if not most, physicians in FQHCs do not meet these requirements, and therefore do *not* need to follow Part 2, even if they have received the 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.

### WHY?

#### 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](#).<sup>ii</sup>

**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.<sup>iii</sup> However, they will only be considered a “program” covered by Part 2 if:

1. They work in the identified SUD unit; *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 physician’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 in question 5 below.

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

While SAMHSA has not offered a 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.<sup>iv</sup>

**5. 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.

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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.

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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.

**6. If a physician puts his or her name on the SAMHSA Buprenorphine Treatment Locator, does Part 2 apply?**

For the reasons described above, inclusion on the SAMHSA Buprenorphine Treatment Locator or any other public listing of physicians who prescribe buprenorphine does not in and of itself subject the physician to Part 2. Physicians practicing in FQHCs and other general medical facilities only are subject to Part 2 if the physician practices within an identified SUD unit, or the SUD services comprise the physician's primary function and he or she is identified as providing such services.

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

**For additional RESOURCES:**

**The resources cited in this technical assistance are also available among the Center of Excellence for Protected Health Information's [resource library](#). Please consider [signing up for updates](#) regarding the Center of Excellence for Protected Health Information, including news about the publication of new resources and training opportunities addressing federal privacy protections for SUD and mental health records.**

*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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*policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, organizations imply endorsement by the U.S. Government.*

<sup>i</sup> 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](#).

<sup>ii</sup> 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>.

<sup>iii</sup> See page 7, [Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me?](#) (SAMHSA & ONC, 2018).

<sup>iv</sup> See page 6, [Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me?](#) (SAMHSA & ONC, 2018). 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.

<sup>v</sup> Physicians who receive Part 2-protected records are “lawful holders” and must comply with Part 2’s privacy rules with respect to those Part 2-protected records. See note ii, *supra*.