



August 21, 2019

Dear Dr. Costello:

Thank you for reaching out to the Center of Excellence for Protected Health Information (CoE-PHI) to request Technical Assistance related to federal privacy law. The CoE-PHI is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) to improve provider communication, treatment access, and quality of care for people receiving care for substance use disorder (SUD) and/or mental health (MH). The CoE-PHI is a partnership between Cicatelli Associates Inc. (CAI) and the Legal Action Center (LAC).

In response to your request dated July 25, 2019, regarding the application of 42 CFR Part 2 to Licensed or Certified Alcohol and Drug Counselors, we have prepared the enclosed resource. We look forward to your thoughts on this resource, and whether any additional information would be useful in implementing the information contained in this written Technical Assistance.

Sincerely,
The CoE-PHI Team



When does 42 CFR Part 2 apply to SUD services in primary care settings?

QUESTION: I'm a Licensed Alcohol and Drug Counselor working in an FQHC. Do I have to follow 42 CFR Part 2?

ANSWER: Licensed Alcohol and Drug Counselors (“LADC”) are required to follow 42 CFR Part 2 (“Part 2”) if the LADC meets the definition of a “Part 2 Program.” 42 CFR § 2.11. The following explains when a licensed alcohol and drug counselor or other person who performs SUD diagnosis, treatment, or referral for treatment in a general medical facility, such as a federally qualified health center (FQHC) or community health clinic (CHC), becomes a “Part 2 program.”ⁱ

Discussion

As a provider in an FQHC that delivers SUD diagnosis, treatment or referral, you need to follow Part 2, *if*

- 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.

Even when providers do not meet the definition of a Part 2 Program, 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](#).ⁱⁱ

2. What does it mean to be “federally assisted?”

Medical personnel and other staff in general medical facilities such as FQHCs and CHCs are “federally assisted” if they or their agency are a certified Medicare/Medicaid provider, receive funds from a federal agency (including through

ⁱ 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 [Center of Excellence for Protected Health Information](#).

ⁱⁱ 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>.



state block grants for SUD services), and additional activities listed in 42 CFR § 2.12(b). However, they will only be considered a “program” covered by Part 2 if:

- They work in the identified SUD unit; or
- 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 provider’s “primary function” is providing SUD diagnosis, treatment, or referral for treatment?

There is no official definition, but recent guidance from SAMHSA and the Office of the National Coordinator (ONC) offers some guideposts: [Disclosure of Substance Use Disorder Patient Records: Does 42 CFR Part 2 Apply to Me?](#) (SAMHSA & ONC, 2018).ⁱⁱⁱ

- The *occasional* prescribing of medication to treat OUDs to a *handful* of patients would not meet the threshold of primary function
- *Only* treating patients with SUDs would meet the threshold of primary function.
 - 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.^{iv}

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.

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

^{iv} 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.



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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.

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

^v 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.



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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