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42 CFR Part 2 Compliance: Does it Apply to You?

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AGENDA

42 CFR Part 2: Webinar #1

1. Overview
2. Applicability
3. Case Studies

UPCOMING WEBINARS

42 CFR Part 2 Compliance Webinar Series:

Webinar #2: Patient Consent & Notice Requirements
(August 14, 2018)

Webinar #3: Disclosures Without Patient Consent
(August 16, 2018)

QUESTIONS

Today's webinar will address the following questions:

- **What information is protected under Part 2?**
- **Must my organization comply with Part 2? Does my organization operate a Part 2 program?**

The upcoming webinars will address the following questions:

- **What are the required elements for a Part 2 disclosure form?**
- **My organization participates in a health information exchange. Are there applicable Part 2 requirements?**
- **What are the Part 2 Programs requirements for disclosing patient information to auditors, contractors or vendors and law enforcement and/or courts?**

1. Overview



DISCLOSURE: GENERAL RULE

- **General Rule:** Information that identifies an individual as a patient of a Part 2 program is confidential and may not be disclosed without patient consent, unless an exception applies
 - Unlike HIPAA, *patient consent is required* even for disclosures for the purposes of treatment, payment or health care operations
- **We will discuss the nuances of disclosures with and without patient consent during Webinars #2 and #3**

PART 2: BASICS

- **Statute:** 42 U.S.C. § 290dd-2
- **Regulations:** 42 CFR Part 2 (“Confidentiality of Substance Use Disorder Patient Records”)
- **Federal Agency:** Substance Abuse and Mental Health Services Administration (“SAMHSA”), of the U.S. Department of Health & Human Services (“HHS”)
- **Purpose:** Enacted to encourage people to seek and receive SUD treatment when needed and without stigma.

DEFINITIONS: 42 CFR § 2.11

Substance use disorder (SUD): A cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. Excludes tobacco or caffeine use.

Disclose: To communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person.

Records: Any information, whether recorded or not, created by, received, or acquired by a Part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts). Includes both paper and electronic records.

Patient identifying information: The name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy either directly or by reference to other information.

RELATIONSHIP TO STATE LAWS AND HIPAA

- **“Part 2” is a floor; not a ceiling**
- **State law may not authorize or compel any disclosure prohibited by Part 2**
- **State laws may, however, be more restrictive than those set forth in Part 2**
- **Some alignment between Part 2 and HIPAA, but in some instances Part 2 provides more stringent federal protections than those of HIPAA**



PART 2: IN THE NEWS

- **SAMHSA “Final Rule”**: First substantive revision to Part 2 regulations since 1987.
 - **Issued**: January 18, 2017
 - **Effective Date**: March 21, 2017
 - **Available at**:
 - 82 FR 6056
 - <https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00719.pdf>
 - **Purpose**: To modernize Part 2 “by facilitating electronic exchange of [SUD] information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having or having had a substance use disorder.”

PART 2: IN THE NEWS

SAMHSA's 2018 "Final Rule": Additional revisions proposed in NPRM in the 2017 Final Rule

- **Issued:** January 3, 2018
- **Effective Date:** February 2, 2018 (except for certain contracts)
- **Available at:**
 - 83 Fed. Reg. 239
 - <https://www.gpo.gov/fdsys/pkg/FR-2018-01-03/pdf/2017-28400.pdf>
- **Purpose:** Allows for an abbreviated notice on redisclosure and addresses the circumstances under which "lawful holders" and their legal representatives, contractors, and subcontractors may use and disclose patient identifying information for purposes of payment, health care operations, and audits and evaluations

PART 2: IN THE NEWS

- **Funding Opportunities:**

- June 2018: SAMHSA announced award of \$930 million in State Opioid Response Grants
- Sept 2017: HRSA announced award of \$200 million in supplemental funds to health centers nationwide to tackle mental health and opioid overdose crisis
- **Accordingly, imperative to know whether “Part 2” applies to your organization and what it means**



See HRSA Press Release:

<https://www.hhs.gov/about/news/2017/09/14/hrsa-awards-200-million-to-health-centers-nationwide.html>

ENFORCEMENT

- **Criminal penalty for violation:**
 - Any person who violates any provision of Part 2 is subject to fine in accordance with Title 18 of the U.S. Code
- **Reports of violations:**
 - Reports of any violation of Part 2 may be directed to U.S. Attorney for judicial district in which violation occurs
 - Reports of any violation of Part 2 by an opioid treatment program may be directed to U.S. Attorney for judicial district in which violation occurs, as well as the SAMHSA office responsible for opioid treatment program oversight

See 42 CFR §§ 2.3-2.4

2. Applicability



42 CFR PART 2: APPLICABILITY

Part 2 applies to:

- 1. Federally assisted Part 2 programs**
- 2. Lawful holders of Part 2 protected information**

APPLICABILITY



APPLICABILITY: FEDERALLY ASSISTED

- **Conducted (in whole or in part) by federal government**
- **Supported by federal funding**
 - Includes federal block grants or other funds channeled through state or local governments (e.g., Medicaid)
 - Funding does not need to be for SUD services
- **Carried out under federal license, certification, registration or authorization**
 - Certification of provider status under the Medicare program
 - Authorization to conduct methadone maintenance treatment
 - Registration to dispense a substance under the CSA to the extent the controlled substance is used in the treatment of substance use disorders
- **Receives tax exempt status from the IRS**

See 42 CFR § 2.12(b)

APPLICABILITY: PROGRAM

1. An individual or entity (**other than a general medical care facility**) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment
2. An **identified unit within a general medical facility** which **holds itself out** as providing and provides, substance use disorder diagnosis, treatment, or referral for treatment
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

See 42 CFR § 2.11

APPLICABILITY: PROGRAM

1. An individual or entity (other than a **general medical care facility**) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment

See 42 CFR § 2.11

APPLICABILITY: PROGRAM

“General medical facility”: This term is not defined in the current regulations; however, SAMHSA has stated in prior guidance and reaffirmed in comments to the 2017 Final Rule that federally qualified health centers are generally considered “general medical facilities.” Other examples of “general medical facilities” include hospitals and trauma centers.

See 82 Fed. Reg. 6066

APPLICABILITY: PROGRAM

2. An *identified unit within a general medical facility* which *holds itself out* as providing and provides, substance use disorder diagnosis, treatment, or referral for treatment

APPLICABILITY: PROGRAM

“Holds itself out”: SAMHSA did not define “holds itself out” in the current regulations; however, in comments to the 2017 Final Rule SAMHSA stated that the phrase “means any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment or referral for treatment, including but not limited to:

- Authorization by the state or federal government (e.g., licensed, certified, registered) to provide, and provides, such services;
- Advertisements, notices or statements relative to such services; or
- Consultation activities relative to such services.”

See 82 Fed. Reg. 6066

APPLICABILITY: PROGRAM

3. ***Medical personnel or other staff in a general medical facility*** whose ***primary function*** is the provision of substance use disorder diagnosis, treatment or ***who are identified as such*** providers

APPLICABILITY: PROGRAM

“Primary function”: SAMHSA did not define “primary function” in the current regulations; however, in comments to the 2017 Final Rule SAMHSA stated that it “did not propose a definition of ‘primary function’ because it has not historically received many, if any, questions on its meaning.”

See 82 Fed. Reg. 6066

APPLICABILITY: PROGRAM

“Identified as such”: In the comments to 2017 Final Rule SAMHSA stated that “the medical personnel or other staff must be identified as such specialized medical personnel or other staff *by the general medical facility.*” (emphasis added)

See 82 Fed. Reg. 6071

APPLICABILITY: PART 2 PROGRAM



APPLICABILITY: LAWFUL HOLDER

- Restrictions on disclosure apply to:
 - Individuals or entities who receive patient records directly from a Part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on re-disclosure in accordance with § 2.32.

See 42 CFR § 2.12 (d)(2)(i)(C)

APPLICABILITY: LAWFUL HOLDER

“Lawful holder”: SAMHSA did not define “lawful holder” in the current regulations; however, in comments to the 2017 Final Rule SAMHSA stated that 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.

- SAMHSA stated that it was not feasible to define all lawful holders but provided the following examples: a patient's treating provider, a hospital emergency room, an insurance company, an individual or entity performing an audit or evaluation, or an individual or entity conducting scientific research.

See 82 Fed. Reg. 6068

CASE STUDY #1

ABC Health Center has six sites, including Fairview Clinic which provides Medication-Assisted Treatment (MAT). Other ABC Health Center providers regularly refer their patients in need of SUD services to the Fairview Clinic. The Fairview Clinic is certified and accredited as an opioid treatment program by SAMHSA.

Does ABC Health Center operate a Part 2 program?

CASE STUDY #1

Yes, the Fairview Clinic is a Part 2 program.

- ABC is federally assisted (e.g., FQHC designation).
- ABC is a general medical facility. The Fairview Clinic is an identified unit within ABC Health Center that holds itself out (e.g., through federal certification and accreditation) as providing and provides SUD treatment services.

CASE STUDY #2

Community Health Center, Inc. (CHC) recently applied for and received federal grant funding to hire an LCSW whose primary responsibility will be to provide SUD counseling and referral. The job description for this new position states that the LCSW will primarily provide SUD services. The LCSW will work at CHC's main clinical site, which primarily furnishes primary care services.

Will adding the LCSW mean that CHC operates a Part 2 program?

CASE STUDY #2

Yes, adding the LCSW will mean that CHC operates a Part 2 program.

- CHC is federally assisted (e.g., FQHC designation).
- CHC Inc. meets the definition of a program because it is a general medical facility that employs personnel whose primary function is for the provision of diagnosis, treatment, or referral for treatment of patients with SUDs. The job description identifies that the LCSW is providing SUD services.

CASE STUDY #3

CHC has a patient, Mary Jones, who receives SUD services from the LCSW. Ms. Jones also receives dental services from CHC.

Are Ms. Jones's dental records protected under Part 2?

CASE STUDY #3

- No, the patient's dental records are not protected by Part 2.
- Part 2 protects patient information generated within the Part 2 program. The dental department is outside of CHC's Part 2 program which includes the SUD services provided by the LCSW.
 - In addition, for purposes of the next webinar, note that Part 2 only protects information identifying a patient as being or having been diagnosed with a SUD, having or having had a SUD, or being or having been referred for treatment of a SUD either directly, by reference to publicly available information, or through verification of such identification by another person.

CASE STUDY #4

Neighborhood Health Center is also expanding access to SUD counseling services in its community. Such counseling services are incorporated into primary care visits. Each care team will administer SBIRT and provide counseling as appropriate. Neighborhood Health Center doesn't have any particular site or staff members whose primary function is providing SUD services. Neighborhood Health Center advertises on its website that its scope of services now includes substance use disorder screening and counseling.

Does Neighborhood Health Center operate a Part 2 program?

CASE STUDY #4

No, Neighborhood Health Center does not operate a Part 2 program.

- Neighborhood Health Center is federally-assisted (e.g., FQHC designation).
- Neighborhood Health Center holds itself out as providing SUD services, but does not have (1) an “identified unit” that provides SUD diagnosis, treatment, or referral for treatment or (2) medical personnel or other staff whose primary function is the provision of SUD diagnosis, treatment or referral for treatment.

CASE STUDY #5

Integrated Health, Inc. (IHI) is a community health center that treats the whole person in an integrated care setting. Although IHI does not advertise that it provides SUD treatment services, its physicians have received waivers from SAMHSA to prescribe buprenorphine for the treatment of opioid use disorders.

The physicians at IHI treat a diverse group of patients. Occasionally, the physicians encounter patients with an opioid dependency and provide MAT with buprenorphine. However, the physicians do this only for a handful of patients.

Does IHI operate a Part 2 program?

CASE STUDY #5

No, IHI does not operate a Part 2 program.

- IHI is federally assisted (e.g., FQHC designation).
- IHI physicians are registered with the DEA to prescribe controlled substances for the treatment of SUDs and have received a physician waiver from SAMHSA to prescribe buprenorphine. However, the physicians are at a general medical facility where their primary function is not providing diagnosis, treatment, or referral for treatment for a SUD.

Final Thoughts



FINAL THOUGHTS

- **Determine whether Part 2 applies to:**
 - Your organization's current or planned substance use disorder services (diagnosis, treatment or referral)
 - Records received by your organization
- **Document your analysis and conclusion**
- **As you develop additional substance use disorder services, determine whether Part 2 applies**
- **Join us for the next two webinars which will highlight key compliance requirements under Part 2**

QUESTIONS?

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