



DOES 42 CFR Part 2 APPLY TO MY PRACTICE?

Scenario 2 (Mixed Use Facility)

Does Part 2 Apply to Acme?

YES

- ✓ Dr. Tyler works at a general medical facility where her primary function is for the provision of diagnosis, treatment, or referral for treatment of 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.



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Can Acme Disclose PHI?

Relating to SUD: Dr Tyler needs to obtain Brenda's consent to disclose information that would identify her as a patient with a SUD.

This includes disclosures to other providers at Acme (**which includes necessary medical personnel**).

If Brenda's SUD patient records are available to other providers at Acme through the facility's EHR system, Brenda's consent form must name Acme or individual providers at Acme if she wants to share her records with them.

The consent form would need to comply with all of the requirements specified in Part 2 (i.e., identify the SUD information in the Amount and Kind section, identify the purpose of the disclosure, etc.).

Brenda's information would also need to be accompanied by a notice of prohibition on re-disclosure.



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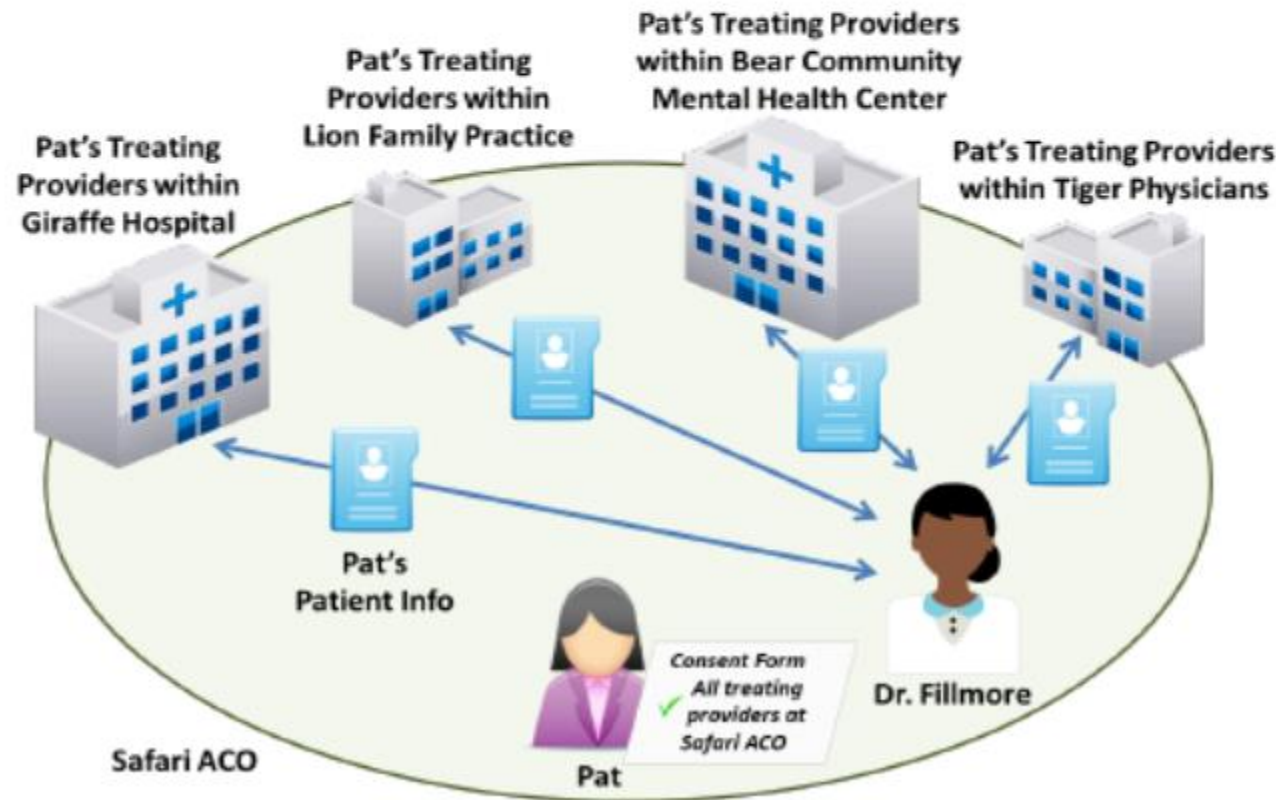
NOTE

Part 2 permits providers at Acme to acknowledge that Brenda is a patient at Acme without her consent. Because Acme is a mixed-use facility that provides services other than diagnosis, treatment, or referral for treatment for a SUD, acknowledging the presence of a patient at Acme would not necessarily identify that patient as having or having had a SUD. However, Acme providers could not disclose that Brenda is a patient of a Part 2 Program (e.g., that Brenda is a patient of Dr. Tyler) without her consent because that would identify her as having or having had a SUD.



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SCENARIO 3: ACCOUNTABLE CARE ORGANIZATION (ACO)





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Scenario 3 (ACO)

Safari ACO includes Lion Family Practice (Lions), Tiger Physicians Group (Tigers), Giraffe Hospital (Giraffes), and Bear Community Mental Health Center (Bears).

Dr. Fillmore works at Bears, a mixed-use facility. She is recognized as the facility's lead SUD physician and primarily treats patients with SUDs.

Dr. Fillmore often prescribes controlled substances for detoxification or maintenance treatment to his patients, including Pat.



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Scenario 3 (ACO)

Can Dr. Fillmore disclose PHI to Pat's other providers in the ACO?

Dr. Fillmore would need Part 2 consent to disclose information about Pat's treatment for a SUD to any other of her treating providers from Lions, Tigers, Giraffes, or Bears.

Pat's information would also need to be accompanied by a notice of prohibition on re-disclosure rather than naming each of her treating providers on the consent form, Pat could name Safari ACO and use a general designation (e.g. "all of my treating providers").

If Pat used a general designation, the consent form must include a statement indicating that, upon request, Pat is entitled to receive a list of all entities that have received her information under the general designation.



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Scenario 4 (Integrated Care Setting)

Blue Mountain Physician Group is a group of providers that treats the whole person in an integrated care setting.

Although Blue Mountain 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.



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Scenario 4 (Integrated Care Setting)

- ✓ Dr. Pierce is a provider at Blue Mountain and treats 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 such services do not constitute his primary function at Blue Mountain.



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Scenario 4 (Integrated Care Setting)

- ✓ One of his patients, Brooke, came to see him for a respiratory infection.
- ✓ Brooke had previously received treatment for an OUD at an inpatient treatment facility not affiliated with Blue Mountain but recently relapsed.
- ✓ When Dr. Pierce saw Brooke for the respiratory infection, she mentioned that she was experiencing withdrawal symptoms from opioid use.
- ✓ Dr. Pierce prescribed an antibiotic for the infection and started MAT with buprenorphine.



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Scenario 4 (Integrated Care Setting)

Does Part 2 Apply?

NO

Dr. Pierce is federally assisted because he's 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.



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Scenario 4 (Integrated Care Setting)

Can Dr. Pierce disclose PHI?

In this case, Dr. Pierce is not a Part 2 Program and therefore is not subject to the disclosure restrictions of Part 2. However, before he discloses Brooke's information, Dr. Pierce still needs to consider privacy requirements under HIPAA and state privacy laws.



VS





SAMHSA vs HIPAA

The HIPAA regulations say that a patient's medical records, or Protected Health Information (PHI), may not be released by the patient's healthcare provider except under the following circumstances:

- Submitting claims to the patient's health plan
- Coordinating benefits with health plans
- Communicating with health plans to confirm coverage and eligibility, or check on the status of claims
- Obtaining referral certification and authorizations from the patient's health plan
- Medical emergencies or when necessary for additional medical treatment
- When the provider believes it is in the patient's best interest to share information with another provider



SAMHSA vs HIPAA

The 42 CFR Part 2 (SAMHSA) regulations have adopted the HIPAA privacy rules but also add additional protections and restrictions on what may be disclosed relating to substance abuse records which federally assisted programs maintain.

Providers must adhere to both HIPAA and 42 CFR Part 2 regulations to remain fully in compliance



SAMHSA vs HIPAA

SAMSHA is a little like HIPAA on Steroids





SAMHSA vs HIPAA

Disclosures without consent:

While the HIPAA regulations permit the release of patient information without consent for purposes of treatment or payment, SAMHSA is much more restrictive. There are only limited exceptions, such as for medical emergencies or for provider audits and evaluations, when information can be disclosed without patient consent.

Some types of data exchanges can take place without patient authorization as long as patient data is shared only under a qualified service organization agreement (QSOA), or when exchange takes place between a program covered under Part 2 and an organization that controls that program.



SAMHSA vs HIPAA

Disclosures without consent (continued):

A qualified service organization (QSO) is:

NOTE: New Mexico's Health Information Exchange (HIE) is a Qualified Service Organization (QSO) – SYNCRONYS is also an HIE

- A provider or organization that provides services to a Part 2 program, such as data processing; bill collecting; dosage preparation; laboratory analyses; or legal, medical, accounting, or other professional services.
- Has a written agreement with a Part 2 program that says the QSO will adhere to regulations whenever it receives, store, processes or deals with those records in any way.
- The QSO must also agree to resist any attempt to attain patient records through judicial proceedings except as the Part 2 regulations permit



WHAT HAS CHANGED?





WHAT HAS CHANGED?

Part 2 regulations serve to protect patient records created by federally assisted programs for the treatment of substance use disorders (SUD).

These revisions further facilitate better coordination of care in response to the opioid epidemic while maintaining confidentiality protections against unauthorized disclosure.



WHAT HAS CHANGED?

Applicability and Re-Disclosure

Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated.

Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.