



Behavioral Health IT Summer Webinar Series

42 CFR Part 2: Myths & Scenarios

Kate Tipping, JD, Public Health Advisor
Deborah Reid, JD, Senior Health Policy Attorney, Legal Action Center
Katie O'Neill, JD, Consultant, Legal Action Center



SAMHSA
1 Choke Cherry Road
Rockville, Maryland 20857



Housekeeping

- Webinar being recorded
- All lines muted
- Send questions using “Questions” box in control pane
- Q&A session at the end



Purpose and Learning Objectives



- Become more knowledgeable about the legal implications of HIPAA Privacy Rule and 42 CFR Part 2
- Review mechanisms to work with 42 CFR Part 2 to share information between providers
- Understand how the electronic health records environment impacts compliance with 42 CFR Part 2

Note: This webinar is for information purposes only and is not intended as legal advice. Specific questions regarding federal law should be referred to your legal counsel.

Presenters



Kate Tipping, JD
SAMHSA



Deborah Reid, JD,
Legal Action Center



Katie O'Neil, JD
Legal Action Center

About SAMHSA's Health IT Strategic Initiative



Goal: Widespread implementation of Health IT systems that support quality integrated behavioral health care for all Americans

- Ensure that behavioral health provider networks fully participate in the adoption of Health IT and interoperable electronic health records (EHRs)
- Support the behavioral health aspects of Health IT based on the standards and systems promoted by the Office of the National Coordinator for Health IT (ONC)
- Support linkage with systems relevant to behavioral health that support prevention, treatment, wellness, and recovery

The Legal Framework: Federal Health Privacy Laws

Two Federal Laws

- HIPAA: Health Insurance Portability and Accountability Act, specifically the HIPAA Privacy and Security Rules
- Federal law and regulations protecting confidentiality of alcohol and drug treatment and prevention information: 42 U.S.C. § 290dd-2, and 42 CFR Part 2



The Legal Framework: State Laws



Many State Laws

- Many state laws protect “sensitive” health information, including mental health information, HIV/AIDS and other health conditions deemed sensitive under state law.

Communication Strategies

- Communication strategies among providers, insurers, and government agencies must be developed with these federal and state laws in mind.

Confidentiality: Federal Health Privacy Law Framework

Protecting the confidentiality of people receiving substance use disorder (SUD) treatment must be balanced with the ability to share information amongst physical health and SUD providers

Patient
Confidentiality



Information
Sharing among
Providers

HIPAA Privacy Rule and 42 CFR Part 2 Basics



HIPAA in Brief



HIPAA = The Health Insurance Portability and Accountability Act of 1996

The HIPAA Privacy Rule establishes a “floor” or minimum to protect the privacy of protected health information (PHI) about individuals

- Applies to PHI no matter how it is shared (electronic, written, or oral)
- The Security Rule only pertains to electronic PHI
- Also establishes patient rights to access and amend their information

What is 42 CFR Part 2?

42 CFR Part 2 are **regulations** that implement **Federal law (42 USC § 290dd-2)** that protect the confidentiality of substance abuse records of any person who has applied for or been given a diagnosis or treatment for alcohol or drug abuse at a federally assisted program.



What is the Purpose of 42 CFR Part 2?

- Encourage people to seek treatment without fear that by doing so their privacy would be compromised
- Sharing of alcohol and drug patient information can lead to:
 - ✓ Negative perceptions and discrimination
 - ✓ Criminal legal consequences
 - ✓ Civil legal consequences:
 - **Loss of child custody**
 - **Loss of employment**
 - **Loss of housing**

Who is Covered Under 42 CFR Part 2?

Drug and alcohol treatment **programs** that are **federally-assisted** *must follow* 42 CFR Part 2



Quick HIPAA–42 CFR Part 2 Comparison



- 42 CFR Part 2 has been around much longer
- HIPAA Privacy Rule offers a floor of protection—42 CFR Part 2 is more protective of privacy
- HIPAA Privacy Rule does not require patient authorization to disclose information for treatment, payment, or health care operations—**42 CFR Part 2 *does* require consent**
- When health care providers are covered by both HIPAA Privacy Rule and Part 2, they must follow both; when they are different, providers must follow whichever one gives patients more privacy protections

Part 2 and Disclosure: The General Rule

Disclosure of information that identifies a patient (directly or indirectly) as having a current or past drug or alcohol problem (or as participating in a drug or alcohol program) is generally prohibited.

Unless:

- The patient consents in writing, or
- Another (limited) exception applies

Part 2: Impact of Adoption of EHRs and HIEs



- Historically, with paper records, Part 2 programs had nearly exclusive access to information. These programs were knowledgeable about the protections under 42 CFR Part 2.
- Adoption of EHRs and Health Information Exchanges (HIE) increases the risk of inappropriate disclosure of records:
 - ✓ Expands the universe of people who have access to these records
 - ✓ Many of the providers who now have access are not familiar with the restrictions placed on disclosure under 42 CFR Part 2

Part 2: Impact of Adoption of EHRs and HIEs



Regardless of the type of EHR system in place, providers must be mindful of the requirements of 42 CFR Part 2 when including alcohol and drug patient records.

PHI can flow a number of ways through Health IT:

- From provider EHR to HIE
- A provider can store EHR data in an outside system (“in the cloud”) and should have appropriate agreements in place (BA and/or QSOA)
- Providers with EHRs can share information via health information exchange with client consent

Myth 1: Consent and Disclosure



Myth 1: Consent Requirements



Myth 1a: All disclosures require consent



Myth 1b: The Part 2 protections that restrict information-sharing—and particularly the consent requirement—pose a barrier to providing high-quality, coordinated, and integrated care to those with substance use disorders, including those covered by Medicaid

Myth 1: Sample Scenario



Betty, a patient at ABC drug treatment program, overdoses and lapses into a coma.

Question

- Can ABC drug treatment program disclose Betty's information to the emergency room (ER) of a local hospital so it can treat her overdose?
- If so, can the ER doctor inform Betty's family that she is in treatment at ABC drug treatment program?

Myth 1: Sample Scenario, Pg. 2

Answer

- (A) Yes, program ABC may disclose to the ER since this is a medical emergency; however, the ER cannot disclose to Betty's family that she is in treatment for a SUD.
- (B) Yes, program ABC may disclose to the ER since this is a medical emergency; and the ER can disclose to Betty's family that she is in treatment for a SUD.
- (C) No, program ABC may never disclose information protected by 42 CFR Part 2 unless Betty provides consent.



Myth 1 Debunked

Correct Answer

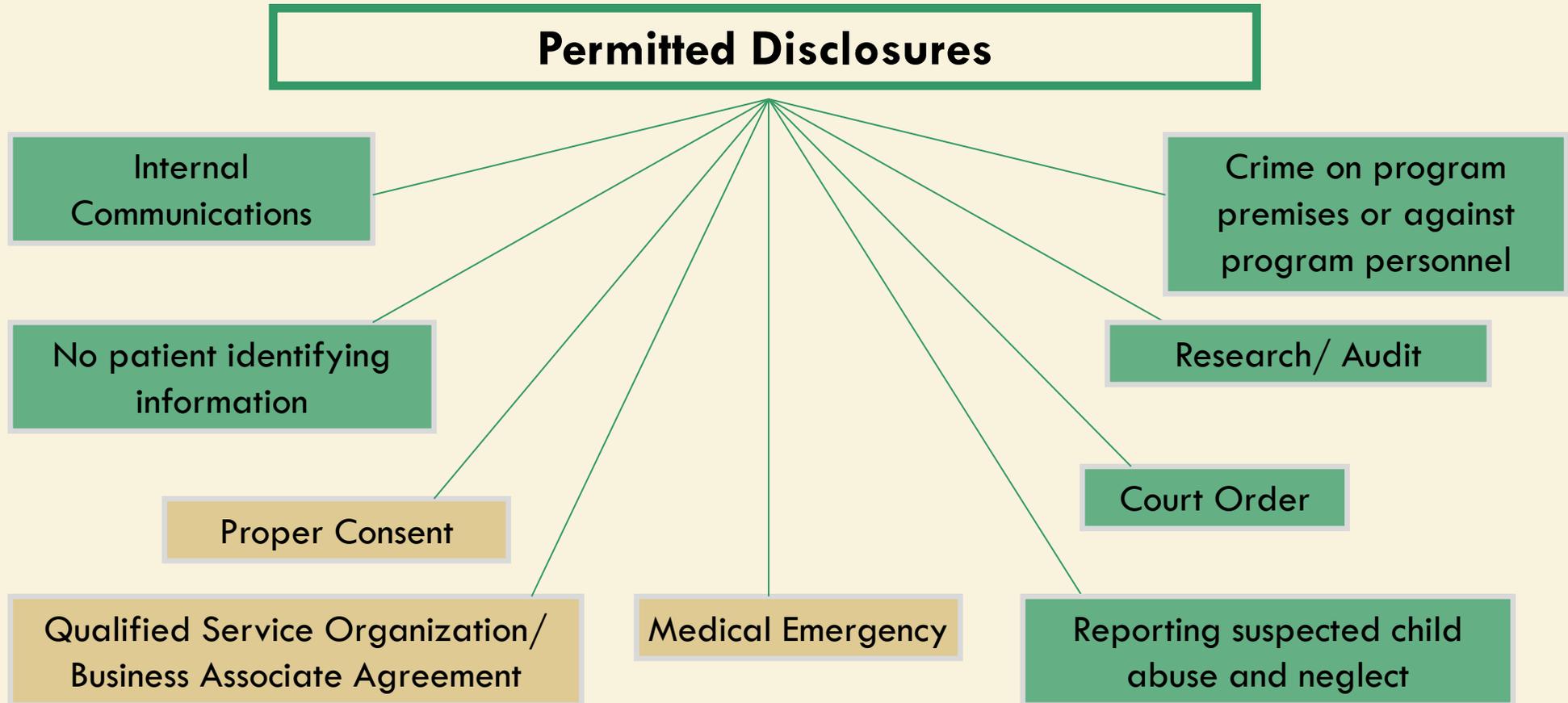
(B) Yes, program ABC may disclose to the ER since this is a medical emergency; and the ER can disclose to Betty's family that she is in treatment for a SUD.

Why is this Answer Correct?

- It is a medical emergency
- The ER may disclose to Betty's family, because once the info protected by Part 2 was disclosed to medical personnel, it lost its Part 2 protection and may be re-disclosed as permitted by HIPAA



42 CFR Part 2 and HIPAA Privacy Rule: Exceptions to General Rule



Mechanism for Disclosure 1: Written Consent

- Most disclosures are allowed if patient signed a **valid consent/ authorization form** that has not expired or been revoked
- The consent must adhere to **proper format** – otherwise it is NOT sufficient!
- HIPAA Privacy Rule: Provide patient with **copy** of authorization



Mechanism for Disclosure 1: Written Consent, Pg. 2



Part 2 requires that, whenever patient information is disclosed with consent, it must be accompanied by **Written Prohibition on Redisclosure** 42 CFR §2.32.

- Written statement indicates information disclosed is protected by federal law and that recipient may not disclose further unless permitted by the regulations
- This is true for verbal disclosures as well

Mechanism for Disclosure 2: QSOA

Can disclose without patient consent to certain outside organizations that provide services to the program or its patients through a **Qualified Service Organization Agreement (QSOA)**

- HIPAA Privacy Rule calls these organizations Business Associates (BAs)
- 42 CFR Part 2 calls these organizations Qualified Service Organizations (QSOs)

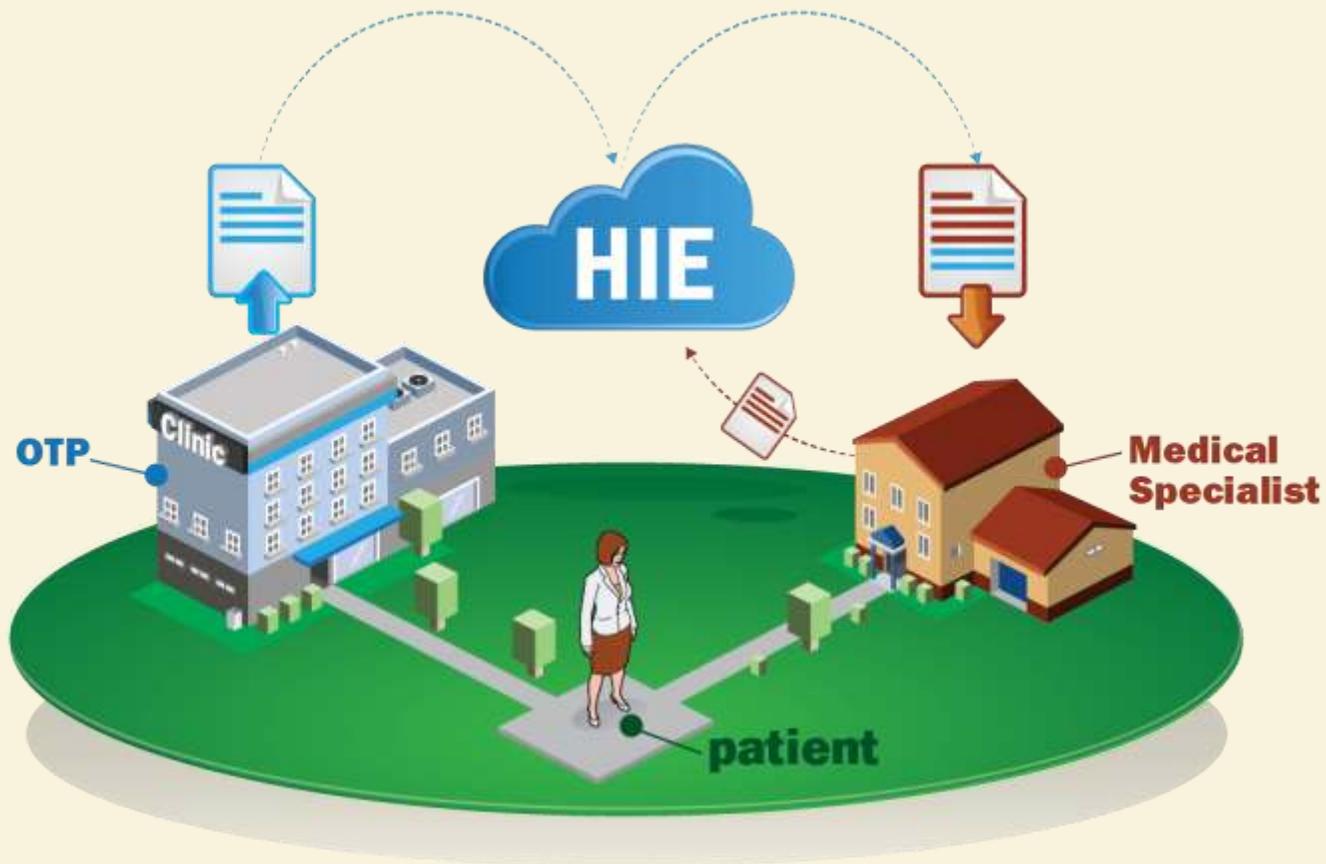


Mechanism for Disclosure 2: QSOA, Pg. 2

A QSO means a person or organization that:

- Provides services to a Part 2 program (e.g., data processing, dosage preparation, lab analyses, legal services)
- Has entered into a two-way written agreement with a Part 2 program that:
 - ✓ Authorizes communication of information between the two parties that is necessary for the QSO to perform its duties under the QSOA; and
 - ✓ Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the program, it is fully bound by the written regulations.

Myth 2: Sharing Data Electronically



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Myth: 42 CFR Part 2 does not allow Part 2-protected patient information to be included within HIE systems, or to be shared among HIE participants.

Myth 2: Sample Scenario



Dr. John, a physician in ABC Drug Treatment Program, needs to consult about his patient with a physician in another health care facility. Both Dr. John's program and the other health care provider are connected through the Michigan HIE and utilize the same electronic health record system.

Question

Can Dr. John share his patient's entire health record with the new provider, including Part 2 protected information?

Myth 2: Sample Scenario, Pg. 2

Answer

- (A) Yes, regulations permit the SUD patient's information to be shared among health care providers so long such sharing is authorized by a proper consent or QSOA.
- (B) Yes, but only anonymously—without revealing any personally-identifying information about the patient.
- (C) No, because protected health information cannot be shared electronically.



Myth 2 Debunked

Correct Answer:

(A) Yes, regulations permit the SUD patient's information to be shared among health care providers so long such sharing is authorized by a proper consent or QSOA.

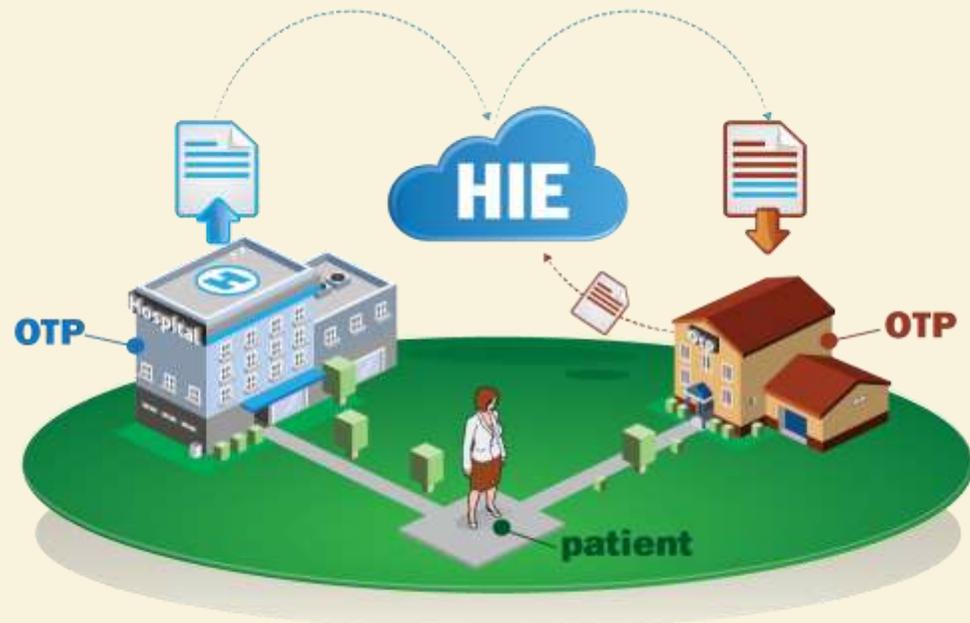


Myth 2: SAMHSA Health IT Solution

Consent2Share

- Data segmentation and consent management tool
- Supports information exchange
- Compliant with privacy and confidentiality regulations including 42 CFR Part 2

For more About Consent2Share
Click here: [Consent2Share](#)



Myth 3: Accessing Information



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Myth: No one outside the health system can access protected health information.



Myth 3: Sample Scenario



Sam, a patient in XYZ Drug Treatment Program, is involved in a major heroin distribution ring and has been distributing drugs to other patients on the program premises.

Question

Can Sam's program tell the police and release information to the prosecutor?

Myth 3: Sample Scenario, Pg. 2

Answer

- (A) No, because no one outside the health system can access protected health information
- (B) Yes, because both the HIPAA Privacy Rule and Part 2 allow a program to report patient crimes on its premises to law enforcement
- (C) Yes, but only anonymously – without revealing any patient-identifying information about Sam



Myth 3 Debunked

Correct Answer:

(B) Yes, because both the HIPAA Privacy Rule and Part 2 allow a program to report patient crimes on its premises to law enforcement



Why is this Answer Correct?

- It is permissible under the HIPAA Privacy Rule to disclose PHI for law enforcement purposes, (§164.512(f)(5), (6) and
- Part 2 permits covered programs to report to a law enforcement agency crimes on program premises or against program personnel, 42 CFR Part 2, (§ 2.12(C)(5)

Myth 3 Debunked

Facts About Disclosure Outside the Health System

HIPAA Privacy Rule permits disclosures for:

- Public health activities
- Victim of abuse or neglect
- Judicial/Administrative proceedings
- Law enforcement
- Threats to health or safety
- Court-ordered examinations
- Correctional facilities
- Through business associate agreements

42 CFR Part 2 permits disclosures:

- To other systems with patient consent or QSOA
- For public health research
- For child abuse reporting
- For crimes on premises or against staff
- For criminal justice system if treatment is made a condition of parole or release

42 CFR Part 2: Things to Remember

- Some of the ways in which a Part 2 “program” can include and share alcohol and drug records info in EHR systems include:
 - ✓ Written patient consent
 - ✓ Medical emergency exception
 - ✓ QSO Agreements
- These are the same ways alcohol and drug records protected by Part 2 can be integrated into EHR systems with providers not covered by Part 2.



42 CFR Part 2 Resources

[Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange \(2010\)](#)

Frequently asked questions issued by SAMSHA to clarify issues relating to the federal regulations governing the confidentiality of alcohol and drug information and electronic health information exchange.

[Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2 \(2011\)](#)

Frequently Asked Questions issued by SAMSHA to clarify issues relating to the federal regulations governing the confidentiality of alcohol and drug information—known as 42 CFR Part 2.

[The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule \(2004\)](#)

Guidance for treatment programs that are subject to and complying with Part 2 requirements.

[Confidentiality of Alcohol and Drug Records in the 21st Century \(2010\)](#)

Policy paper explaining Legal Action Center's vision for the confidentiality of substance use treatment records in the 21st century, including how health information technology and 42 CFR Part 2 work together.

Questions & Answers



Upcoming Webinar in the Summer Series!

Mark Your Calendars!

OTP Service Continuity Pilot: Initial Findings, Challenges and Solutions

Presented by: Dina Passman, SAMHSA and the Michiana Health Information Network

Tuesday, September 22
1:00 – 2:00 p.m. Eastern



Want to Learn More?



- Visit the SAMHSA website and Store at www.samhsa.gov
- Contact the SAMHSA Health IT team at samhsa.hit@samhsa.hhs.gov

Thanks!

