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IAP Medicaid Innovation Accelerator Program

Medicaid Innovation Accelerator Program (IAP)

Substance Use Disorders (SUD) Targeted Learning Opportunities (TLO)

TLO2: Integration of Primary Care and SUD Services

Session 1: Strategies for Sharing Information Consistent with 42 CFR Part 2 – 04/13/15

Presenters

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Agenda

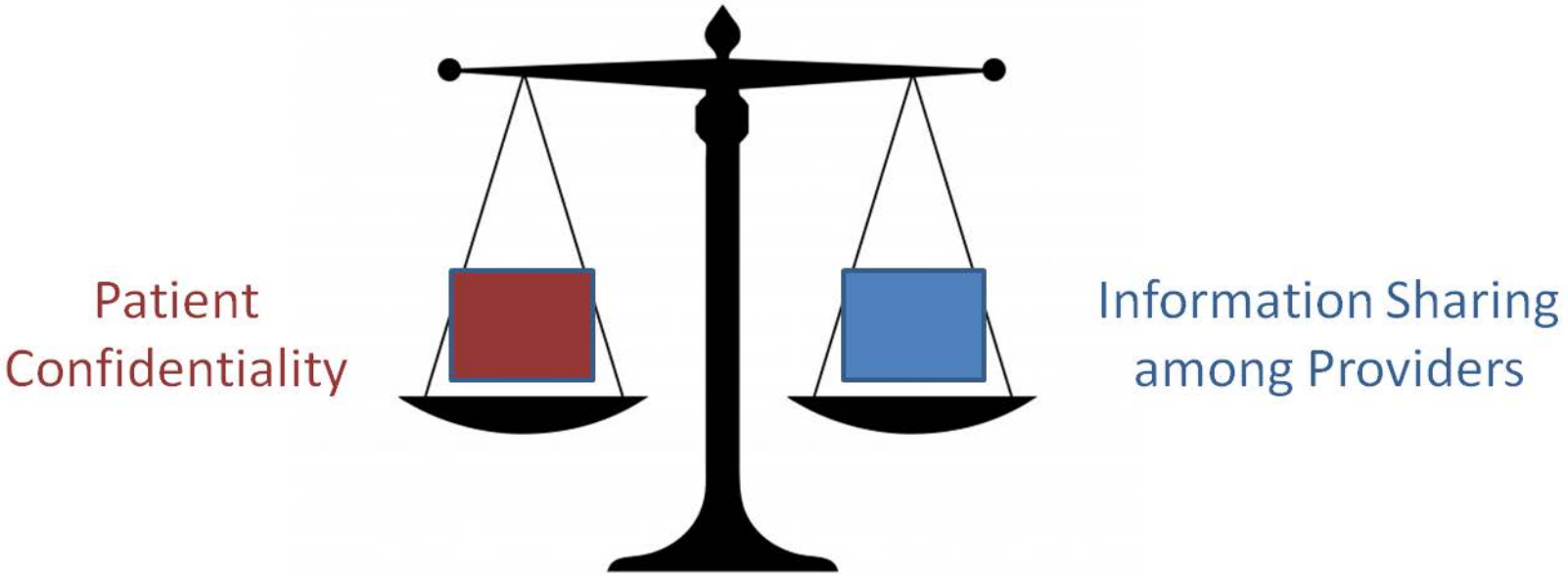
- Purpose and Learning Objectives
- Background and Overview of 42 CFR Part 2
- Mechanisms to work with 42 CFR Part 2 to Share Information Between Providers
- 42 CFR Part 2 and the Criminal Justice System
- Impact of EHR/HIE on 42 CFR Part 2
- Missouri Experience

Purpose and Learning Objectives

- Become more knowledgeable about the legal implications of 42 CFR Part 2
- Review avenues for working with the provider community to promote communication between SUD providers and primary care providers
- Review avenues for promoting communication between the criminal justice setting and SUD providers
- Understand how the electronic record environment impacts compliance with 42 CFR Part 2

Confidentiality – Federal Health Privacy Law framework

- Protecting confidentiality of people receiving SUD treatment must be balanced with the ability to share information amongst physical health and SUD providers



Federal (and State) Health Privacy Laws in Play

- Two federal laws:
  - HIPAA: Health Insurance Portability and Accountability Act, implemented by the HIPAA Privacy Rule
  - 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
- State laws protecting "sensitive" health information, including mental health information, HIV/AIDS and other health conditions deemed sensitive under state law
- Communication strategies among providers, insurers and government agencies must be built with these legal ground rules in mind

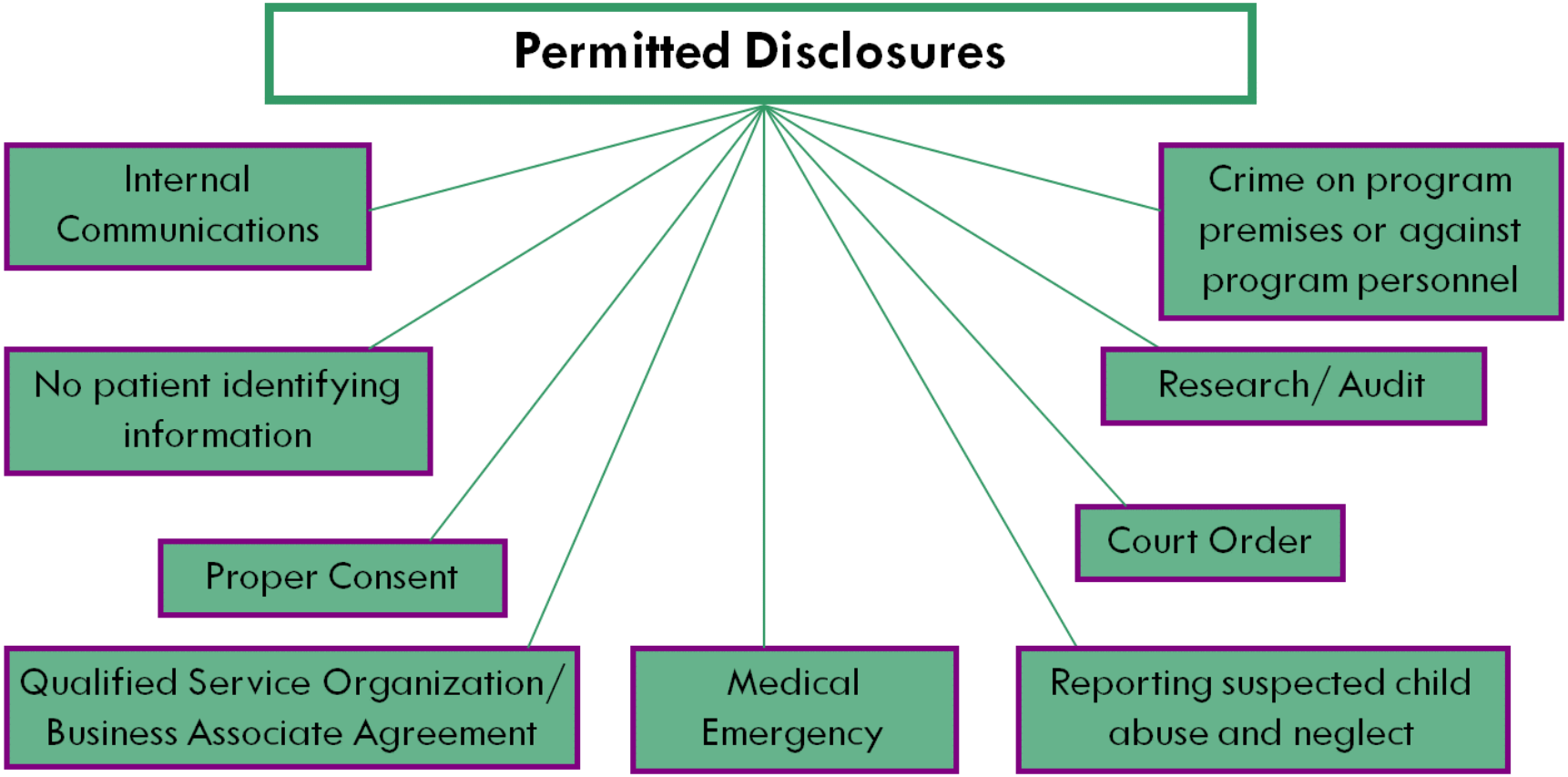
Overview of 42 C.F.R. Part 2 ("Part 2")

- First federal confidentiality law
- Enacted in early 1970s
- Purpose of law: Ensure privacy protections essential to encourage people to seek treatment in the face of great stigma concerning addiction
- The Part 2 regulations "impose restrictions upon the **disclosure and use** of alcohol and drug patient records which are maintained in connection with any **federal assisted** alcohol and drug abuse program"

42 C.F.R. Part 2 and Consent: 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/alcohol program) is generally prohibited
- Unless:
  - Patient consents in writing, or
  - Another (limited) exception applies

42 C.F.R. Part 2 and HIPAA: Exceptions to General Rule



Types of Providers Who Must Comply with 42 CFR Part 2

- To be a "program that falls under 42 CFR Part 2, an individual or entity must be federally assisted and hold itself out as providing, and provide, alcohol or drug abuse diagnosis, treatment, or referral for treatment." (42 CFR § 2.11)

Some Key Differences Between HIPAA and 42 CFR Part 2

- HIPAA allows disclosure without consent to other health care providers and insurers; 42 CFR Part 2 does *not*
- 42 CFR Part 2 prohibits disclosure of alcohol/drug information that was disclosed pursuant to patient consent
- HIPAA allows many disclosures to law enforcement & criminal and civil justice systems that 42 CFR Part 2 does *not*
- Different consent requirements (e.g., designation of receiving party is more specific under 42 CFR Part 2)

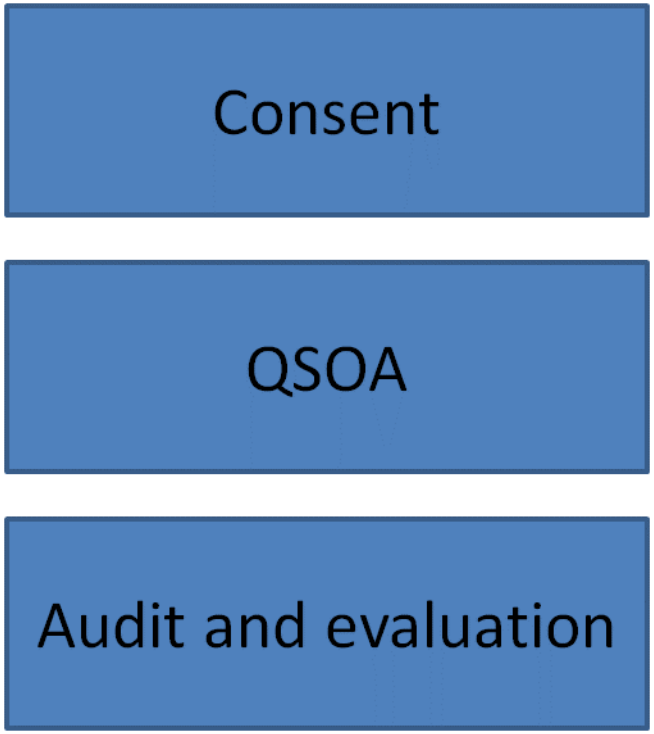
Discussion and Questions

Common Misperceptions about 42 CFR Part 2

- **The restrictions that Part 2 imposes upon information-sharing – and particularly the consent requirement – poses a barrier to providing high-quality, coordinated and integrated care to those with substance use disorders, including those covered by Medicaid.**
- 42 CFR Part 2 does not allow Part 2–protected patient information to be included within in electronic health information exchange (HIE) systems, or to be shared among HIE participants.

Mechanisms for Disclosure Between Providers and Other Key Stakeholders

- The main tools enabling and facilitating communications among Part 2 and other providers, payers, etc. are:



Mechanism for Disclosure #1: Consent Form

- Proper format for consent to release info must be in writing:
  - Name/general designation of program making disclosure
  - Name of individual/entity receiving disclosure
  - Name of patient who is subject of disclosure
  - Purpose/need for disclosure
  - Description of how much & what kind of info will be disclosed
  - Patient's right to revoke consent, and any exceptions
  - Date/event/condition on which consent expires
  - Patient signature
  - Date signed

- HIPAA: Program's ability to condition treatment, payment, enrollment, or eligibility on the consent

Mechanism for Disclosure #1: Consent Form – Cont'd.

- Whenever patient information is disclosed with consent, it must be accompanied by Written Prohibition on Redisclosure
- **Rule**: Any disclosure made pursuant to written patient consent must be accompanied by written statement that the information disclosed is protected by federal law and that the recipient may not disclose it further unless permitted by the regulations
  - This is true even for verbal disclosures
  - Sample Notice Prohibiting Redisclosure at Legal Action Center

Mechanism #2: Qualified Service Organization Agreements

- Two-way agreement between a Part 2 Program and the entity providing the service.
- Authorizes communication between those two parties of information that is necessary for the QSO to perform its duties under the QSOA

Mechanism #2: Qualified Service Organization Agreements – Cont'd

- A QSOA means a person or organization that:
  - Provides services to a Part 2 program, such as data processing, bill collecting, dosage preparation, lab analyses, or legal, medical, accounting or other professional services, and
  - Has entered into a written agreement with a program under which that person;
    - Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the program, it is fully bound by these regulations; and
    - If necessary, will resist in judicial proceedings any efforts to obtain access to patient records, except as permitted by these regulations.

QSO/BA Agreements: Rule

- OK to disclose without patient consent to certain outside organizations that provide services to the program or its patients
  - HIPAA calls these organizations Business Associates (BAs)
  - 42 C.F.R. Pt. 2 calls these organizations Qualified Service Organizations (QSOs)
- Examples of services provided by BAs/QSOs:
  - Data processing, dosage prep, lab analyses, vocational counseling, patient transport, legal or accounting services, electronic storage of patient records, etc.

Mechanism #3: Audits and Evaluations

- Part 2 permits disclosures to persons and organizations authorized to conduct audits and evaluation activities, but imposes limitations by requiring any person conducting the audit or evaluation to agree in writing that it will redisclose patient identifying information only:
  - Back to the program, or
  - Pursuant to a court order to investigate or prosecute the program (not a patient), or
  - To a government agency that is overseeing a Medicare or Medicaid audit or evaluation (42 CFR § 2.53 (c),(d)).

Promoting Effective Communication Between SUD and Primary Care Providers

- Consent Forms:
  - Patients can sign consent forms to authorize disclosure to primary care, mental health and other health care providers
  - Consents can be two-way, i.e., authorize disclosures between SUD providers and other health care providers

Promoting Effective Communication Between SUD and Primary Care Providers (cont'd)

- QSOAs
  - SUD providers can sign QSOAs with other health care providers that provide a service to them
    - Providing mental or physical health services for the SUD providers' patients
  - QSOAs authorize SUD provider to disclose to the other health care provider information it needs to provide the service, and the other health care provider can disclose information back to the SUD provider

Challenges for Coordination Between the Criminal Justice Setting and SUD Providers

- Assuring voluntary and informed consent
- Addressing Concerns regarding potential adverse consequences if/when protected info disclosed and used within criminal justice system

Coordination Strategies for Criminal Justice Settings

- Consent in criminal justice cases:
  - Consent (which ordinarily can be revoked at any time) can be made irrevocable until a certain specified date or condition occurs, and the duration of the consent can be linked to the final disposition of the criminal proceeding.
  - Purpose of exception: Allow programs to provide information even after the client leaves treatment. If the client does not comply with treatment, the program can report the problem to the judge or prosecuting attorney handling the case, or testify in a probation revocation hearing because there has been no final disposition of the criminal matter. (Note that HIPAA requires that all consents be made revocable.)

Coordination Strategies for Criminal Justice Settings – Cont'd.

- Court Order when there is no consent form:
  - Authorizing court order is necessary to disclose information. (See 42 CFR §§ 2.61 – 2.67.) Subpoenas and court orders other than those issued pursuant to Part 2's requirements are not sufficient.
  - Court orders can be issued to investigate or prosecute patients only if the crime involved is "extremely serious." Crimes involving drug sale or possession do not meet that criterion. (42 CFR § 2.65(d)(1)).

Promoting Effective Communication Between SUD and Managed Care

- Consent:
  - Consent forms can and should authorize disclosure of whatever information is needed by managed care companies both to manage care and to enable billing and payment
  - Providers should have patients sign consent forms at their first contact with the patient, i.e., at intake.

Break for Discussion

Common Misperceptions about 42 CFR Part 2 (cont'd)

- The restrictions that Part 2 imposes upon information-sharing – and particularly the consent requirement – poses a barrier to providing high-quality, coordinated and integrated care to those with substance use disorders, including those covered by Medicaid.
- **42 CFR Part 2 does not allow Part 2–protected patient information to be included within in electronic health information exchange (HIE) systems, or to be shared among HIE participants.**

Correcting the Misperception

- The Part 2 regulations do permit SUD patient information to be shared among health care providers, payers, and government authorities who need effective, real-time access to health information about those with SUDs that is relevant to their care, including information included in electronic health information systems, when warranted.

How Adoption of EHRs and HIEs Changes the Game

- Historically with paper records, Part 2 programs had the most access to information and were knowledgeable about the protections under 42 CFR Part 2
- Adoption of EHRs and HIEs increases the risk of inappropriate disclosure of records
  - Expands the universe of who has 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

Electronic Health Records

- How can alcohol/drug treatment records (covered by 42 C.F.R. Part 2) be included in electronic health record (EHR) systems?
- SAMHSA has issued two sets of guidance documents regarding EHR systems and HIE
  - "Applying the Substance Abuse Confidentiality Regulations to and Health Information Exchange (HIE)"
  - "Applying the Substance Abuse Confidentiality Regulations: 42 CFR Part 2 (Revised)"

Is There a Need to "Modernize" 42 CFR Part 2 for New Health IT Environment?

- SAMHSA held a listening session in 2014 and invited comment on whether current consent requirements should be modified to make it easier for HIEs to share SUD treatment information.
- Goal is to facilitate information exchange while respecting the legitimate privacy concerns of patients due to the potential for discrimination and legal consequences.

Communications Between Pt. 2 Programs and Other EHRs/HIE Participants

- Same key mechanisms apply:
  - **Consent***
    - Required for SUD treatment information to go into EHRs/HIE
    - List entities with access to the information through the EHR/HIE
  - Qualified service organization agreements
  - Audit and evaluations
  - Medical emergency

EHR/HIE FAQs Q1

- Does the federal law that protects the confidentiality of alcohol and drug abuse patient record allow information about patients with SUDs to be included in electronic health information exchange systems?
  - Yes with patient consent
  - Consent needs to include all entities that have access to the EHR/HIE

EHR/HIE FAQs Q4

- For the purposes of the applicability of Part 2, does it matter how HIOs are structured?
  - No. Part 2 always applies.
  - HIOs may take any number of forms and perform a variety of functions:
    - Provide the infrastructure to exchange patients' health records among network participants
    - Serve as a data repository that holds or stores patient records supplied by entities participating in the HIO network and then makes them available for exchange in response to requests from network participants;
    - Provide a record locator for HIO participants & and match individuals to their records from different places;
    - Review and respond to requests for patient records from HIO participating providers.

EHR/HIE FAQs Q7

- May information protected by Part 2 be made available to an HIO for electronic exchange?
  - Information protected by Part 2 may only be made available to an HIO for exchange if:
    - A patient signs a Part 2-compiant consent form authorizing the program to disclose the info to the HIO, or
    - A Qualified Service Organization Agreement is in place between the Part 2 program and the HIO.

EHR/HIE FAQs Q8

- If Part 2 information has been disclosed to the HIO, either pursuant to a Part 2-compliant consent form authorizing such disclosure or under a QSOA, may the HIO then make that Part 2 information available to HIO-affiliated members?
  - Yes, if the patient signs a Part 2-compliant consent form.
  - Yes, if when a QSOA is in place between the two.

EHR/HIE FAQs Q13

- Can a single consent form be used to authorize the disclosure of Part 2 Information to an HIO, as well as authorize the disclosure of that information to other identified parties, such as HIO affiliated members?
  - Yes.
  - A single consent form can authorize a disclosure of information about a patient to one recipient, such as an HIO, and simultaneously authorize that recipient to redisclose that information to an additional entity or entities provided that the purpose for the disclosure is the same.
  - The required statement prohibiting disclosure must accompany the information disclosed through consent, so that each subsequent recipient of that information is notified of the prohibitions on disclosure.

EHR/HIE FAQs Q18

- Under Part 2, can an HIO use a consent form that provides for disclosure to "HIO members" and refers to the HIO's website for a list of those members?
  - No.
  - Consent forms must include the names of **ALL** individuals or organizations who will be the recipients of the Part 2 data.
  - All HIO affiliated members that are potential recipients of the Part 2 data can be identified by attachment to the consent form.
  - Reasons:
    - Ensure that patients sufficiently informed about the disclosures under the consent
    - Many individuals throughout the country still do not have computers or access to the Internet

EHR/HIE FAQs Q9

- How do different HIO patient choice models regarding whether general clinical health information may be disclosed to or through an HIO affect the requirements of 42 CFR Part 2?
  - All must be compliant with Part 2. Some models may require consent where it isn't required under Part 2.
  - Consent models
    - "No consent" – Still requires patient Part 2 compliant consent
    - "Opt out" – Still requires patient Part 2 compliant consent
    - "Opt in" – May require consent despite the presence of a QSOA

EHR/HIE FAQs Q6

- Under Part 2, can a Qualified Service Information Agreement (QSOA) be used to facilitate communication between a Part 2 program and an HIO?
  - Yes
  - A Part 2 program can communicate with a Qualified Service Organization – in this case the HIO – through a two-way written agreement with the HIO – the QSOA.
  - Communication is limited to the information needed by the HIO to provide services to the program.
  - The HIO may also communicate with the Part 2 program and share information it receives from the program back with the program.
  - Patient consent is not needed to authorize such communications between the HIO and the Part 2 program when a QSOA is in place between the two.

EHR/HIE FAQs Q10

- If an HIO is holding or storing Part 2 patient data through a QSOA, can the HIO redisclose the data coming from the Part 2 program to a third party without patient consent?
  - Only in very limited circumstances.
  - An HIO may disclose the Part 2 information to a contract agent of the HIO, if it needs to do so in order to provide the services described in the QSOA, and as long as the agent only discloses the information back to the HIO or the Part 2 program from which the information originated.

EHR/HIE FAQs Q10 – Cont'd.

- The HIO would not be allowed to redisclose the information to third parties, including HIO affiliated members, except in a medical emergency (discussed in other FAQs), because the HIO affiliated members are not acting as agents of the HIO, but rather are receiving services provided by the HIO. Consequently, if an HIO wants to redisclose the Part 2 program's records to a participating member, it would need the consent of the patient.

EHR/HIE FAQs Q17

- Under Part 2, can an HIO reveal that a patient has had an encounter at a mixed use facility (or "general medical" facility) as long as the HIO does not reveal that the patient was in the mixed use facility's Part 2 program?
  - Yes
  - Reason: No information that identifies the person, either directly or indirectly as having a current or past drug/alcohol problem or as being a patient in a Part 2 program – is being disclosed

EHR/HIE FAQs Q28

- Under Part 2, may an HIO system make clinical decision support functions (e.g. showing a patient's medications to clinicians when they write prescriptions, automatically ordering meds, and/or alerting clinicians about potential drug interactions) available to HIO affiliated health care providers in a medical emergency?
  - Yes. Access without patient consent is permitted for information protected by Part 2 in circumstances that meet Part 2's definition of a medical emergency. (42 CFR § 2.51).

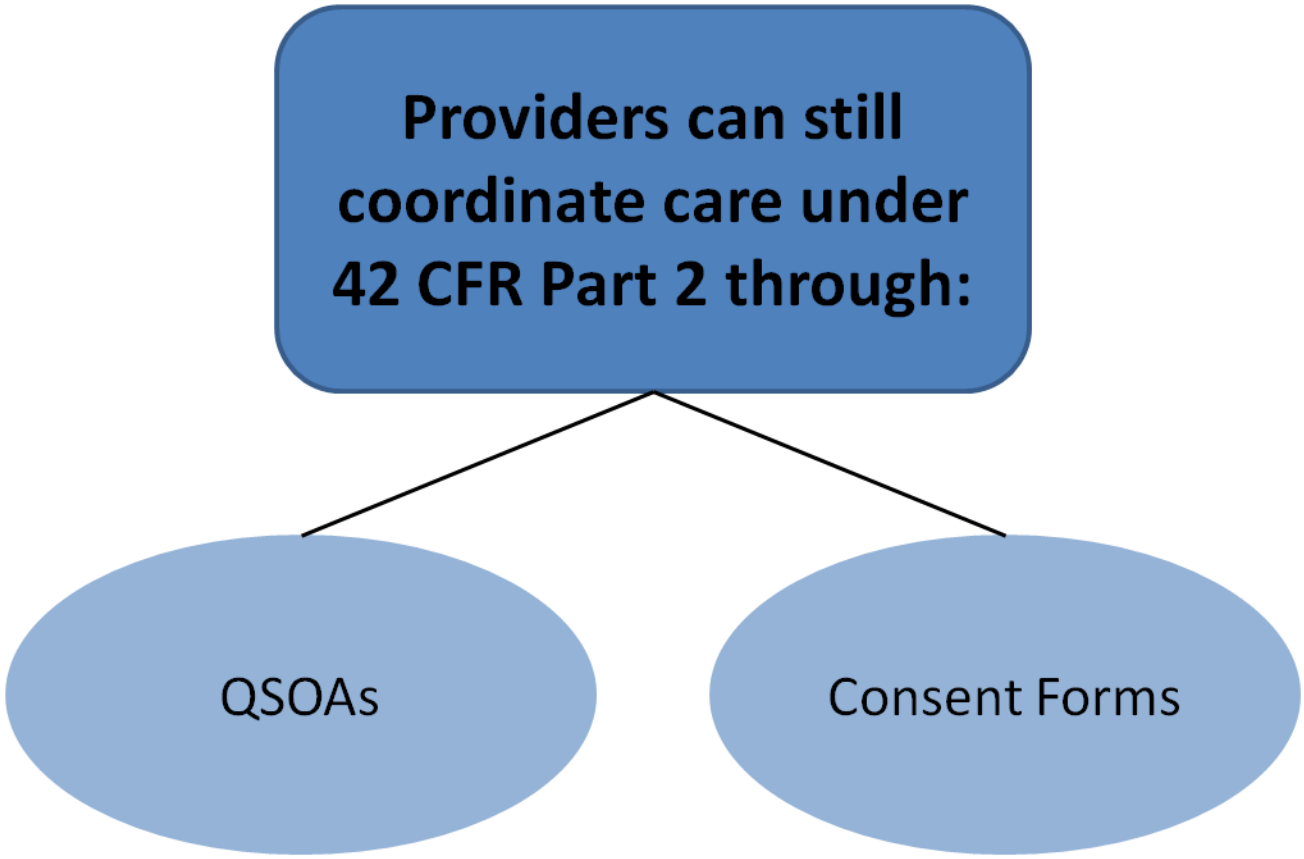
Break for Discussion (1 of 2)

Missouri Experience

- Mechanisms MO used to encourage coordination between SUD providers and primary care providers compliant with 42 CFR Part 2
- Ways Medicaid and the state SSA worked together to accomplish this goal

Break for Discussion (2 of 2)

Summary


Providers can still coordinate care under 42 CFR Part 2 through:
QSOAs
Consent Forms

Resources

- SAMHSA FAQ 1: "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)" (2010), Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)
- SAMHSA FAQ 2: "Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2 (REVISED)" (2011), Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2 (Revised)
- Legal Action Center: Legal Action Center - Substance Use: Confidentiality Resources