Applying 42 CFR Part 2 to Behavioral Health and Primary Care Providers

December 17, 2015 11:00am-1:00pm

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Oregon Health Authority

CO SIM State Innovation Model

Colorado Department of Health Care Policy and Financing

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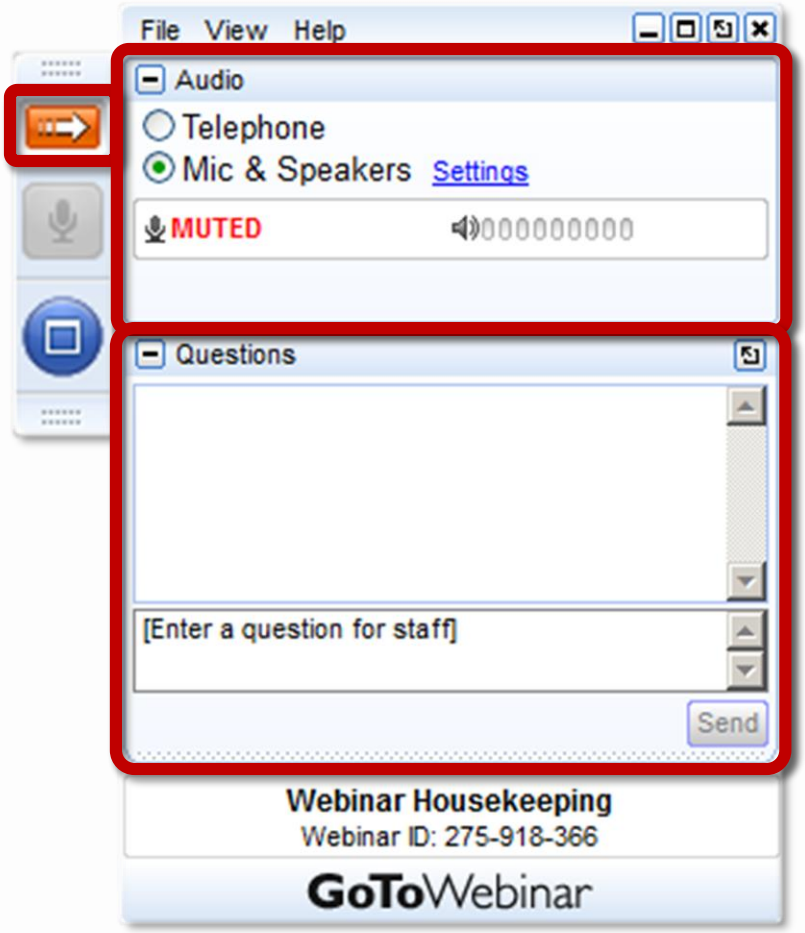

Webinar Agenda

- Overview of the Webinar
- Part 1: Navigating the federal “Part 2” rules
- Question and answer
- Part 2: Navigating the federal “Part 2” rules
- Question and answer
- Next steps and resources

Presenter

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Mr. Belfort is a partner in the healthcare practice of Manatt, Phelps & Phillips, LLP and has over 20 years of experience representing healthcare organizations on regulatory compliance and transactional matters. Mr. Belfort's practice focuses on the following areas:

- Managed Care and Accountable Care,
- HIPAA/Privacy, and
- Fraud and Abuse

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Navigating the Federal "Part 2" Rules

Oregon Health Authority and Colorado Department of Health Policy and Financing

December 17, 2015

Agenda

- The Relationship Between the Part 2 Rules and Other Privacy Laws
- Who is Covered by the Part 2 Rules?
- When Disclosure of Records Is Permitted Without Patient Consent
- Patient Consent Requirements
- Special Challenges for Electronic Health Information Exchanges Under the Part 2 Rules

The Patchwork of State and Federal Privacy Laws

Federal Laws

- HIPAA
- 42 CFR Part 2
- Other laws governing family planning agencies, the VA, etc.

State Laws

- Comprehensive confidentiality laws
- Information-specific laws
  - HIV
  - Mental health
  - Substance abuse
  - Genetic testing
- Entity-specific laws (hospitals, physicians, insurers, etc.)

The “More Stringent” Tests

HIPAA vs. State Laws

- HIPAA preempts state laws that **permit** disclosure unless the state law is “more stringent” than HIPAA
- More stringent means the law provides a higher level of patient privacy protection
- But HIPAA allows all disclosures **required** by state laws

Part 2 vs. Other Laws

- A provider subject to Part 2 must comply with Part 2 if it is more stringent than other applicable state or federal laws
- No exception for disclosures required by other state or federal laws

Example: Interplay Between State Law and Part 2

- Q. A state law requires all licensed health care providers to make their records available to state public health authorities for purposes of tracking communicable diseases. Is a Part 2 program permitted to disclose its records to public health authorities for this purpose? Is it required to do so?
- A. The Part 2 program is neither permitted nor required to disclose its records for this purpose. The Part 2 rules do not contain an exception for public health disclosures and do not permit disclosures required by state laws.

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Definition of Part 2 Provider

"Federally Assisted"

- Receives federal grants or other federal funds (Medicare, Medicaid, etc.) even if not used for substance abuse treatment
- Tax exempt
- Issued federal license such as DEA registration to dispense controlled substances

Any of the above

"Program"

- Holds itself out to the public as providing alcohol or drug abuse diagnosis, treatment or referral for treatment

AND

- Actually provides such services

Not a general medical facility but could be unit or group of individuals within such a facility

Covered by Part 2 or Not?

Type of Provider	Subject to Part 2?
Emergency department of general hospital.	No. The ED does not hold itself out as providing specialized substance abuse services.
Licensed mental health facility.	Generally, no. Mental health treatment is distinguishable from substance abuse treatment. If the facility does not specialize in the latter, it is not subject to Part 2.
Substance abuse unit that is part of a general hospital but is not a separate legal entity.	Yes. A unit or program within a larger organization can be subject to Part 2 even if the majority of the organization's services are not.

Covered by Part 2 or Not?

Type of Provider	Subject to Part 2?
For-profit substance abuse residential facility that accepts only cash payment from patients.	Maybe. The facility would not be federally assisted unless it maintained a DEA registration.
Internist who provides periodic advice about substance abuse to patients as part of his or her primary care practice.	No. The internist does not hold himself/herself out as providing specialized substance abuse treatment services.
Retail pharmacy that dispenses Suboxone based on prescriptions written by Part 2 program physicians.	No. Pharmacy does not hold itself out as providing specialized substance abuse treatment. But pharmacy records may be subject to Part 2 if the prescription was sent directly to the pharmacy by a Part 2 prescriber.

Covered by Part 2 or Not?

Type of Provider	Subject to Part 2?
Clinic or residential program licensed by state to provide alcohol or drug abuse treatment.	Yes. A facility or program that holds a specialized state license will be deemed to hold itself out as providing specialized services.
Community health center that is not licensed as a substance abuse treatment provider but advertises its expertise in serving patients with substance abuse conditions.	Probably. If the center promotes its substance abuse service capacity and provides or makes referrals for substance abuse services, it is subject to Part 2. (There may be state licensing issues with this advertising.)

Are Recipients of Part 2 Information Subject to Part 2?

- The receipt of records from a Part 2 program pursuant to a patient consent does not, by itself, make the recipient a Part 2 provider
- **But**, the recipient cannot re-disclose such records except as permitted by Part 2
- Part 2 programs disclosing records pursuant to patient consent must provide a standard warning notice to recipients explaining the restrictions on re-disclosure
  - Notice typically accompanies records when delivered in paper form
  - If information is provided orally, notice must be sent at or before the time the information is communicated
  - Electronic exchanges must integrate the notice into their systems

Required Warning Notice

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

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What Is a Part 2 Record?

- Clinical information if it identifies a patient
- A patient's name or other non-clinical information (e.g., address, SSN, photograph) to the extent it indicates the patient received Part 2 services
- **Not** de-identified data

What Is a Disclosure?

- Provision of information to outside person or entity
- Access by any internal personnel who do not work in the Part 2 program or provide centralized administrative services to the program

Emergency Medical Treatment

- Disclosure permitted to treat patient in a medical emergency
- Emergency defined as “an immediate threat to the health of any individual and which requires immediate medical intervention”
- Existence of emergency must be determined by health are professional
- Part 2 program must document nature of emergency and date/time of disclosure

Research

- Qualified researcher
- Protocol for maintaining data security and preventing re-disclosure
- Research approved by IRB or other body consisting of three or more independent individuals
- No identification of patients in research reports

Crimes on Program Premises

- Disclosure directly related to patient's commission of crime on program premises or against program personnel (including threat to commit such a crime)
- Disclosure limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last known whereabouts

Child Abuse Reporting

- Disclosure permitted for reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities
- Exception only covers initial report; restrictions continue to apply to program records if sought in any civil or criminal proceedings relating to the report

Program Audit and Evaluation

- Government agency or private third party payer that pays for program services, or QIO
- Deemed qualified to conduct audit by program director
- Agrees in writing to comply with Part 2 restrictions on re-disclosure
- If records copied or removed from premises, agrees to secure records and destroy identifiers upon completion of audit

Court Orders

- Requires subpoena “so ordered” by the court
- Court must follow specified notice and hearing procedures before issuing order
- Procedures differ depending on whether records are sought for criminal prosecution or other purposes

Qualified Service Organizations

- QSOs are persons or entities that need access to records to provide services to Part 2 programs, such as:
  - Data processing
  - Billing and collection
  - Laboratory analysis
  - Care coordination
  - Legal, medical, accounting or other professional services
- Part 2 programs must enter into a Qualified Service Organization Agreement with each QSO:
  - Comply with Part 2 rules
  - Resist disclosure in judicial proceedings as required of Part 2 programs

Comparison of Part 2 and HIPAA Exceptions

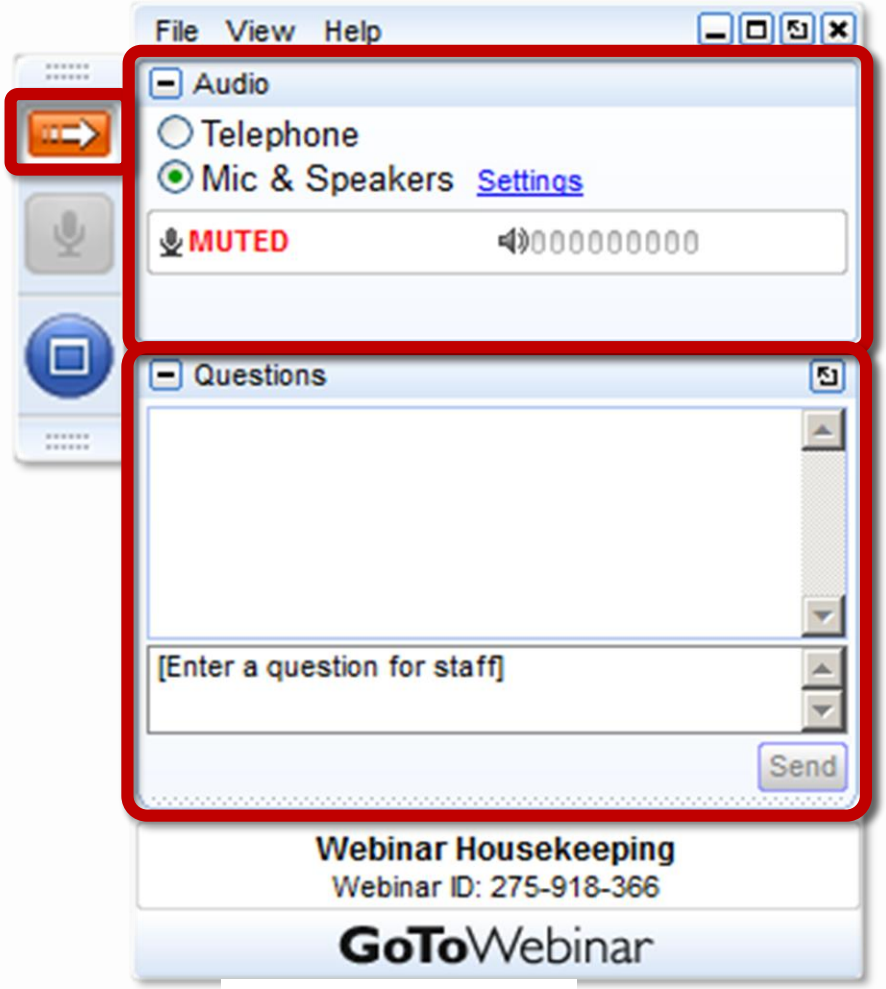
Purpose of Disclosure	HIPAA Exception?	Part 2 Exception?
Emergency treatment	Yes	Yes
Non-emergency treatment	Yes	No
Payment	Yes	No
Health care operations (e.g., quality improvement, care management, etc.)	Yes, to other covered entities	No, only to QSO
Research	Yes, if certain conditions are met	Yes, if certain conditions are met
Subpoena	Yes, if patient notice or protective order	No. Requires court order

Examples: Is Patient Consent Required?

- Q1. A hospital that operates a general medical facility and a substance abuse treatment unit wants to contact a patient's insurer to verify that the patient is still covered. Is patient consent required?
- A1. If the hospital request does not identify which part of the hospital is providing services to the patient, patient consent is not required. Patient consent would be required if the nature of the request disclosed that services were being provided by the substance abuse treatment unit (e.g., the hospital asked about the scope of substance abuse treatment coverage).
- Q2. A health plan has received claims from a Part 2 program pursuant to the patient's consent. The plan wants to share the claims data with an outside vendor to perform a quality review analysis. Is patient consent required?
- A2. Probably yes. Only a Part 2 program may share data with a QSO under a QSOA. A party providing services to a recipient of Part 2 data, such as a health plan, does not appear to meet the definition of a QSO.

Questions and Answers

Please type your questions into the question box



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Elements of Valid Consent

- Specific name or general designation of the program or person permitted to make the disclosure
- Name or title of individual or the name of the organization to which disclosure is to be made
- Name of patient
- Purpose of disclosure
- How much and what kind of information is to be disclosed
- Dated signature of patient or personal representative
- Statement that consent is subject to revocation except to the extent already relied on
- The date, event, or condition upon which the consent will expire

Form of Permissible Consent

Type of Consent	Permissible	Not Permissible
Signed written consent form	X	
On-line form with electronic signature	X	
Oral consent		X

Consent for Services Provided to Minors

- State law dictates who must sign consent
  - If, in accordance with state law, minor obtains services without approval of parent or guardian, minor must sign consent
  - If state law requires approval of parent or guardian for treatment, minor **and** parent/guardian must sign consent
- If state laws require approval of parent/guardian for treatment, minor's request for treatment can be disclosed to parent/guardian only with minor's consent unless (i) minor lacks capacity and (ii) program director determines disclosure may reduce substantial threat to life or well-being of minor or another person

Examples: Are These Consents Valid?

- Q1. The consent states that disclosure may be made to any other health care providers delivering medical treatment to the patient. Valid?
- A1. No. The consent cannot list a "class" of recipients. It must identify the specific persons or entities to whom information will be disclosed.
- Q2. The consent states that information may be disclosed for treatment purposes without specifying the type of treatment. Valid?
- A2. Yes. A general description of the purpose is sufficient.
- Q3. The consent states that it remains in effect until revoked by the patient. Valid?
- A3. No. The consent must state an expiration date or event. A perpetual consent that continues until revocation is not permitted. But an event such as "death" could be specified in the consent.

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What is a Health Information Exchange?

- Network of health care providers and potentially other organizations that have entered into participant agreements with each other or a centralized exchange operator
- Connected through an electronic system that facilitates data exchange among participants
- Different technical models:
  - Centralized data repository
  - "Federated" model where records are pulled from each participant's system in response to a query to a patient record locator
- Different consent models:
  - Opt out
  - Patient consent at point of disclosure
  - Patient consent at point of access

How Is Data Exchange Different in an HIE?

Traditional Paper Record Exchange	Electronic Health Information Exchange
One-to-one exchange	One-to-many or many-to-many exchange
Human review of records prior to disclosure	Automated disclosure without human review
Part 2 program knows when disclosure being made	Part 2 program may not know when disclosure being made
Patient usually aware that disclosure being made	Patient often unaware that disclosure being made

Guidance Provided by SAMHSA on HIE's

Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)

http://archive.samhsa.gov/healthPrivacy/docs/EHR-FAQs.pdf

Uploading Data to an HIE

SAMHSA Guidance

- Permitted without patient consent if HIE operator has signed a QSOA with the Part 2 program
- No access to the data by HIE participants is permitted until the patient provides consent

Implications

- Immediate availability of data in emergency rooms through “break the glass” functionality
- Immediate availability of data in other clinical settings upon receipt of patient consent in “consent to access” model

Description of Part 2 Programs in Consent Form

SAMHSA Guidance

- Consent can refer generally to all Part 2 programs participating in the HIE

Implications

- Accessing providers can obtain valid consent without identifying all participating Part 2 programs, which will likely change over time

Description of Data Recipients in Consent Forms

SAMHSA Guidance

- Specific persons or entities to whom data is being disclosed must be named in the consent form or an attachment to the form
- Reference to a website or other resource where patients can view a regularly updated list of HIE participants is not permitted

Implications

- An HIE-wide consent that permits all HIE participants to obtain access to all HIE records is not adequate unless a list of all participants is attached to the form
- Even if a list of participants is attached, when new participants join the HIE, they will not be covered by the consent

Use of Omnibus Consent Form

SAMHSA Guidance

- A consent form that covers all health information can satisfy Part 2 if all of the required Part 2 elements are included in the form
- A separate Part 2 consent form is not required

Implications

- An accessing provider does not have to obtain two separate consents from patients in order to access Part 2 data

Recording Disclosures for Emergency Treatment Purposes

SAMHSA Guidance

- A Part 2 program does not satisfy the requirement of documenting a disclosure for purposes of emergency medical treatment if the disclosure is maintained in the HIE's record system
- The documentation must be maintained in the Part 2 program's record system

Implications

- Since Part 2 program will typically be unaware of emergency treatment disclosure, it must be notified by hospital or HIE
- Notice must include all of the information the Part 2 program is required to document in its records

Common Challenges in HIE

- Filtering or segregating Part 2 data from other records if:
  - HIE using opt out model
  - HIE participants using HIE-wide consent
- Providing warning notice about re-disclosure with each disclosure made pursuant to patient consent
- Communicating emergency treatment access back to Part 2 programs
- Distinguishing between services provided to minor pursuant to minor's informed consent vs. parent's informed consent for purposes of determining validity of consent to disclose Part 2 information

Q & A

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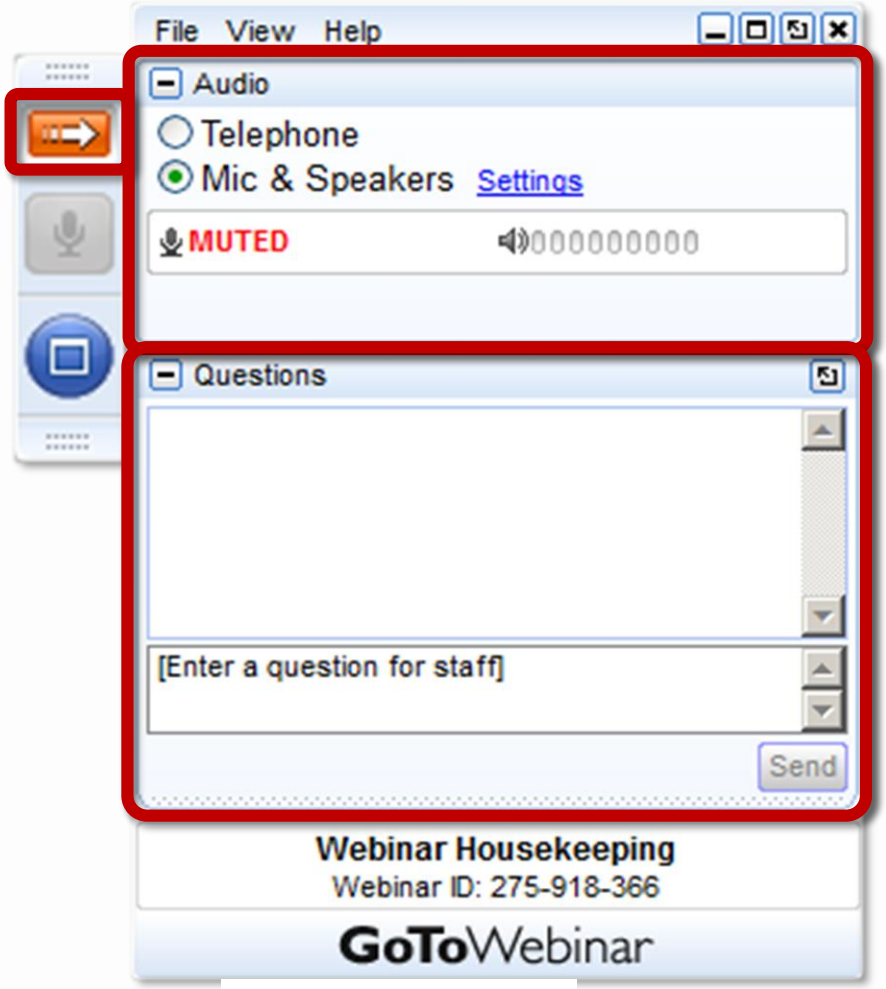

OHA's Next Steps

- Conduct additional webinars
- Develop a model Qualified Service Organization Agreement
- Collaborate on OHA and Jefferson HIE ONC grant
- Develop a provider toolkit covering privacy laws, case studies of allowable sharing, model forms, and FAQs
- Engage federal partners in discussions about modifications to Part 2
- Continue to consult with other states

Colorado's Next Steps and Resources

- Develop and disseminate guidance for practices/providers
  - Myths vs realities
  - White paper
- Collaborate with stakeholders around the development of a standardized consent form
- Consult with other states and federal partners

Resources

For more information and access to today's slides and webinar recording, please visit:

http://www.oregon.gov/oha/amh/Pages/bh-information.aspx

For more information on Colorado's State Innovation Model Grant work, please visit:

www.coloradosim.org

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