



**School of Law / Institute for
Health Policy & Practice**
Health Law & Policy

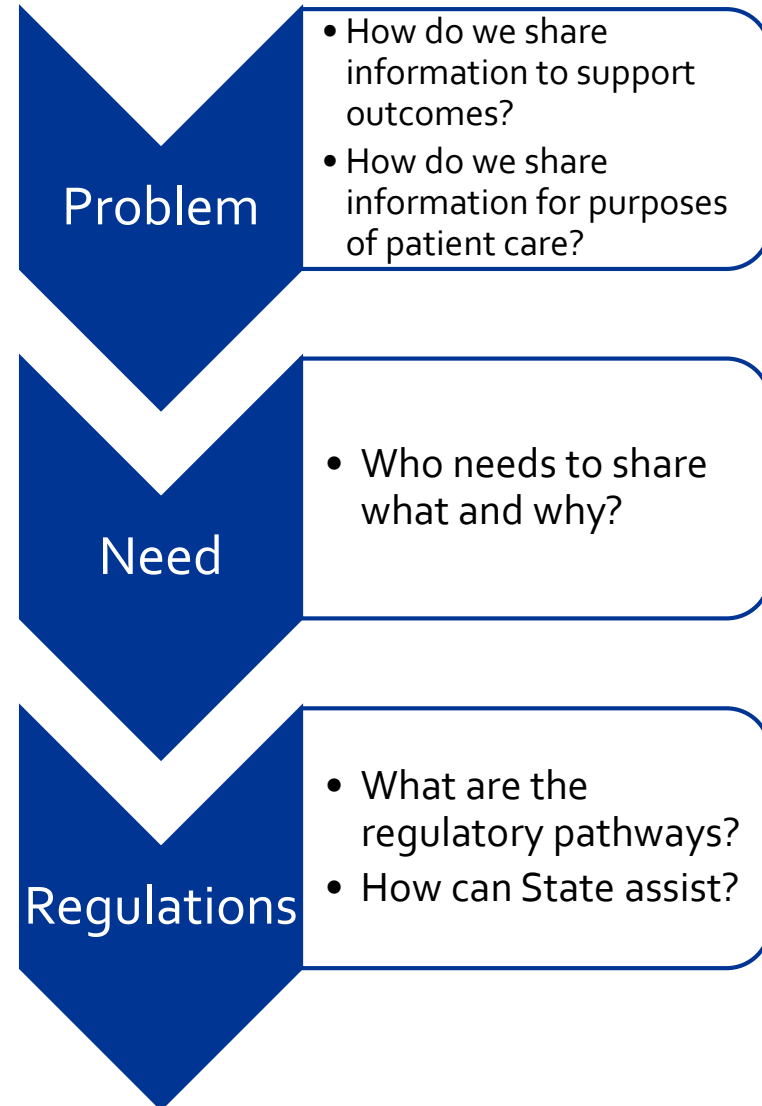
**42 CFR PART 2
INTEGRATED DELIVERY SYSTEMS AND
CONFIDENTIALITY ISSUES
MARCH 20, 2018**

**Institute for Health Policy and Practice
UNH School of Law**

Why are we here?

- To assist with transparent problem solving around confidentiality restrictions that may limit information sharing.
 - Information sharing may be desired to demonstrate outcomes.
 - Information sharing may be desired to facilitate integrated patient care.
- To help all IDN participants and agents map information sharing needs.
- We are here to help translate regulatory pathways.
- We are here to provide technical assistance to all of you at the request of DHHS.

We are not providing legal advice. We are providing educational and technical assistance that should not take the place of legal advice.



Part 2 2018 Timeline

**Review 2017
Bootcamp
Materials**

July 13th Webinar

March 20

March 27

Thereafter

Home Work:
Review
definitions, collect
data sharing
plans, data needs
and barriers.

*March 20
In-Person Session*

- Part 2 level set
- Map data disclosure needs and current state
- Review new definitions and disclosure pathways focusing on QSO, audit/evaluation and payment/healthcare operations.

*March 27th
In-Person Session*

- Translate current state to ideal regulatory state
- Clarify types of forms, contractual updates and policies necessary for IDNs based on Part 2 providers
- Identify unmet needs

Future Sessions

Today's Agenda

- Introduction:
 - Why are we here
 - Goals of March 20 and March 27
- Brief Part 2 Level Set
- Identifying Questions Break Out Session and Debrief: Mapping Current State
 - **Where** is the BH information going?
 - **What** BH information is being shared?
 - **Why** is it being shared?
- Part 2 Context: Available Exceptions in post-2018 amendments
- Goals for mapping regulatory options on March 27



Assumptions....

All IDN participants may need to share Part 2 information beyond treating providers.

- Our goal during these March 2018 sessions is to find out how the regulations may support disclosures of Part 2 information for purposes other than diagnosis, treatment and referral.
- We will lay out the changes in the rule that enable disclosures for integrated care and treatment, including care and case management, and support amended consents processes in light of new rules.

What Are the Part 2 Rules?

42 CFR Part 2 are the federal Substance Use Disorder (SUD) confidentiality regulations issued by the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (“SAMHSA”) protecting the confidentiality of SUD treatment records.

Part 2 Rules....



Are different
from HIPAA

Disclosures
require specific
exceptions

Should not be a
barrier to
integrated
delivery of care!

Remember Why We Have Part 2

Problem

- Bias in treatment of substance use patients
- Negative impact from seeking treatment in child custody, prosecution, discrimination.

Legislation/Regulation

- Restrict disclosure of substance use disorder treatment records. No sharing without patient consent, except in rare circumstances

Implementation Issues

- Opioid epidemic
- Integrated models of care
- Prohibition against treatment disparities
- Manage unintended consequences
- Care and treat patient

The Rules Have Changed Again - January 3, 2018 Rules

January 2018 (83 Fed Reg. 239)

- Rules still *not* aligned with HIPAA
- Easier to disclose information with consent to third party payers and their agents for the purpose of payment and health care operations: ***consents should be modified accordingly***
- Expands the ability of Medicaid and regulated entities to share Part 2 information with contractors and quality improvement organizations for evaluation purposes: ***audit and evaluation relationships should be reviewed.***
- Provides language for a brief and simple prohibition on “re-disclosure”: ***consents, notices and agreements should be updated.***



MAPPING THE PROBLEM

First Steps:



Question

- What entity is seeking to disclose or receive Part 2 information?



Question

- For what purposes are the disclosures being made (when not for treatment)?



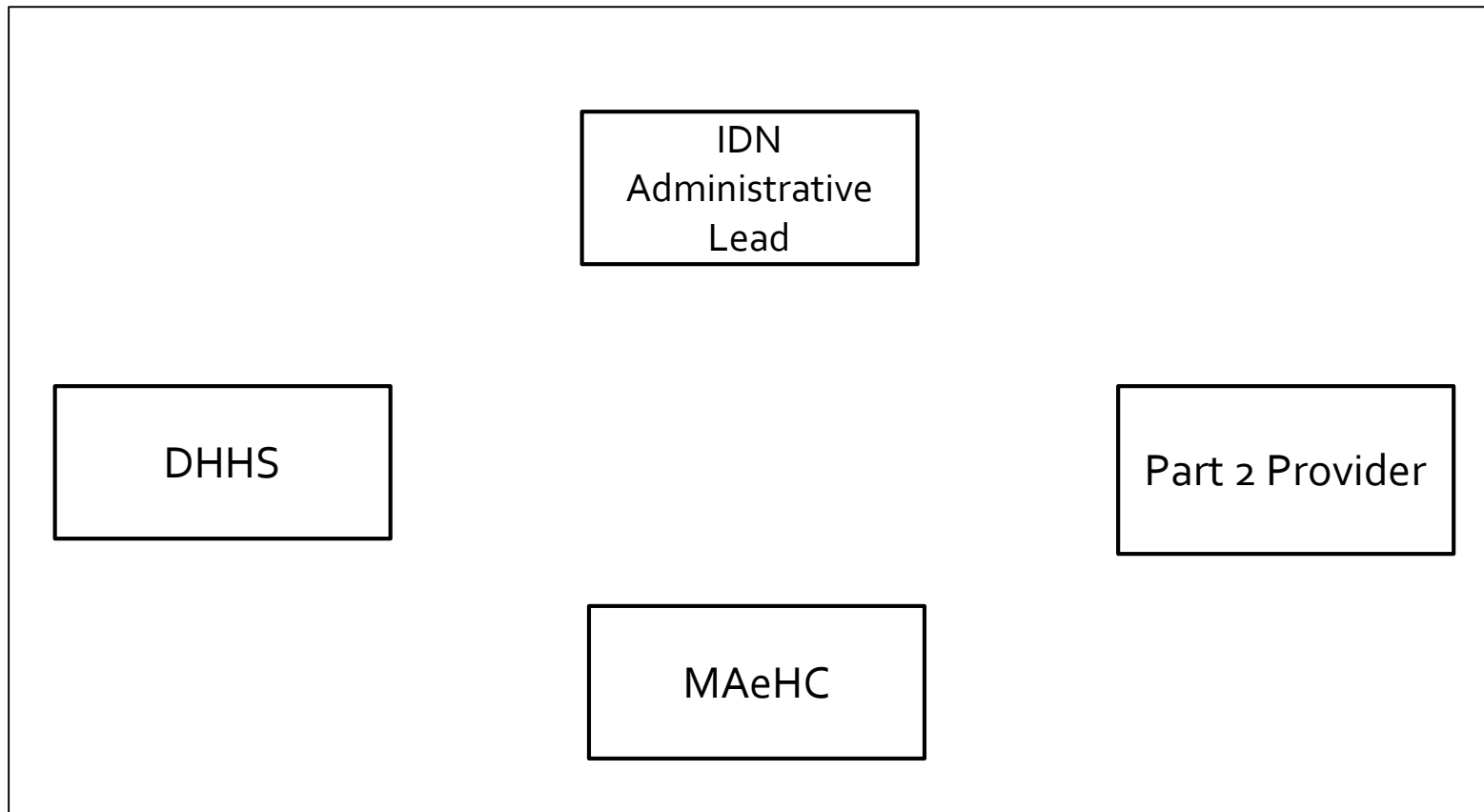
Question

- What Part 2 exception applies?

TODAY

- We need to create a map of necessary disclosures
- We are going to focus on exceptions that allow for sharing without consent
 - Audit and evaluation
 - Qualified Services Organizations
- We will then focus on expanded purposes that may be facilitated by uniform and simplified consents
 - Payment and health care operations
 - General designation
- We will then map solutions

DHHS Medicaid Example



Who Are You? MAPPING INSTRUCTIONS

Using the “Information Exchange Mapping Worksheet”, identify:

- **WHERE** the information is going
 - **WHAT** information is being shared
 - **WHY** it is being shared
 - Key functions!
-
- The “Information Exchange Identifying Questions” provide further assistance in this exercise.

IDENTIFYING SOLUTIONS

Audit and Evaluations: Medicaid, CMS regulated entities and their agents

Qualified Services Organizations and their agents

Start big!



Part 2 is Not Alone: Overview of Applicable Privacy and Confidentiality Law

Jurisdiction	Statute/Regulation	Scope
Federal	HIPAA Privacy Rules	Protects individually identifiable health information maintained by providers, payers and their contractors from disclosure. Heightened protections for psychotherapy notes.
	42 CFR Part 2	Protects the confidentiality of substance abuse patient records from disclosure without express patient consent
New Hampshire	RSA 332-I:1	Medical information in the medical records in the possession of any health care provider shall be deemed to be the property of the patient.
	RSA 318-B:12-a	Protects reports and records of treatment of minors for drug dependency as confidential.
	RSA 330-A:32	Protects communications between mental health practitioners and patients as privileged.
	RSA 330-C:26	Protects information held by a licensed alcohol or other drug use professional performing substance use counseling services unless permitted by 42 CFR Part 2.



Who Is Covered by Part 2 Restrictions?

Part 2 Program/Provider:

1. An individual or entity (or a unit in a general medical care facility) that ***holds itself out as*** providing and ***does provide*** SUD t/d/r; or
2. Medical personnel or staff in a general medical care facility ***whose primary function is*** the provision of such services and who are identified as SUD providers.

Lawful Holder: An individual or entity who has received such information as a result of written patient consent or one of the exceptions to Part 2 who is therefore required to comply with 42 CFR Part 2



What is Part 2 Protected Information?

Part 2 Records:

- Information, whether recorded or not, created, received or acquired by a Part 2 provider relating to a patient (for example, diagnosis, treatment and referral for treatment, billing, emails, voice mails, etc).

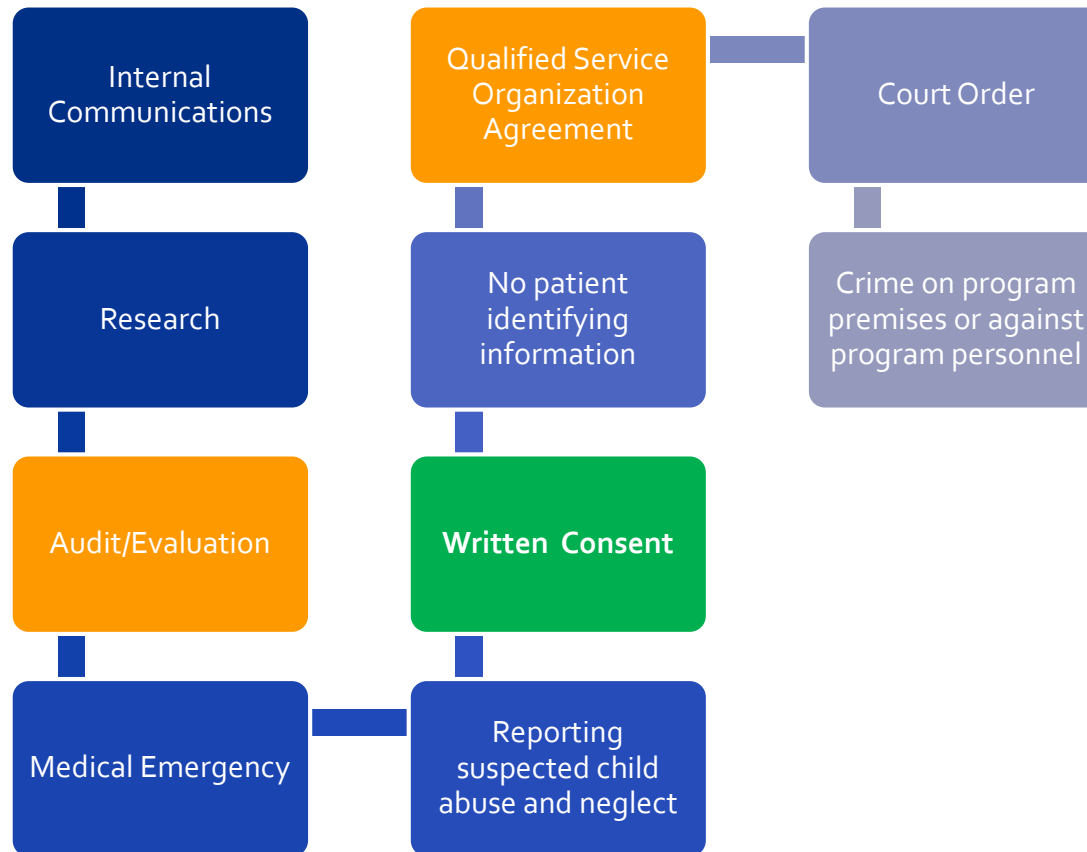
Information, whether or not recorded, which:

- Would identify a patient as a SUD patient
- Is SUD patient information obtained or created by a federal program for the purpose of treating alcohol or drug abuse, making a diagnosis for treatment, or making a referral for that treatment.

Part 2 Basics for Part 2 Providers and Lawful Holders

- I. Patient Records Security policies that meet the new Part 2 standards
- II. Notice of privacy rights that meet Part 2 requirements
- II. Compliant consent forms
- III. Non re-disclosure notices when Part 2 information disclosed
- IV. Qualified Service Organization Agreements are other agency agreements when necessary

NO Disclosure Unless Part 2 Exception



All Disclosures by Consent Must Be Accompanied by Magic Language

- All disclosures by Part 2 providers and lawful holders made pursuant to a written consent must be accompanied by language reminding recipient that re-disclosure is prohibited.
- Note that disclosures by Part 2 providers or lawful holders made without consent but pursuant to a lawful exception also may require contract or legal agreement language that includes but is not limited to the prohibition on re-disclosure language.
- 2018 Rules include a long form and a short form
- Long form is recommended
- Short form is:

“42 CFR part 2 prohibits unauthorized disclosure of these records”

Audit and Evaluation

Audit and Evaluation Exception allows Part 2 programs and other lawful holders to disclose Part 2 information without patient consent to comply with an audit or evaluation.

- Medicaid can use an agent to conduct audits or evaluations.
- Medicaid may access records of entities it regulates including those it regulates as part of a CMS approved waiver for purposes of conducting a program audit or evaluation.
- The purposes of the audit or evaluation can include compliance with rules, laws, policies and waivers.
- Medicaid can use agents to conduct the audits
- Any agent assisting in the audit must put in place certain safeguards to ensure the Part 2 information is protected.

Audit and Evaluation Exception Cont.

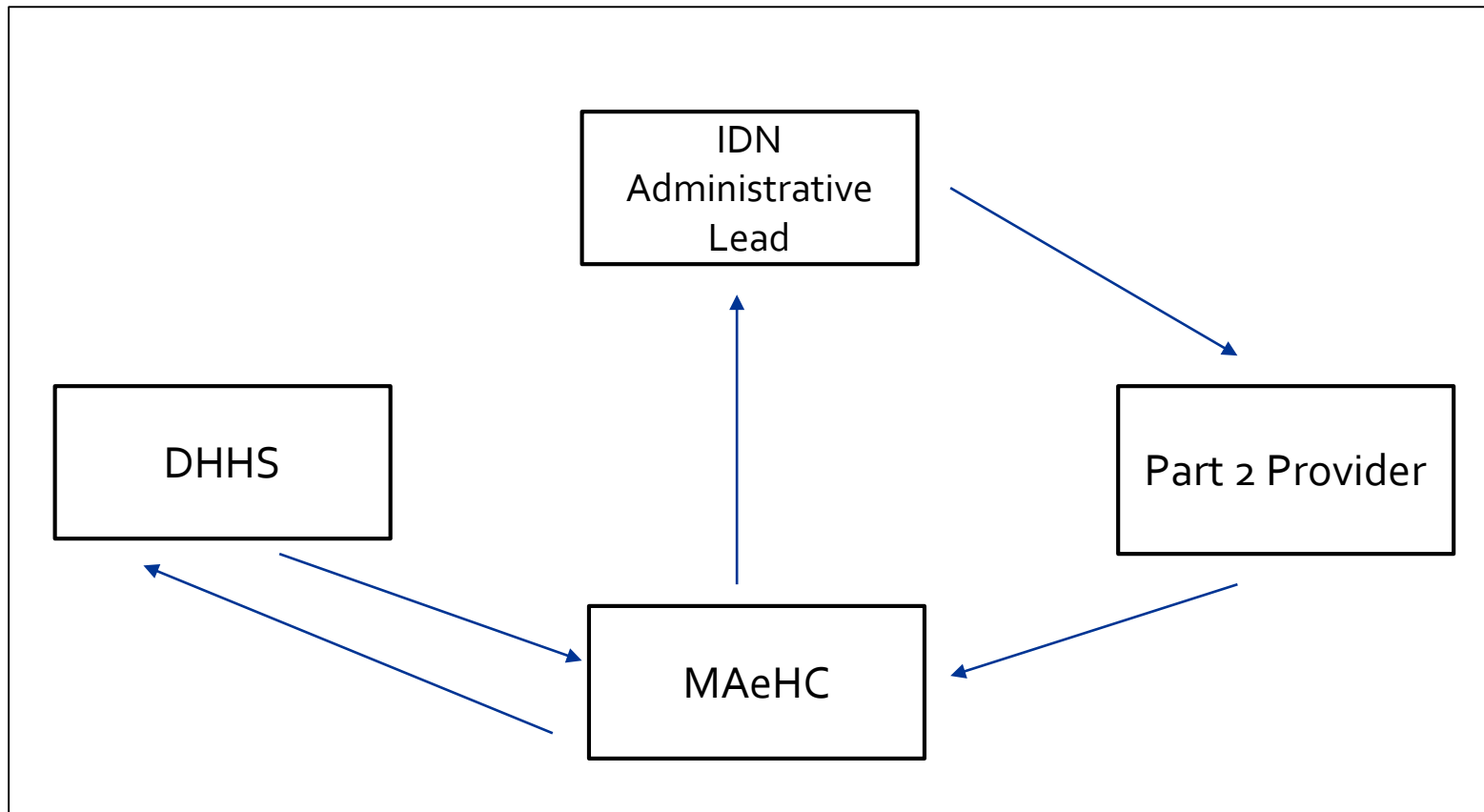
The 2018 Rules allow for "CMS Regulated Entities" like an ACO or potentially an IDN to participate in the audit or evaluation

- The 2018 rules clearly explain that certain ACOs or "other similar CMS-regulated health care models" may need to evaluate the impact of integrated care on outcomes by relying upon participating provider records.
- The DSRIP waiver includes conditions and obligations associated with the performance by Medicaid, the IDNs and certain IDN partners in relation to the waiver evaluation.
- ***Example: a "state may wish to do an audit to see how many individuals who leave state-supported correctional facilities subsequently receive substance use disorder treatment"***
- Such audits and evaluations may be done by contractors on behalf of Medicaid and third party payers.
- IDNs, that are sufficiently prepared to serve as CMS regulated entities, may participate in the audit and evaluation activities.

A&E Disclosure Flow



Medicaid Example Revisited



Qualified Services Agreement Exception

(2.14(c)(4))

A QSO is an individual or entity that provides a service to a Part 2 program consistent with a Qualified Services Organization agreement.

- QSO services include: 2.11
 - *data processing*
 - *bill collecting*
 - *dosage preparation*
 - *lab analysis*
 - *legal, accounting*
 - *population health management*
 - *medical staffing or other professional services or*
 - *services to prevent or treat child abuse.*
- A QSOA is a two way agreement – it only allows disclosure between the Part 2 program and the QSO (not other lawful holders)
- A QSO may disclose **Part 2 information with third party contracted agents** helping them provide services described in the QSOA and only as long as the agent only further discloses the information back to the QSO or to the Part 2 program from which it came.
- The QSO becomes a “lawful holder” that has Part 2 information due to an exception

Population Health Management as a Qualified Service

- ***Population Health management***” includes “increasing desired health outcomes and conditions through monitoring and identifying individual patients within a group.
- SAMHSA agrees that patients with SUD “often have comorbid conditions” and “proactive, preventive and chronic care is important to achieving desired outcomes.”
- Any QSOA would be limited to the office or unit responsible for population health management in the organization (for example, the ACO, IDN, CCO or MCO), not the entire organization.

Care coordination and medication management were not added to the list of permissible services offered by a QSO under a QSOA

QSO Agreements -

- The QSO must enter into an **agreement** with the **Part 2 program**
 - The agreement must acknowledge the QSO's obligations to comply with Part 2
 - The QSO must agree to resist in judicial proceedings efforts to obtain access to Part 2 information except as permitted
- Part 2 program can only share **what's necessary** for the QSO to provide the services to the Part 2 program.
- The QSOA can be part of a Business Associates Agreement

Medicaid and QSOs

- Medicaid and other third party payers are not considered Part 2 Programs! Therefore, they can not disclose information to other parties pursuant to a QSOA.
- But Medicaid could be a QSO in agreement with a Part 2 program. The QSOA authorizes communication only between the Part 2 program and the QSO.
- Medicaid or other departments at DHHS could provide QSO services under a QSOA to a Part 2 provider and use an agent to help perform the services.

(Legal Action Center Example: 3/6/18)

A Part 2 Program enters into a QSOA with the state health department so the state health department may provide population health management services to the Part 2 Program. In this example, only the state health department employees engaged in providing population health management services can access the information.

QSOA Disclosure Flow



Payment and Health Care Operations by Consent

- Patients can now consent to sharing Part 2 information with third party payers for purposes of “payment and health care operations”
- With consent, third party payers and their agents can access the Part 2 information for such purposes.
- In addition, if a lawful holder has the Part 2 information by consent, it too can share with agents for purposes of payment and health care operations.
- The 2018 rules also clarified when a third party can be identified in a consent in order to allow for the disclosure of Part 2 records generally to “all of my mental health care providers”.

Exchange + General Designation of Treating Providers

- Third Party plus a General Designation that may include “all treatment providers”
- The Third Party exchange has added responsibilities to ensure the authorized providers only receive Part 2 information
- Third Party exchange has responsibility to maintain list of entities disclosed to.
- Third Party exchange has responsibilities around confidentiality of records under Part 2
- Part 2 patient must be notified on the consent of the “right” to receive a disclosure list
- Disclosures must be made with appropriate notice of prohibition on redisclosure.

Next Session

- Finding pathways!
 - Audit and Evaluation pathways
 - QSO pathways
 - Consent options: payment and health care operations
 - What could be accomplished by universal consent language?



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