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

42 CFR PART 2 INTEGRATED DELIVERY SYSTEMS AND CONFIDENTIALITY ISSUES MARCH 27, 2018

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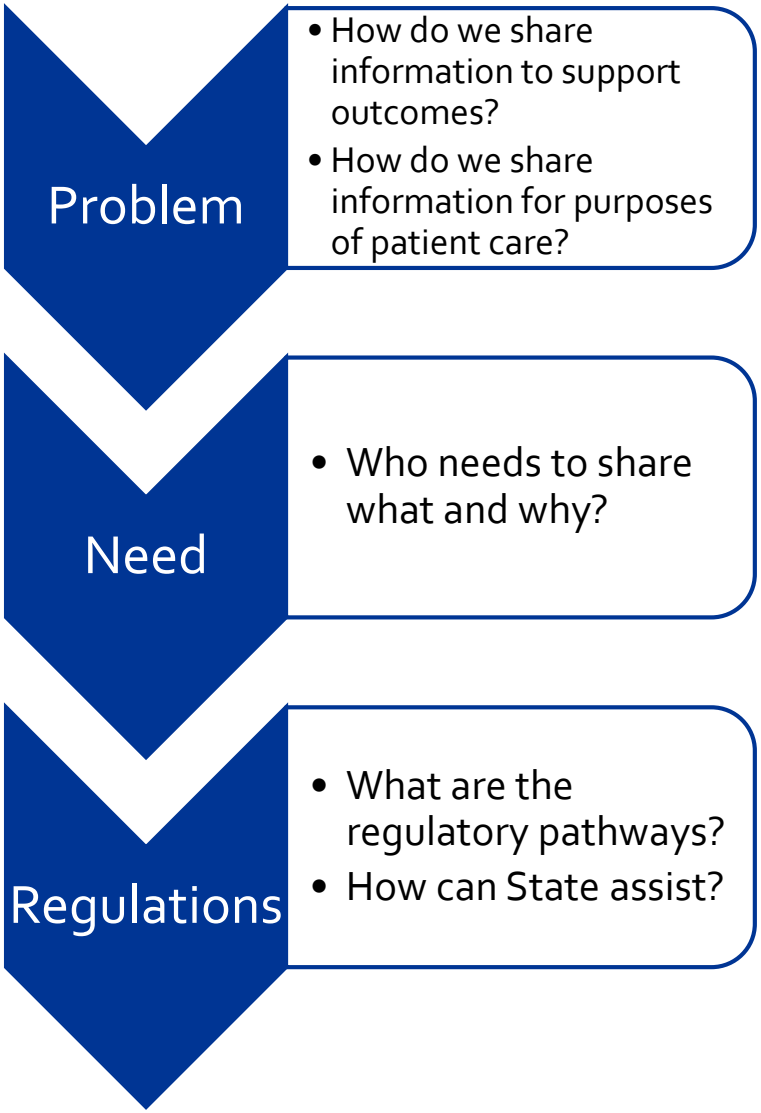
Why are we here?

- 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 providng educational and technical assistance that should not take the place of legal advice.



Part 2 2018 Timeline

Review 2017 Bootcamp Materials

July 13th Webinar

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 regulatory pathways available
- Hear from vendors
- Identify unmet needs

Future Sessions

Today's Agenda

- Introduction and Synthesis review
- Audit and Evaluation Practical Application and Full Group Discussion
- 2018 Consent Exceptions
- Shared Care Planning Practical Application and Full Group Discussion
- Questions and Closing Remarks

Goals of Session 1

1) Level set on 42 CFR Part 2 rule changes published January 3, 2018

2) Ask participants to consider current "information flow" needs and dream needs

3) Establish regulatory "funnel". Highlight Part 2 exceptions that allow for disclosures without consent

4) Help map the state evaluation data/information flow needs and regulatory pathway

5) Highlight next exceptions without consent and send IDNs off with flow homework

Goal of Session 2

1) Provide necessary deeper learning around 2018 changes
2) Synthesize information/data flows from last session
3) Finalize review of Audit and Evaluation Information Flow and discuss next steps
4) Review consent exceptions and regulatory pathways post 2018
5) Provide examples from Region 1 of CMT pathway
6) Identify unmet needs

Remember assumptions!

Regulatory Reminder: First steps

Question

- Who is a Part 2 Program?
- Who are the Part 2 patients?
- Who are the lawful holders?

Question

- Who is disclosing or re-disclosing Part 2 information?
- To Whom?

Question

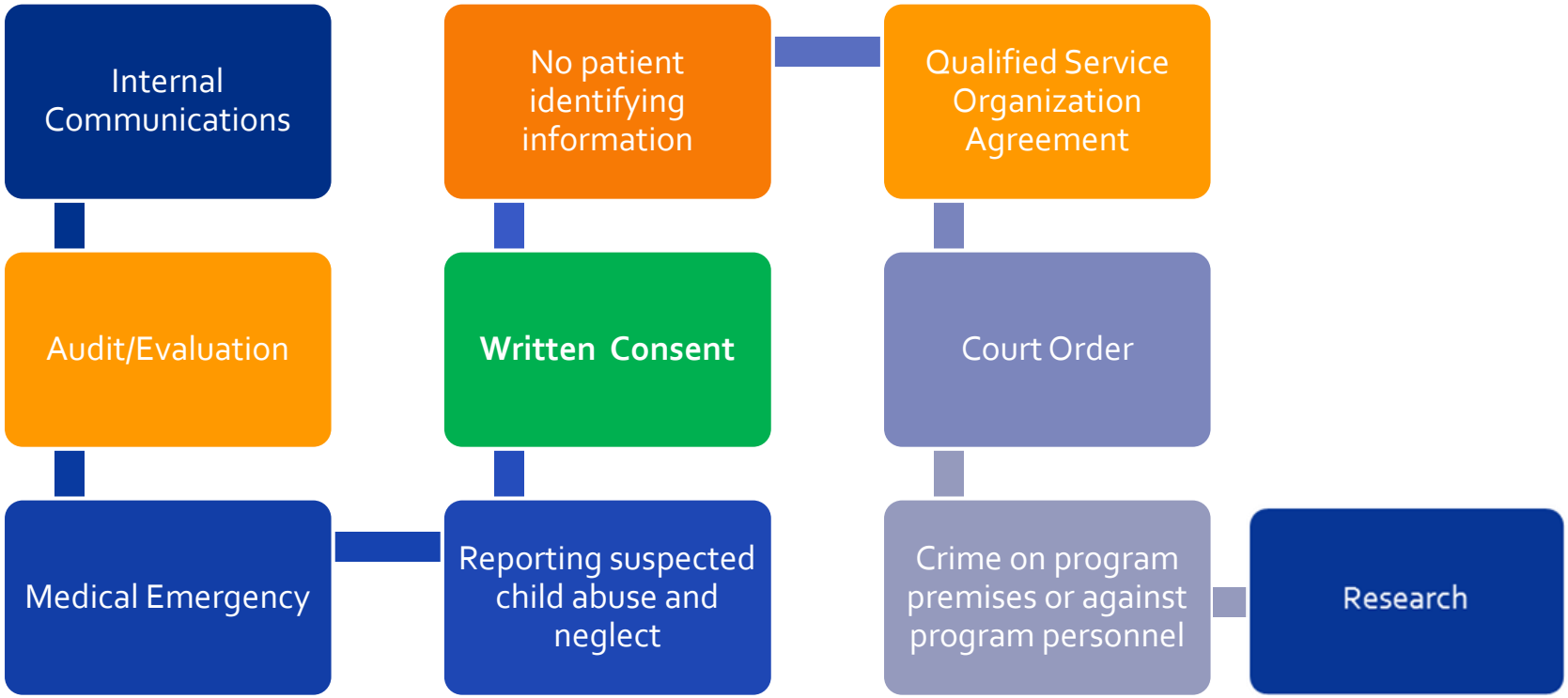
- What is the purpose of the disclosure or re-disclosure?
- What exception allows you to disclose or redisclose Part 2 information?
- Compliance obligations?

Summary of Synthesis

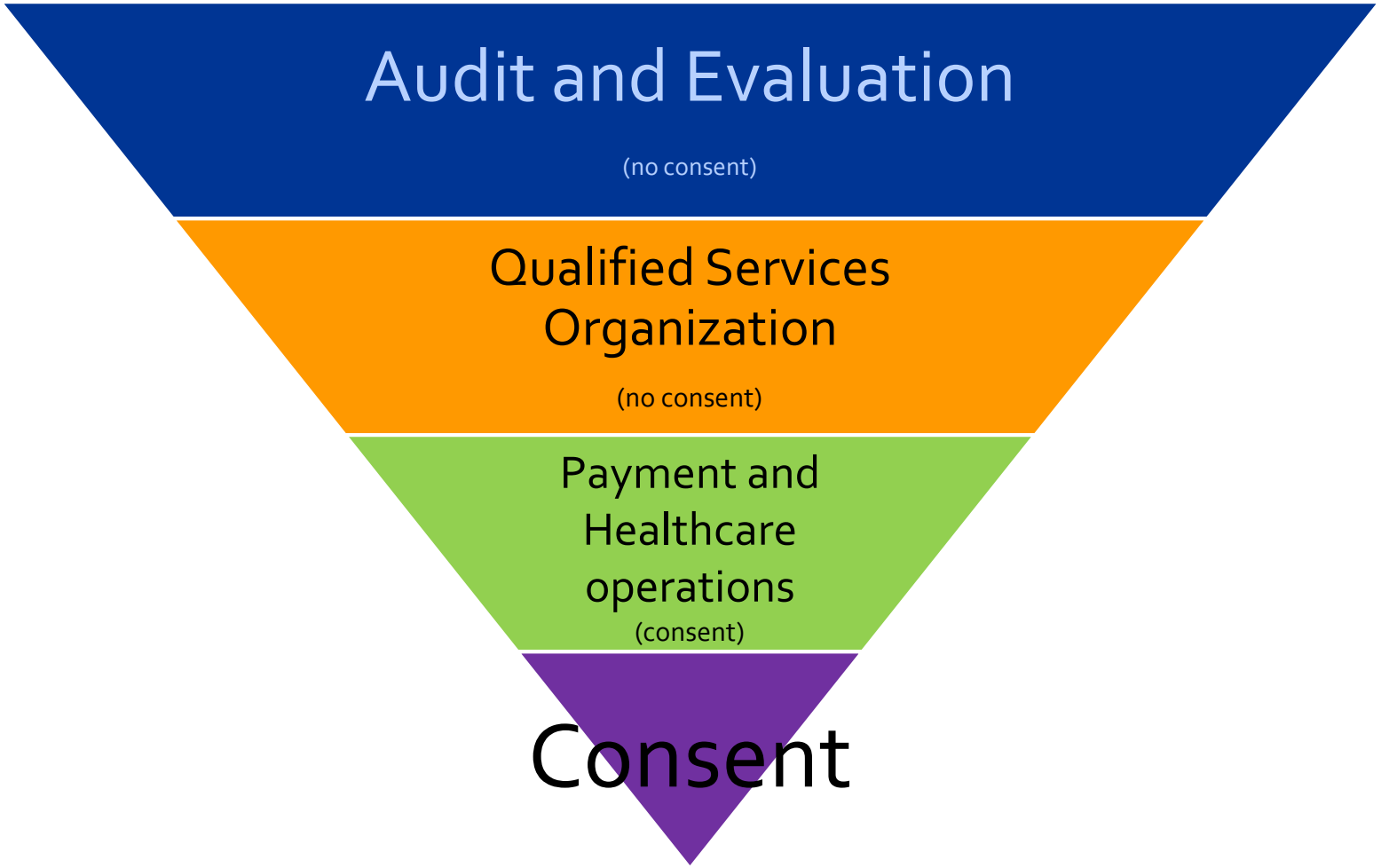
- Review excel document
- Highlight issues for today's discussion

PART 2 EXCEPTION FUNNEL

NO Disclosure Unless Part 2 Exception



Part 2 Exception Funnel



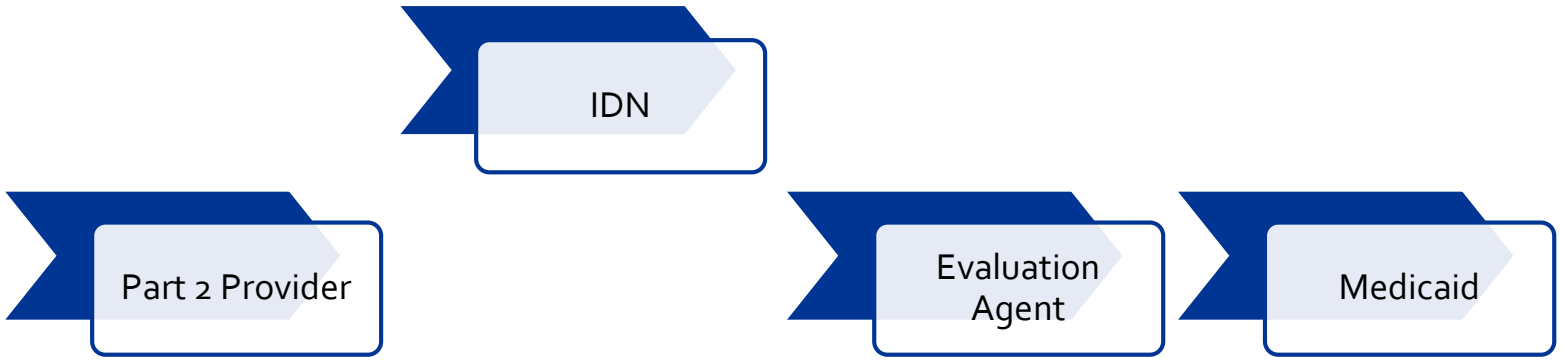
AUDIT AND EVALUATION DETAILS

Audit and Evaluation

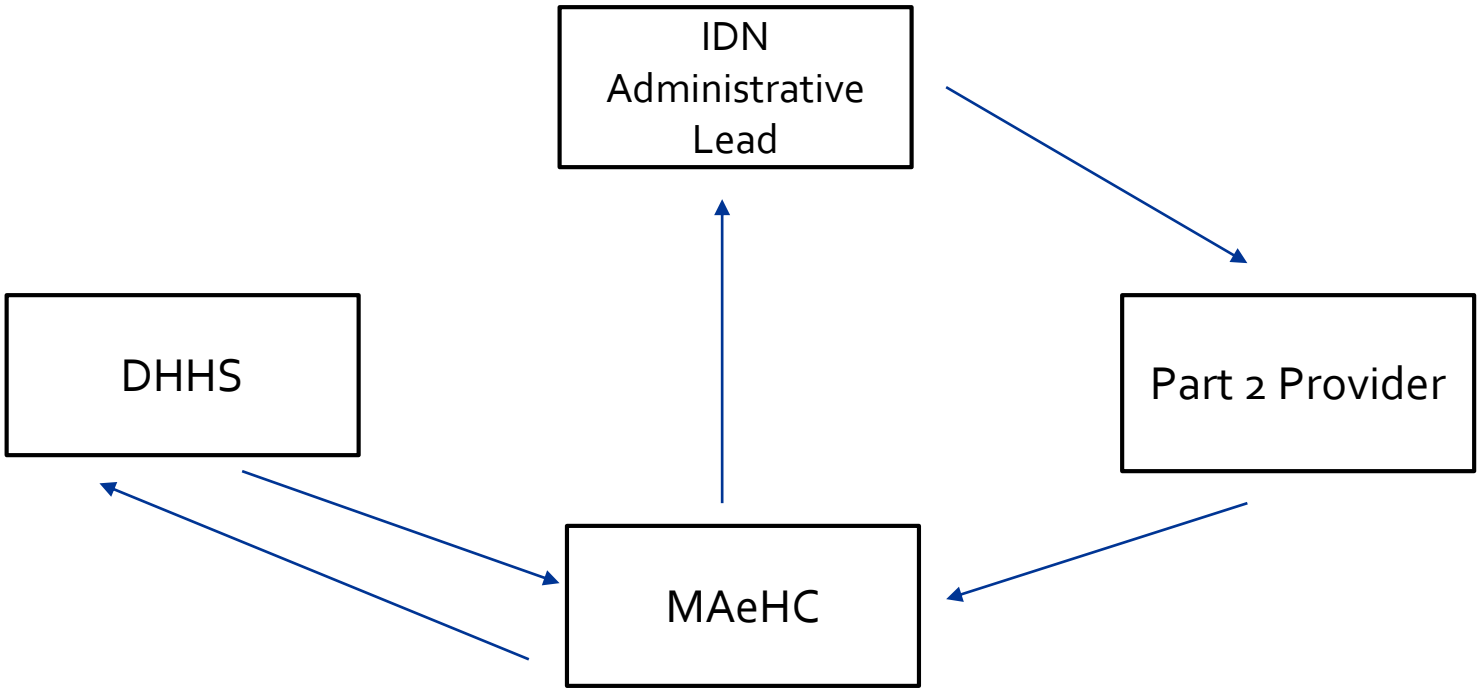
Audit and Evaluation Exception allows Part 2 programs and other lawful holders to disclose Part 2 information without patient consent to comply with audit or evaluation requests by State, IDN (as CMS regulated entity)or their agents.

- SAMHSA "recognizes" that state government often needs to access records, including of Part 2 programs, held by entities they regulate in order to evaluate compliance.."
- Agents can conduct the audit
- CMS-Regulated entities can engage in evaluation process as well
- Part 2 providers and other lawful holders are permitted to make disclosures for audit and evaluation purposes

A&E Disclosure Flow



DSRIP Evaluation Example Revisited



Live Show Clean-up

An entity conducting the evaluation must…

- Maintain and destroy the patient identifying information consistent with the confidentiality policies and procedures required under the rules
- Retain the records in compliance with applicable laws
- Comply with limitations on disclosure including:
  1) Providing information only back to the Part 2 program or lawful holder it came from
  2) Using information only for purposes of audit or evaluation

IDNs as CMS-Regulated Entities

Examples of circumstances that make an entity CMS-regulated:

- ✓Organization is required to meet CMS audit and evaluation requirements
- ✓Direct supervision by CMS through DHHS waiver
- ✓CMS established regulations governing conduct or qualification through STCs and waiver agreements
- *CMS approval of state plans or waivers establishing and governing entity like an IDN (for Medicaid and CHIP)*

• 42 CFR Part 2 Final Rule, January 18, 2017, p. 6103.

The 2018 Rules allow for "CMS Regulated Entities" like an ACO or 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.
- **Does the IDN have in place…? (all are required):**
  1) Administrative and/or clinical systems; and
  2) A leadership and management structure (including a governing body and CEO) who oversees management and CMS agreement compliance); ***and***

IDN Evaluation cont.

3) A signed participation agreement with CMS/DHHS (or similar document), stating (all are required):

- It is subject to periodic evaluations by CMS/State/agent to ensure entity meets certain quality and cost measures; and
- It has designated an Executive with authority to bind the organization to: (a) confidentiality obligations (including Part 2) and (b) conditions of the participation/waiver agreement; and
- The audit or evaluation involving patient identifying information occurs in a confidential and controlled setting approved by the designated executive;
- Reports or other documents resulting from evaluation do not allow for direct or indirect identification of a patient as having or having had a substance use disorder;
- Must establish polices and procedures to protect the confidentiality of identifying information consistent with Part 2 and only for purposes of the evaluation.

Compliance Tips

- Confidentiality Policies and procedures
- Identify staff for purposes of evaluation process and health information/data exchange
- Implement security safeguards consistent with rules
- Develop capability to ensure any disclosures to agents or state include "prohibition against re-disclosure notice"
- Check agreements for appropriate "purpose", Part 2 language and appropriate notices.

2018 PART 2 DETAILS

Emergencies and Consent Exceptions

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.

NH Rules Apply

- He-M 309.05:Rights of patients receiving services from a CMHC
- (f)(4) allows information to be released to the department for evaluation and other monitoring and planning functions.
- Information can be released by consent

Part 2 Medical Emergency Exception (§2.51) - Comparison

Old Standard (pre-2017 Final Rule)	New Standard (post-2017 Final Rule)
Immediate threat to health + Immediate intervention required Patient identifying information may be disclosed without consent to medical personnel in need	Bona fide medical emergency + Consent cannot be obtained Patient identifying information may be disclosed without consent to medical personnel in need

Medical Emergency (§2.51) - Determination

Bona fide medical emergency + consent cannot be obtained = patient information MAY be disclosed to medical personnel with need

Bona Fide Medical Emergency

- Determination made by any health care provider treating the patient for the medical emergency
- The new rule gives providers more discretion in determination
  - ER visit does NOT automatically equal an emergency

Consent Cannot be Obtained

- The patient must be incapable of consenting, not refusing to consent
  - If the patient refuses to consent then patient identifying information CANNOT be shared under the medical emergency exception
  - Examples of when prior informed consent cannot be obtained: not legally competent, involuntary commitment

Medical Emergency (§2.51) - Documentation

- Immediately following disclosure the Part 2 program must document *in writing*:
  - Who received the information? Name and Affiliation
  - Who Disclosed the Information? Name
  - When did the disclosure happen? Date and Time
  - Why was the information disclosed? Nature of emergency

Changes to the Consent Provisions

- Payment and health care operations
- General designation flexibility

Consent Basics:

When there is a disclosure of information that could include Part 2 information from a Part 2 provider or lawful holder, ask:

- To Whom
- Purpose
- Amount and Kind

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** 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"

Patient Consent: Elements (2.31)

Part 2 Consents (2.31)

- In writing (paper or electronic)
- Name of the patient
- Name of the entities or individuals making the disclosure (either because they are a Part 2 provider or because they have SUD/Part 2 records)
- Description of **how much** and **what kind** of information is to be disclosed
- "***To Whom***" the disclosure will be made:
  - Name
  - Entities with treating provider relationships
  - Third party payers
  - Name of entity that facilitates exchange of information & general designation of type of treating providers
- ***Purpose*** of the disclosure
- Patient right to revoke unless consent already acted upon
- Expiration date
- Patient signature (electronic signature allowed)

Lawful holders who receive Part 2 information pursuant to a consent can now disclose such records for "payment and health care operations" to agents. (2.33)(1/18)(p. 243)

- Lawful holder who has Part 2 information pursuant to a consent
- Can disclose Part 2 information for payment and health care operations.
- Can disclose to lawful contractors, subcontractors or legal representative to carry out payment and/or health care operations on behalf of the lawful holder.

E.g., A hospital who receives Part 2 information pursuant to a consent can disclose information for purposes of quality assessment or incident review.

E.g., a third party payer who receives the information pursuant to a consent can disclose to agents for utilization review.

Optional Consent Language:

"…to my third party payer, [Medicaid MCO] and the NH Department of Health and Human Services, including for payment and health care operations."

Health Care and Payment Operations (list)

1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;

(2) Clinical professional support services (*e.g.*, quality assessment and improvement; initiatives, utilization review and management services);

(3) Patient safety activities;

(4) Activities pertaining to:
- (i) The training of student trainees and health care professionals;
- (ii) The assessment of practitioner competencies;
- (iii) The assessment of provider and/or health plan performance;
- (iv) Training of non-health care professionals;

(5) Accreditation, certification, licensing, or credentialing activities;

(6) Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;

(7) Third-party liability coverage;

Health Care and Payment Operations (list)

(8) Activities related to addressing fraud, waste and abuse;

(9) Conducting or arranging for medical review, legal services, and auditing functions;

(10) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;

(11) Business management and general administrative activities, including, but not limited to, management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;

(12) Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;

(13) Resolution of internal grievances;

(14) The sale, transfer, merger, consolidation, or dissolution of an organization;

(15) Determinations of eligibility or coverage (*e.g.* coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(16) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(17) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.

Appropriate **Legal Document** Must be Created

- Lawful holders have **2 years** to enter into appropriate legal documentation with agents for payment and health care operations. Section 2.33
- Information disclosed must be limited to that which is necessary to carry out purpose of disclosure.
- Legal Documents must provide that contractor/agent is:

1) Fully bound by provisions of Part 2 upon receipt of the patient identifying information.
2) Informed of the Part 2 "prohibition on re-disclosure notice"
3) Must implement appropriate safeguards to prevent unauthorized uses and disclosures;
4) Must report any unauthorized uses, disclosures or breaches of patient identifying information to the lawful holder.
5) Prohibited from re-disclosing to other agents unless they are contracted to perform the payment/health care operations functions for lawful holder or lawful holder agent.

"To Whom" 2018

"To Whom"	Allows for disclosure to…
Individual's Name	Third Party (This designation must be used for any third party who is not a treating provider)
Entity's Name	Treating providers at entity
Third Party Payer's Entity Name "for payment and health care operations"	Third party payer for payment and health care operations. Lawful holder and agents for P&HCO
Third party entity & 1) Names of individuals 2) Participating treating providers 3) General designation of "treating providers"	Treating providers through an information exchange **remember past present & future*

3P Entity Exchange & General Designation

- Allows for a third party exchange to provide information to generally designated treating providers.
- **Consent language option**:

"All of my health information including my substance use disorder treatment information to all of my past, present and/or future treating providers who participate in the [NH Exchange]"

"All of my health information including my SUD treatment information to the ACO Exchange, Best NH Hospital, Dr. Suzie Q, and Ortho Heaven"

Consent to Exchange with Treating Providers

- 'I understand and agree disclosures and re-disclosures both verbally and in writing of my health information including my mental health and substance use disorder information may be made to and by my past, current and/or future treating providers for the purpose of *my ongoing treatment and recovery and helping me manage my care*, through the [IDN as an Exchange] or [CMT as an Exchange].'
- 'I understand that I have the right to ask [Name at the Information Exchange] to give me a list of entities to which my information has been disclosed.'
- To Whom? Purpose? Amount and Kind?

When using an Exchange

- Exchange must confirm disclosures consistent with general designation
- Exchange must provide patient a list if requested of disclosures
- Part 2 patient must be notified on the consent form of the "right" to receive a disclosure list
- Disclosures must be made with appropriate notice of prohibition on re-disclosure
- Exchange must meet all confidentiality obligations required by Part 2 and the law.

Care Coordination and Case Management – Clinical not administrative functions under Part 2

- Care coordination and case management functions are considered clinical care functions by SAMHSA
- Part 2 information can't be shared with a care manager or for care management reasons to another treating provider under a QSO
- A third party payer can't use Part 2 information to engage in direct care management with a patient even under the "payment and health care operations" exception
- SAMHSA understands the risks of excluding case or care management from the definition and will be "convening relevant stakeholders to determine the effects of 42 CFR part 2 on patient care, health outcomes and patient privacy"
- In order for the IDN or its agents to share Part 2 information received by the state with Part 2 providers for purposes of care management, case management or patient care, a specific patient consent identifying the treating provider entity must be used

"Care coordination has a patient treatment component" ~SAMHSA

- Disclosures by lawful holders pursuant to payment consent does NOT allow disclosures for substance use disorder patient diagnosis, treatment or referral for treatment
- QSOs can NOT be used to disclose information for care coordination or care management services
- "SAMHSA believes it is important to maintain patient choice in disclosing information to health care providers with whom patients have direct contact"
- **Care coordination and case management are considered clinical care, and NOT health care operations or QSO activities**

Region 1-IDN Flow Show

Wrap Up

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