

Part 2 Data Governance Meeting

Vermont Health Information Exchange (VHIE)

Prepared for the Part 2 Data Governance Group

5/16/2023

Shared Values and Goals

- Ensuring access and minimal barriers to services for all Vermonters
- Clear and shared understanding of governance process
- We will establish data governance prior to any data being sent
- Patients are at the center of their health data – all individuals can make informed decisions about the use of their health data
- Policy makers / payers are able to assess value of programs and adapt to changing needs
- AHS will not share data with law enforcement or anyone else

Agenda

- Level-setting/training/education on Part 2 provisions [*John W., VITL Legal*]
 - [Session will be ***recorded*** by VITL]
- Discussion
- Planning for Upcoming Meetings

ATTORNEYS
AT LAW

PRIMMER PIPER
EGGLESTON &
CRAMER PC

Part 2 Substance Use Disorder Confidentiality An Operational Overview

May 16__, 2023

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Goals

1. Develop a shared understanding of how the Part 2 Substance Use Disorder (SUD) Confidentiality Rule affects
 - access,
 - use,
 - disclosure, and
 - redisclosure.of Part 2 records
2. Identify questions for further discussion.

AGENDA

1. Background of the Part 2 Rule – From 1970 to present
2. What is a Part 2 Program?
3. What is a Part 2 Record?
4. What is a Part 2 Lawful Holder?
5. What are the Consent Requirements and Exceptions?
6. Part 2 Information on an HIE.

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Historical Background of the Part 2 Rule

Legislative Historical Background

- Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act, 1970, amended 1974 (The Hughes Act)
- Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972
 - Protect confidentiality for people seeking treatment
- CARES Act 2020

Part 2 Rule – Policy Interests

US Dept of Health, Education and Welfare, 1975

- Confidentiality of Alcohol and Drug Abuse Records 42 CFR Part 2

Strict confidentiality

encourage people to seek treatment by reducing risks in participating in treatment

- Criminal prosecution
- Loss of child custody/parental rights
- Loss of housing
- Loss of employment

Different Policy Interests

Health Ins. Portability and Accountability (HIPAA)

- **Patients do not control** access, use and disclosures for Treatment, Payment, or Health Care Operations (TPO)
- Protect confidentiality, accessibility, and integrity of PHI
- Patient authorization required for disclosures other than TPO, with exceptions.

Part 2

- **Patients control** access, use and disclosure
- Protect confidentiality from stigma associated with treatment
- Consent required for almost all disclosures and redisclosures, with limited exceptions

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What is a Part 2 Program

Part 2 Program

1. Federally assisted
 - Receive federal grants;
 - Participate in state or federal health programs; or
 - Receive tax deductions or are tax-exempt; **and are**
2. SUD Provider: How entity **holds itself out**
 - a. Individual or entity (other than a general medical facility) that **holds itself** out as providing SUD diagnosis, treatment or referral
 - b. An **identified unit** within a general medical facility that **holds itself out** as providing SUD dx, tx, referral; or
 - c. Staff in a general medical facility **whose primary function** is identified as providing SUD dx, tx, or referral



SCENARIO 1: OPIOID TREATMENT PROGRAM

ABC Treatment Center



Dr. Van Buren

**Charlie's
SUD Info**



Primary Care Office



Dr. Harrison



Consent Form
✓ *Dr. Harrison*

Charlie

General medical facility – Not a Part 2 Program

Primary Care Office



Dr. Harrison

- Integrated care setting
- Provides a variety of services may include MAT, SUD counseling
- **Clinicians** that provide SUD diagnosis, treatment, or referral **do not identify** their **primary or principal function as SUD**

General medical facility – Unintentional Part 2

Primary Care Office



Dr. Harrison

Website and signage

- Identified psychiatrist with subspecialty in addiction psychiatry
- MD's only service listed SUD diagnosis, and treatment
- Two LADCs with a primary function to provide SUD counseling

Whether Part 2 applies based on decision of how organization

- holds itself out, and/or
- defines individual's primary function

General medical facility - Emergency Dept

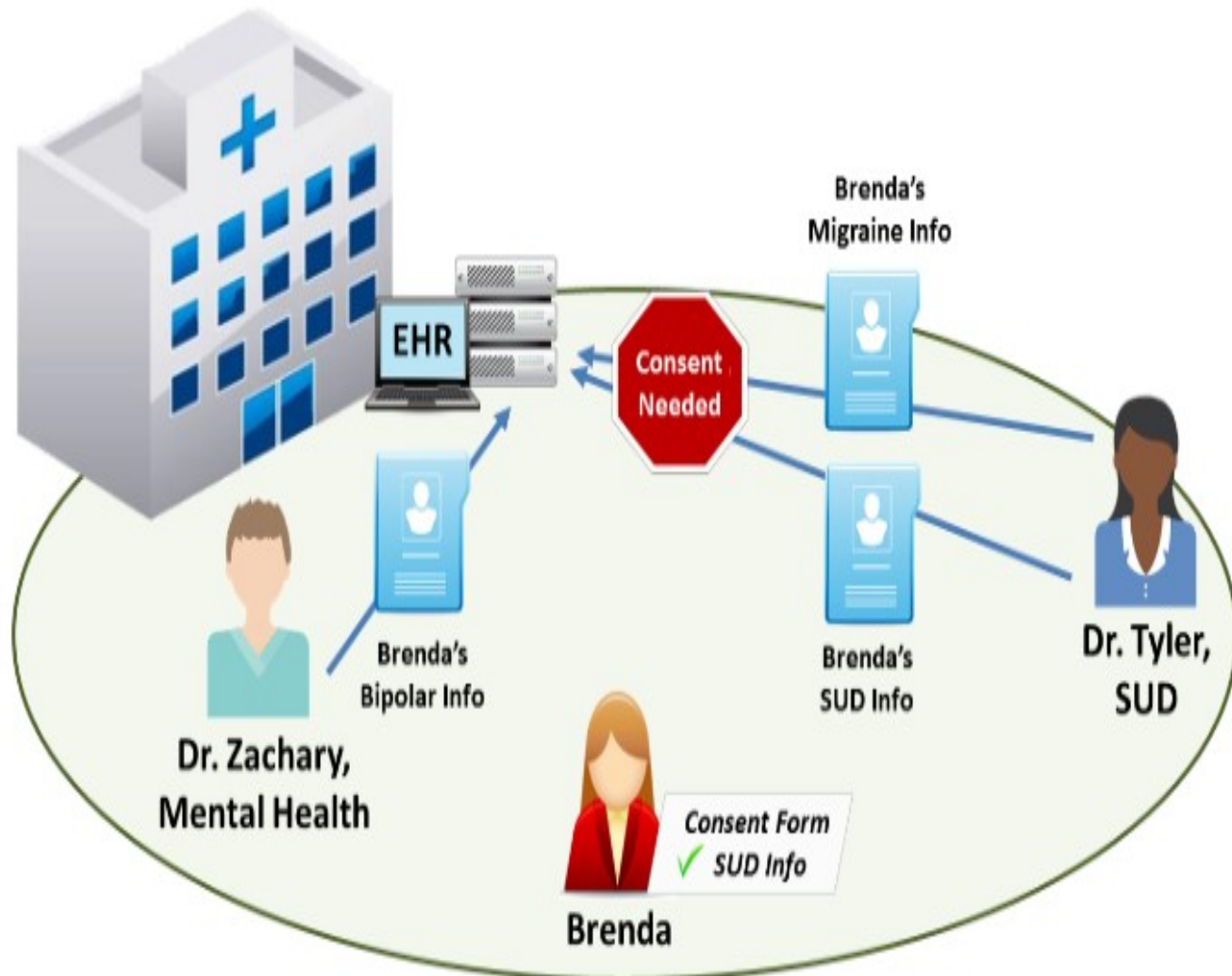
Screening, Brief Intervention, and Referral to Treatment (SBIRT)

Screen people who may have a SUD

- **LADC** - Primary function is to provide SUD assessment, treatment, and referral
 - Part 2 Program (need to segregate documentation not co-mingled)
- **RN, PA, SW(LADC)** – SBIRT incorporated into other clinical assessments so that SBIRT not primary function
 - not Part 2, record of assessment and referral part of medical record

SCENARIO 2: MIXED-USE FACILITY

Acme Community Mental Health Center



Dr. Tyler is the Part 2 Program

- Patient consent required for use and disclosure outside of the Program (Dr. Tyler)
- All records that connect Dr. Tyler (program) to a patient are Part 2 records
- Challenge for CMHC to segregate Part 2 Records
- Confirm consent or exception for every disclosure
 - Respond to subpoenas
 - Provide redisclosure notice with records



With Charlie's consent, Dr. Van Buren Charlie's SUD provider may discuss Charlie's SUD treatment with his primary care provider Dr. Harrison.



Dr. Van Buren
SUD provider



Dr. Harrison
PCP

Documentation that Dr. Harrison generates regarding Charlie's SUD, and his treatment based on Dr. Van Buren's and Charlie's oral statements, or information viewed, is not a Part 2 record. (Can't incorporate or transcribe records)

Documentation that Dr. Van Buren generates and discloses to Dr. Harrison retains its characteristics as a Part 2 record, and may be segregated from PHI

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**What is a
Part 2
Record ?**

Part 2 Record

- Information (recorded or not)
- Created, by, received, or acquired **by a Part 2 Program**
- **Relates to a patient**
- **Patient identifying information**
 - Name, address, SSN, photo, or similar info where identity can be determined with reasonable accuracy and speed, or by reference to other publicly available information
 - Does not include internal numbers (MRN) assigned by a program that do not contain numbers (such as SSN or DLN) that could be used to identify a patient with external sources

Records, other than verbal communications for treatment

- Transmitted from a Part 2 Program to a non-part 2 provider
- Retain their characteristics as a part 2 record

SUD Diagnosis Information is a Part 2 Record:

- Any record reflecting a diagnosis identifying a patient as having a SUD; and
- Initially prepared by a Part 2 provider in connection with treatment or referral.
 - Connection between diagnosis and Part 2 Program
 - Retains its characteristics as a Part 2 record

HIPAA and PHI

Any information

- Created or received by a CE or BA
- That relates to past, present, or future of an individual's
 - Physical or mental health condition
 - Provision of health care
 - Payment

PHI = Something to do with health care &_ an individual

E.g. MRN and a provider number = PHI

HIPAA

PII + something about their health care

Part 2

PII + Part 2 Program (diagnosis, tx, or referral)

HIPAA

- Protects information received or created by covered entities (CE) and business associates (BA)
- Regulates CEs and BAs
- Enforcement limited to CEs and BA

Part 2

- Protects records that identify an individual seeking/receiving SUD tx from a Part 2 program
- Regulates SUD patient records from Part 2 programs
- Criminal enforcement for wrongful disclosure, redisclosure, or acknowledging that an individual is a patient in a program applies to Part 2 Program and Lawful Holders

The difference

→ Part 2 protections, obligations, and risks flow with the data to all subsequent holders who receive notice of prohibition on redisclosure

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What is a Part 2 Lawful Holder?

Lawful Holder

An individual or entity who has received a Part 2 record based on patient consent or an exception,

- Recipients are notified of prohibition on re-disclosure w/out consent:
 - Primary care provider
 - Health insurance company
 - Government agency – audit and evaluation
 - Research entity
 - But not another Part 2 program

Notice of Prohibition on Re-Disclosure

To prevent unauthorized re-disclosure, all SUD records must be accompanied with one of the following notices

(1) This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65.

(2) 42 CFR Part 2 prohibits unauthorized disclosure of these records

Part 2 Requirements for Programs and Lawful Holders

1. Security polices for Part 2 records
2. Notice of privacy rights
3. Non redisclosure notices when Part 2 records are disclosed with consent
4. Consent forms

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**What are the
consent
requirements
and
exceptions?**

Need to understand the Consent requirements

Confusion regarding HIPAA authorization requirements

Still common for mental health providers to

- Include in forms and notices of privacy practices that they won't disclose records without patient consent
- obtain patient authorization before disclosing records to other treatment providers
- In Vermont, confusion is due in part to an interpretation of the physician-patient privilege before 2017

Part 2 Consent (Form must have 9 elements)

Consent to Disclosure: To Whom

- Name or title of the individual or entity **to whom** Part 2 information can be disclosed, and re-disclosed (before 2020 ltd to individuals)
- Specify purpose of use, and disclosure of Part 2 information
- Specify amount and kind of information to disclose
- Health Information Exchange
 - Names of participating individuals or entities, or
 - **General designation** of participants that is limited to treating providers
 - Notice to patients that they have a right to be provided a list of entities to which their information has been disclosed within the last 2 years

Disclosures with written consent

- Part 2 program may disclose records in accordance with consent to any person, category of persons, or as generally designated in the consent
- Disclosures for payment or health care operations limited to what is necessary for the purpose described in the consent
- Permissible payment or operations includes (18 activities)
 - Billing, claims management, data processing
 - Quality assessment and improvement, utilization review/mgmt.
 - Accreditation, certification, licensing,
 - Health insurance contracting
 - Care coordination and case management

- **Disclosures to a Qualified Service Organization (QSO)**
 - QSO provides services to a Part 2 Program such as billing, accounting, staffing, lab analysis, legal services, HIE
 - Part 2 program may disclose information to a QSO, w/out patient consent if there is a written agreement (QSOA) authorizing the disclosure, and obligates QSO to resist disclosures for judicial proceedings.
 - QSOA similar to Business Associate Agreement (BAA)
 - **Proposed rule:**
 - BA will also be a QSO for information that is both PHI and Part 2
 - BAA sufficient for both PHI and Part 2 records
 - QSO could re-disclose Part 2 information to 3rd parties eg other QSO

Part 2 for minor patients

Vermont law – 12 years of age or older – 18 VSA 4226

- May consent to alcohol or drug treatment that is ordered by a physician
- Physician obligated to notify parents if immediate hospitalization is required

Part 2 – Minor patient has authority to consent to or withhold consent for disclosure and use of Part 2 information

- Part 2 program may condition treatment upon minor providing consent for disclosure necessary to obtain reimbursement
 - Eg EOB to primary insured
- Part 2 program is not required to provide treatment to minor

Disclosures w/out Patient Consent (3 exceptions)

- **Medical emergencies, Research**
- **Audit and Evaluation:** A Part 2 Program may disclose records w/out consent to:
 - Medicare/Medicaid, ACO or CMS regulated entity, or
 - Government agency that provides financial assistance, or regulates a Part 2 Program for the purposes of:
 - Improving outcomes and care,
 - Ensuring resources are managed effectively,
 - Adjusting payment policies,
 - Reviewing the appropriateness of medical care, medical necessity, and utilization, quality assurance

CARES Act 2020 § 3221, align Part 2 TPO with HIPAA

Requires HHS to revise Part 2 regulations* to include:

- General consent for all future uses and disclosures for TPO in accordance with HIPAA.
- With patient consent, Part 2 Program, CE, BA may use, disclose, and redisclose for TPO in the same manner as HIPAA
- Authorize disclosure of de-identified records for public health purposes.

*§ 3221 Cares Act amends authorizing legislation for Part 2 and HIPAA, and requires HHS to revise regulations to implement and enforce the amendments made by § 3221

- Cares Act changes are not effective w/out final implementing regulations

Part 2 Proposed Rule, Dec. 2, 2022

Single Patient Consent

- Patient may **consent to all future TPO uses, disclosures, and redisclosures** among Part 2 programs, CEs, and BAs
- To Whom – expanded consent to disclosures to:
 - “My treating providers, health plans, third-party payers, and people helping to operate this program”

Allows Part 2 programs to obtain comprehensive consent for future TPO

- Condition treatment on completion of general consent
- Allows use and disclosure for TPO like any other PHI, but
- Need to be able to identify and protect records from use in legal proceedings (maintains need to segment records)

Patient Rights under the current and proposed rule:

Current: patients may determine to whom records may be disclosed, even for TPO

Proposed: Patients may request restrictions in disclosures including for TPO, but Part 2 programs would not be required to agree.

- Guidance: encouraged to make reasonable effort to the extent feasible to comply with request.
- Right to obtain restrictions on disclosures to health plans for services paid in full.

Complexity:

- A recipient of information would need to know, and follow any limitations of patient's consent

Limitations on Disclosures

Part 2 Programs, CEs, other legal holders are prohibited from disclosing records to be used against a patient in any legal proceeding against a patient absent patient consent or a Part 2 court order (more than an subpoena signed by a judge)

- Disclosure must be necessary to protect life or serious bodily injury; or
- Criminal prosecution
- Part 2 Program must resist non-compliant court order
- **Proposed rule:** Public interest and need for information must outweigh potential injury to patient, physician-patient relationship, and treatment services

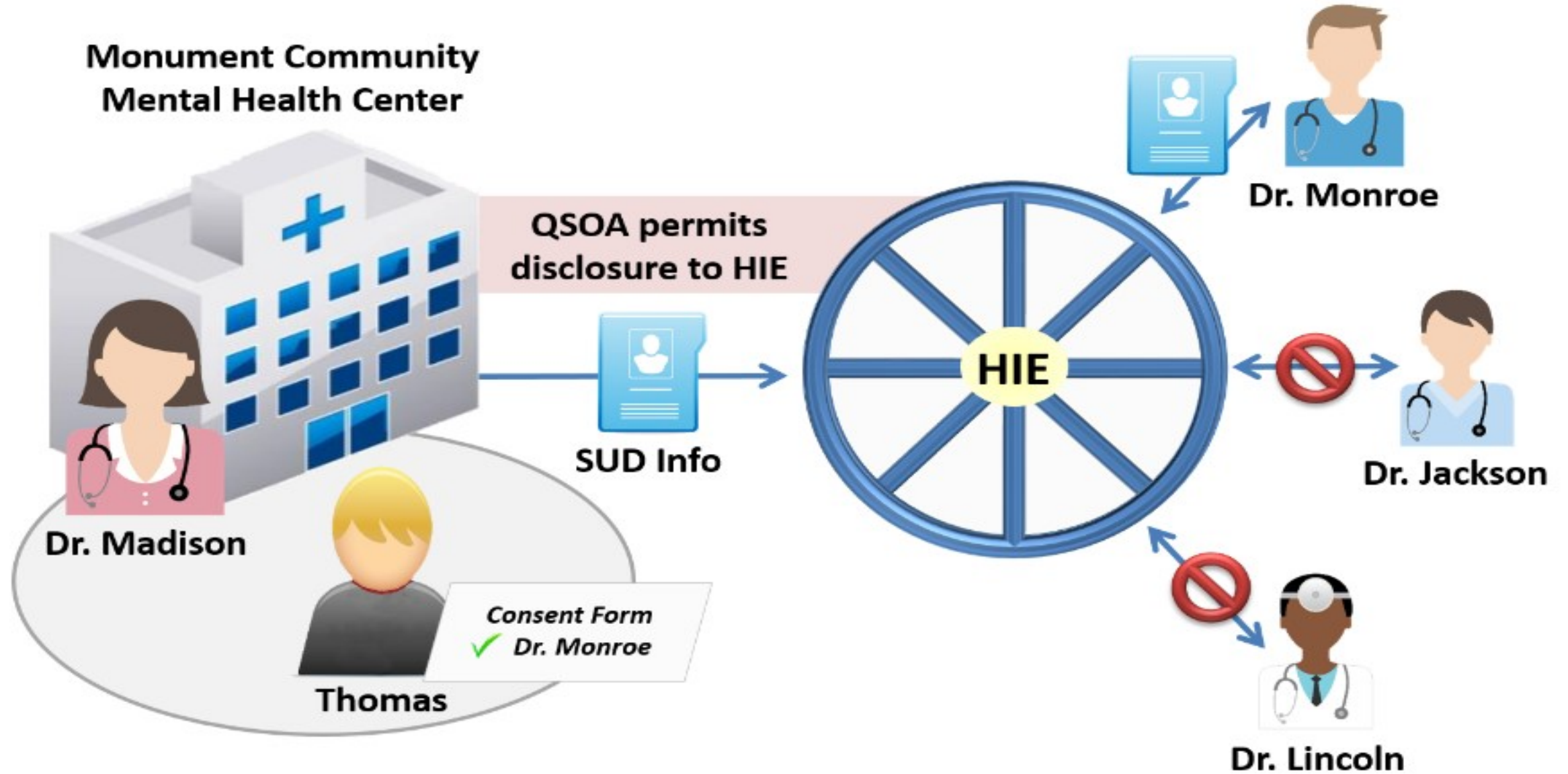
Requirement to identify and protect Part 2 records will create a continued need to segment records.

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Part 2 Information on an HIE

Part 2 Records on an HIE

- HIEs with a QSOA may upload Part 2 information without consent, but may not share information w/out consent to disclose information to the recipients.
- If consent is a general designation for treatment providers, HIE would need to confirm treatment relationship of recipients, and that disclosure is for an authorized purpose.
- Intermediaries, such as HIEs, required to provide patients, upon request, list of entities to which patient's information has been disclosed in the past 2 years.



Intermediaries – Proposed rule

Defines intermediary as a person that receives Part 2 records for the purposes of redisclosing records to one or more participants that has a treating relationship with the patient.

- Limits disclosures from intermediaries to recipients who have a treating provider relationship
 - Rule would limit use and disclosure by an intermediary to a greater extent than a business associate
 - Eg. Limitation for treatment excludes use for non-treatment relationship purposes such as operations for care coordination or for payment purposes

Expands the patient's right to receive an accounting of disclosures from 2 to past 3 years.

This presentation is for general informational purposes only and not for the purpose of providing legal or professional advice on a specific issue or problem.

Due to the rapidly changing nature of the law, information contained in these slides may become outdated and is subject to change without notice.

Questions?

Planning for Upcoming Meetings

- **5/30/2023**
 - Consent, Revocation
- **6/13/2023** *[this meeting will be rescheduled to another day due to an in person CMS/AHS/VITL mtg]*
 - Security, Tagging, Record Retention, Record Destruction
- **6/27/2023**
 - Data Quality, Monitoring, KPI/metrics
- In addition to the above, we have also planned to include a [Culture Change topic], to be presented by Kana Enomoto (*former SAMHSA administrator*)