Why do I have to Worry About 42 C.F.R. Part 2?
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Confidentiality of Substance Use Disorder Patient Records

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Agenda

- Regulatory Requirements and Updates
- Program Applicability
- Sharing Health Information
  - Provider’s Perspective
  - Statewide Care Collaboration Network Perspective
Elliot and 42 C.F.R. Part 2

Our Story

- New Hampshire has the 2nd highest opioid-related overdose deaths in the country.
- New Hampshire is one of the states that spends the least amount of funds on treatment per patient.
- Manchester, NH:
  - Estimated population for 2018 is 111,196 individuals
  - 2009 the first year substance use appeared in the Manchester Community Needs Assessment
  - Since 2015 Elliot has seen a 118% increase in Substance Use Disorder (SUD) visits to the emergency department.

Elliot and 42 C.F.R. Part 2

Our Goals

- Unhindered access to care and medications.
- Increased collaboration and support.
- Compliance with applicable privacy rules.
What is 42 C.F.R. Part 2

**Regulatory Basis**
- 42 U.S.C. 290dd-2; 42 C.F.R. Part 2
- Stricter protections for privacy
  - Protect patients from additional vulnerability due to availability of medical record and stigma.
- Separate from HIPAA and HITECH

**What Information is Protected?**
- Any information identifies a patient as having or had a SUD and is information obtained or maintained by a Part 2 Program.

**Who has to protect this Information?**
- Part 2 Programs
- Lawful Holders
- Third Party Payers
- Entities with direct administrative control over a Part 2 Program

What is 42 C.F.R. Part 2

**What is a Part 2 Program?**
- There are two elements:
  - 1. Federally assisted program and
  - 2. a “Program”

**Federally Assisted Program:**
- A program contracted or directly controlled by a federal department or agency.
- Requires a federal license, certification, registration or authorization.
- Supported by federal funds, even if the funds do not directly pay for SUD treatment, diagnosis, or referral
- A program that is granted tax exempt status or allowed tax deductions for contributions by the IRS.
What is 42 C.F.R. Part 2

What is a “Program”

1. Individual/Entity (not a general medical facility) holds self out as providing AND provides SUD diagnosis, treatment or referral for treatment services.

2. An identified unit within a general medical facility that holds self out as providing AND provides SUD diagnosis, treatment or referral for treatment services.

3. Medical personnel or other staff in a general medical facility that has the primary function of providing SUD diagnosis, treatment or referral for treatment services.

What is 42 C.F.R. Part 2

When do Restrictions Not Apply?

- This is different from “exceptions” to the consent requirements.
- There are specific times when the restrictions on use and disclosure do not apply:
  - Communications between or among personnel of a Part 2 Program.
  - Communications between a Part 2 Program and entity with direct administrative control.
  - Qualified Service Organizations (QSO).
  - Crimes committed on premises.
  - Reports of suspected child abuse and neglect.
What is 42 C.F.R. Part 2

**Consent**

- **General Rule:** A written consent is required unless an exception applies.
- **Consent Requirements:**
  - Patient name
  - Purpose of disclosure
  - Patient’s right to revoke
  - Condition for expiration of consent
  - Patient’s signature and date
  - **Amount and Kind**
    - Requires specificity
    - Specific name or general designation of program or person permitted to make the disclosure
    - **Name or title of the individual or name of the organization that disclosure is being made to**
      - “To Whom”

What is 42 C.F.R. Part 2

**Exceptions to Consent Requirement**

(i.e. disclosures w/o consent):

- **Medical Emergencies**
  - May disclose to the extent necessary to meet a bona fide medical emergency for which patient consent cannot be obtained.
  - Must document disclosure in the patient’s record.
- **Research**
- **Audit and Evaluation**
  - Records not copied or removed
  - Copying and/or removal of records
42 C.F.R. Part 2 – The Future

Proposed Bills
- Federal Government has two proposed bills:
  - H.R. 6082 passed the house June 20th 357-57
  - S/ 1850
- H.R. 6082 Overdose Prevention & Patient Safety Act
  - Received in Senate June 21, 2018
  - Senate referred bill to the Committee on Health, Education, Labor, and Pensions
  - Permitted disclosure includes: treatment, payment, and healthcare operations. i.e. more aligned with HIPAA disclosure rules.
  - Breach notification aligned with HIPAA and HITECH
- S. 1850 Protecting Jessica Grubb’s Legacy Act
  - Read by the Senate and referred to the Committee on Health, Education, Labor, and Pensions September 25, 2017
  - Permitted disclosure includes: treatment, payment, and healthcare operations. i.e. more aligned with HIPAA disclosure rules.

State Law
- Is it equal or more restrictive than federal law?
- New Hampshire RSA 330-C

Patient Confidentiality Governance
### Partners Healthcare Governance Structure

**Enterprise workgroup was created with representation from:**
- Office of the General Council
- Compliance
- Information Security
- Medical Records and Health Information Management
- PCPs, Mental Health Clinicians, Emergency Services
- Key EHR Subject Matter Experts

**Workgroup Goals and Objectives**
- To design enterprise standards to support the Epic build and where applicable, support streamlined workflows and provide appropriate privacy and security protocols
- To understand the Epic functionality and determine the best implementation method to achieve compliance with state and federal laws
- Understand dependencies on the clinical content decisions and build, and the impact to provider and staff workflows
- Workgroup recommendations will be presented to Partners eCare Clinical Council and Clinical Steering Committee for approval and to various eCare Governance councils (i.e. HIS, Patient Access) as needed

**42 CFR Decision Approach**
- Review of State and Federal requirements
- Current state review by site to understand what sites were doing to accommodate regulation
- Reviewed future state options

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### Patient Confidentiality Levels
### Epic Confidentiality Levels

<table>
<thead>
<tr>
<th>Level</th>
<th>Data Types</th>
<th>Epic Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Level Information</td>
<td>Name, DOB, Address, Allergies,</td>
<td>Confidential Patient, Confidential Address, Patient Safety Flag (Partial),</td>
</tr>
<tr>
<td>(Demographic and Clinical)</td>
<td>Medications, Problems, Histories</td>
<td>Employee, VIP/VIP FYI flags for patients identified by entity leadership,</td>
</tr>
<tr>
<td></td>
<td>Immunizations, Imaging</td>
<td>42 CFR Encounter</td>
</tr>
<tr>
<td>Encounter Level Information</td>
<td>Encounter, Notes</td>
<td>Private Encounter, Confidential Guarantor, Patient Safety Flag (Partial),</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Break the Glass- Appropriate (Soft Stop Warning), Break the Glass- Inappropriate (Removes encounter), Sensitive Notes</td>
</tr>
<tr>
<td>Order Level Information</td>
<td>Lab Orders, Lab Results</td>
<td>Sensitive Orders</td>
</tr>
</tbody>
</table>

### Clinical Chart Restrictions
Overview of 42CFR Protections

- 42CFR encounters will only be viewable by 42CFR staff, other mental health providers, and ED clinicians

- All 42CFR departments will be removed from the login/change context department list, only users with their site’s 42CFR sub-template will be able to log into that site’s 42CFR departments

- Cadence schedules will be restricted so that users outside of the 42CFR department do not have access

- All users, except those with a 42CFR sub-template, will receive patient level break the glass on patients that have a 42CFR encounter. HIM and billing are also exempt

<table>
<thead>
<tr>
<th>Current State - 42 CFR Encounter Access</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>User</strong></td>
</tr>
<tr>
<td>McLean 42 CFR Users (logged into a McLean 42 CFR dept.)</td>
</tr>
<tr>
<td>McLean Users (logged into any McLean dept.)</td>
</tr>
<tr>
<td>MGH 42 CFR Users (logged into an MGH 42 CFR dept.)</td>
</tr>
<tr>
<td>BWF 42 CFR Users (logged into a BWF 42 CFR dept.)</td>
</tr>
<tr>
<td>NWH 42 CFR Users (logged into an NWH 42 CFR dept.)</td>
</tr>
<tr>
<td>Mental Health Clinicians (with mental health security templates)</td>
</tr>
<tr>
<td>ED Clinicians (with ED security templates)</td>
</tr>
<tr>
<td>PCPs and other clinicians</td>
</tr>
</tbody>
</table>

NOTE: 42 CFR users must have the sites 42 CFR sub-template to log in
42 CFR Final Rule – Announced on 1/13/17

In Summary......
Now allows for the disclosure of patient information with a consent from a Part 2 program to an intermediary such as an HIE, which may then disclose to its participants that have a treating provider relationship with the patient:
- Treating provider name no longer needs to be specified
- However, the HIE must track and provide listing of disclosures to Patient upon request (disclosures for past 2 years)

Other Highlights:
- To Whom (past/present/future treating providers w/o spec identifying them)
- From Whom – allows also for a general designation on consent
- Re-disclosure Prohibition – data that directly or indirectly identifies the pt.
- Medical Emergencies – clarified language to allow for disclosure
- Research – aligns much of the requirements with HIPAA and Common Rule
- Patient Identifying Information – will need to assess the data in context of the Part 2 program
- Qualified Service Organization – CM requires consent; expanded uses to include PHM
- Other Consent Provisions – may extend for a period of time or until the expiration of an event. (Patient death?)
- What was Not Included – does not align permitted disclosures with HIPAA

42 CFR - Pilot based on Final Rule

What’s changing?
- Currently, Epic users, who work outside of 42 CFR Practices cannot see these encounters, except mental health and emergency department clinicians
- Starting 4/20/2018, users will see patient encounters at these practices for any patient who consents

Who does this change impact and what do I need to know?
- PCPs and Non-ED/Non-Mental Health Clinicians

What you will see:
- 42 CFR encounters. You will need to break the glass for access

What you won’t see:
- You will not see encounters from before the patient consented.

What you need to know:
- Disclosure of 42 CFR Part 2 information is prohibited unless required by law or a patient care emergency
- Never copy and paste the information into your notes, letters or documentation
- Never release or share (verbally, paper or otherwise) unless you have proper patient written authorization. Contact Privacy Office with questions.
- If you don’t need the information in paper form, don’t print it.

For ED and Mental Health Clinicians:
- No change. All 42 CFR encounters will remain available to you as it is currently. You will continue to need to break the glass for access
### Future 42 CFR-Encounter Access with Consent

<table>
<thead>
<tr>
<th>User</th>
<th>MGH Unprotected 42 CFR Departments (Patient Consent)</th>
<th>42 CFR Departments Protected (No Patient Consent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCPs, Specialists and other clinicians</td>
<td>Soft Stop Break the Glass</td>
<td>No Access</td>
</tr>
<tr>
<td>All Users</td>
<td>Soft Stop Break the Glass</td>
<td>No Access</td>
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### Making Sensitive Information Compliance Work in a Statewide Care Collaboration Network
About the Collective Network

National Technology Platform & Governance Framework

- **Applications**
  (e.g., Features, Standard/Configurable Functionality, EMR integrations)

- **Policies & Procedures**
  (e.g., Data Use, Network Access, Sensitive Information, Patient Consent & Opt-Out)

- **Governance & Compliance Administration**
  (e.g., Process, Personnel, Tools, Terms of Use, Subscriber Contracts)

- **Technology Infrastructure & Controls**
  (e.g., MPI, Interfaces, Data Filters, User Permissions, Audit Trail)

Tools for Cross-Continuum Care Collaboration

- **Real-Time Notifications**
  ("Supercharged ENS")

- **Shared Care Planning**

- **Dashboards & Reporting**
**Patient Consent**
- The HIPAA Privacy Rule allows hospitals to disclose PHI for “treatment”, “payment”, “health care operations”, and “public health” activities without patient consent/authorization.
- State laws are consistent with this HIPAA Privacy Rule TPO disclosure framework.
- State laws applicable to a statewide HIE (if applicable) do not apply to CMT and the state does not regulate EDIE (e.g., there are no consent or other requirements applicable to CMT or EDIE/PreManage).

**Sensitive Information (“SI”):**
- Some categories of PHI are subject to extra privacy restrictions (usually via additional patient consent requirements); only includes very specific information sets based on state or federal law; state-specific analysis required to identify SI categories applicable in each state.

**Examples:**
- Psychotherapy notes (per HIPAA)
- Substance abuse treatment information (per 42 CFR Part 2)
- Mental health information (per NH state law)
- HIV test results (per NH state law)
- Genetic testing information (per NH state law)

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**Data Flow Drill-Down for Sensitive Information Compliance**

1. **How is information shared (i.e., **sent to**) the Collective Platform?**
   - Automated data integrations (Example: EMR ADT feed)
   - Patient Eligibility Files (Example: .csv file with patient demographics, care management info)
   - Manual inputs via PreManage or ED ie web portal (e.g., care plans, security events)

2. **How is information accessed through (i.e., **received from**) the Collective Platform?**
   - Enables provider to share SI throughout CMT Network
   - Pursuant to CMT NH Sensitive Information Policy

3. **What controls can we use in both the information sending + receiving process to meet compliance requirements?**
   - **Administrative controls** (contractual requirements, policies + documentation, limit number of users access, role-based permission for users, user training)
   - **Technical controls** (narrow data inputs, data feed filtering, data processing + mapping patient + data tagging to apply SI rules in application [e.g., redisclosure notice], masking providers as data sources)

**Bottom line:** focus on specific use cases enables drill-down to identify specific ways to implement controls (administrative or technical) to address compliance needs.
**NEW: Support for Sensitive Information Consent w/ CMT Special Consent Form**

- **CMT is responsible for:**
  - Providing Special Consent Form
    - SUD information (Part 2)
    - Mental health information (inpatient, outpatient, voluntary, involuntary)
    - HIV/AIDS and STD information
  - ProvidingSpecial Consent Policy + Implementation Instructions + Training Materials
  - Managing technical controls:
    - Redisclosure notice
    - Treating provider relationship
    - Track audit trail
    - Provide electronic summary of Special Consent Form
  - 3rd Party Legal Analysis approving Special Consent Form and Policy

- **Provider is responsible for:**
  - Managing workflow to obtain patient consent using Special Consent Form
  - Indicating patient consent status in Eligibility File

*Also supporting limited “DIY” consent process in New Hampshire

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**Compliance Result from Sender & Receiver Perspectives**

1. **As a sender of information, you have comfort because:**
   - You are only sending information to the minimum extent necessary for the use case
   - You can filter out Sensitive Information (i.e., that can’t be shared without patient consent)
   - If you make an mistake and send SI in a data integration, much lower risk that it is processed/mapped and shared
   - You have a limited number of users with ability to manually share information
   - You have a few, simple rules users can remember when they manually share information to void SI mistakes
   - If you want, you can enable expanded sharing of information through a carefully focused SI patient consent

2. **As a receiver of information, you have comfort because:**
   - You know that most Sensitive Information will be excluded from the Collective Platform (because of the SI controls on sharing information) or is only available to you because a patient has signed a valid SI consent
   - You know that you will only have access to information that is appropriate / permissible for you see
   - If you do see Sensitive Information subject to a redisclosure prohibition, you receive a redisclosure notice so that you know what not to do
Questions?