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
    - 2. “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, Overdose Prevention & Patient Safety Act
  - S. 1850, Protecting Jessica Grubb’s Legacy Act
- Senate referred bill to the Committee on Health, Education, Labor, and Pensions
- Content:
  - Permitted disclosure includes treatment, payment, and healthcare operations i.e. more aligned with HIPAA disclosure rules
  - Breach notification aligned with HIPAA and HITECH
- State Law
  - Is it equal or more restrictive than federal law?
  - New Hampshire RSA 130-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 BHR 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 regulations
- Understand dependencies on the clinical content decisions and build and the impact to provider and staff workflows

HIPAA 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

Patient Confidentiality Levels

<table>
<thead>
<tr>
<th>Epic Confidentiality Levels</th>
<th>Data Types</th>
<th>Epic Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Level Information (Demographic and Clinical)</td>
<td>Name, DOB, Address, Allergies, Medications, Problems, Histories, Immunizations, Imaging</td>
<td>Confidential Patient, Confidential Address, Patient Safety Flag (Partial), Employee, VP/V-VP FYI flags for patients identified by entity leadership, 42 CFR Encounter</td>
</tr>
<tr>
<td>Encounter Level Information</td>
<td>Encounter Notes</td>
<td>Private Encounter, Confidential Guarantor, Patient Safety Flag (Partial), Break the Glass-Appropriate (Soft Step Warning), Break the Glass-Inappropriate (Remove 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. HM and billing are also exempt.

Current State - 42 CFR Encounter Access

<table>
<thead>
<tr>
<th>User</th>
<th>MH, MHN, 42 CFR Departments</th>
<th>PHL, 42 CFR Departments</th>
<th>BMV, 42 CFR Departments</th>
<th>BWF, 42 CFR Departments</th>
</tr>
</thead>
<tbody>
<tr>
<td>MH/42 CFR Users (logged into a 42 CFR App)</td>
<td>Full Access</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Restricted</td>
</tr>
<tr>
<td>MH/42 CFR Users (logged into any 42 CFR App)</td>
<td>Restricted</td>
<td>Full Access</td>
<td>Restricted</td>
<td>Restricted</td>
</tr>
<tr>
<td>BWF, 42 CFR Users (logged into a BWF 42 CFR App)</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Full Access</td>
<td>Restricted</td>
</tr>
<tr>
<td>MHN/42 CFR Users (logged into a MHN 42 CFR App)</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Full Access</td>
</tr>
<tr>
<td>BMV/42 CFR Users (logged into a BMV 42 CFR App)</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Restricted</td>
</tr>
<tr>
<td>Mental Health Clinicians (with mental health security templates)</td>
<td>Soft Step Break the Glass</td>
<td>Soft Step Break the Glass</td>
<td>Soft Step Break the Glass</td>
<td>Soft Step Break the Glass</td>
</tr>
<tr>
<td>ED Clinicians (with ED security templates)</td>
<td>Soft Step Break the Glass</td>
<td>Soft Step Break the Glass</td>
<td>Soft Step Break the Glass</td>
<td>Soft Step Break the Glass</td>
</tr>
<tr>
<td>Other users</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Restricted</td>
<td>Restricted</td>
</tr>
</tbody>
</table>

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

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 names no longer need to be specified
- However, the HIE must track and provide listing of disclosures to Patient upon request (Disclosures for past 3 years)

Other Highlights:
- To Whom (past/present/future treating providers who spec. identifying them)
- From Whom – allows also for a general designation as 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 – CFI 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, users who work outside of 42 CFR Practices cannot see these encounters, except mental health and emergency department clinicians
- Starting 4/20/18, users will see patient encounters at these practices for any patient who

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:
- Disclosures 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>
</tr>
<tr>
<td>McLean 42 CFR Users</td>
<td>Soft Stop Break the Glass</td>
<td>No Access</td>
</tr>
<tr>
<td>BWH 42 CFR Users</td>
<td>Soft Stop Break the Glass</td>
<td>No Access</td>
</tr>
<tr>
<td>NWH 42 CFR Users</td>
<td>Soft Stop Break the Glass</td>
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Making Sensitive Information Compliance Work in a Statewide Care Collaboration Network

About the Collective Network

Tools for Cross-Continuum Care Collaboration
Partners BH Providers

Detailed 3rd party legal memorandum with detailed analysis of applicable federal and state privacy laws

State Specific Sensitive Information Policies

Foley & Lardner Memos for PreManage ED (Edie) & PreManage Primary

High Level Conclusions for New Hampshire

**Patient Consents:**
- The HIPAA Privacy Rule allows hospitals to disclose PHI for "treatment," "payment," "health care operations," and "public health" activities without patient consent / authorization
- State law is consistent with the HIPAA Privacy Rule / PTO disclosure framework
- Some laws applicable to a statewide HIE (if applicable) do not apply to CMT and the state does not regulate EHR (e.g., there are no consent or other requirements applicable to CMT or CMTPreManage)
- Therefore, patient information can be shared without consent for PTO purposes

**Sensitive Information ("SI")**
- Some categories of PHI are subject to extra privacy restrictions (usually via additional patient consent requirements) only includes very specific information set 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)
  - Sexual health information (per HIV state law)
  - HIV test results (per HIV state law)
  - Genetic testing information (per HIV state law)
Data Flow Drill-Down
for Sensitive Information Compliance

1. How is information shared with (i.e., sent to) the Collective Platform?
   - Automated data integrations (Example: EPR ADT lead)
   - Patient Eligibility file (Example: csv file with patient demographics, care management only)
   - Manual inputs via ProManage or ED in 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 pattern + data tagging to apply SI rules in application [e.g., redisclosure notice], making 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
  - S. Information (Part 2)
  - Mental health information (diaper, medication, recorded information)
  - HIV/AIDS and STI Information
  - Providing Special Consent Policy + Implementation Instructions + Training Materials
  - Managing technical controls:
    - managing access
    - auditing
    - monitoring
    - providing answers summary of Special Consent Form
  - **PSI (PDA) & LPA (LDPA) managing Special Consent Policy + Policy**

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

*When supporting limited "DIY" consent process in New Hampshire

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., does not get shared without patient consent)
   - If you make an mistake and send SI in a data integration, much lower risk that it is unethical, illegal and shared
   - You have a limited number of users with ability to manually share information
   - Technical & legal support role users can remember when they manually share information to send SI instead
   - You are not an entity involved expanded sharing of information through a centrally 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 your use
   - 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?