



# 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

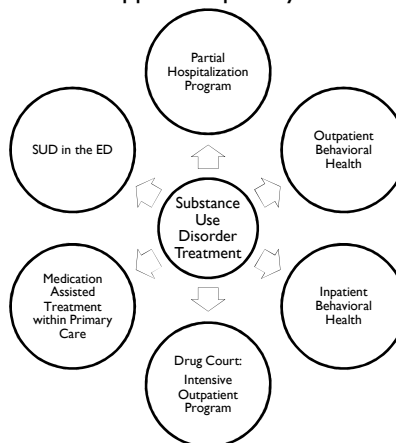
### Our Story

- New Hampshire has the 2<sup>nd</sup> 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:
  - I from the House: H.R. 6082 passed the house June 20<sup>th</sup> 357-57
  - I from the Senate: 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
  - Content:
    - 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
  - Content:
    - 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
- PCP's, 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

Level	Data Types	Epic Tool
Patient Level Information (Demographic and Clinical)	<ul style="list-style-type: none"> <li>Name</li> <li>DOB</li> <li>Address</li> <li>Allergies</li> <li>Medications</li> <li>Problems</li> <li>Histories</li> <li>Immunizations</li> <li>Imaging</li> </ul>	<ul style="list-style-type: none"> <li>Confidential Patient</li> <li>Confidential Address</li> <li>Patient Safety Flag (Partial)</li> <li>Employee</li> <li>VIP/V-VIP FYI flags for patients identified by entity leadership</li> <li>42 CFR Encounter</li> </ul>
Encounter Level Information	<ul style="list-style-type: none"> <li>Encounter</li> <li>Notes</li> </ul>	<ul style="list-style-type: none"> <li>Private Encounter</li> <li>Confidential Guarantor</li> <li>Patient Safety Flag (Partial)</li> <li>Break the Glass- Appropriate (Soft Stop Warning )</li> <li>Break the Glass- Inappropriate (Removes encounter)</li> <li>Sensitive Notes</li> </ul>
Order Level Information	<ul style="list-style-type: none"> <li>Lab Orders</li> <li>Lab Results</li> </ul>	<ul style="list-style-type: none"> <li>Sensitive Orders</li> </ul>

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## 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

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## Current State - 42 CFR Encounter Access

User	McLean 42 CFR Departments	MGH 42 CFR Departments	BWF 42 CFR Departments	NWH 42CFR Departments
McLean 42 CFR Users (logged into a McLean 42 CFR dept.)	Full Access	Restricted	Restricted	Restricted
McLean Users (logged into any McLean dept.)	Soft Stop Break the Glass	Restricted	Restricted	Restricted
MGH 42 CFR Users (logged into an MGH 42 CFR dept.)	Restricted	Full Access	Restricted	Restricted
BWF 42 CFR Users (logged into a BWF 42 CFR dept.)	Restricted	Restricted	Full Access	Restricted
NWH 42CFR Users (logged into an NWH 42 CFR dept.)	Restricted	Restricted	Restricted	Full Access
Mental Health Clinicians (with mental health security templates)	Soft Stop Break the Glass	Soft Stop Break the Glass	Soft Stop Break the Glass	Soft Stop Break the Glass
ED Clinicians (with ED security templates)	Soft Stop Break the Glass	Soft Stop Break the Glass	Soft Stop Break the Glass	Soft Stop Break the Glass
PCP's and other clinicians	Restricted	Restricted	Restricted	Restricted

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

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## 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

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Future 42 CFR-Encounter Access with Consent		
User	MGH Unprotected 42 CFR Departments (Patient Consent)	42 CFR Departments Protected (No Patient Consent)
PCP's, Specialists and other clinicians	Soft Stop Break the Glass	No Access
All Users	Soft Stop Break the Glass	No Access
McLean 42 CFR Users	Soft Stop Break the Glass	No Access
BWF 42 CFR Users	Soft Stop Break the Glass	No Access
NWH 42CFR Users	Soft Stop Break the Glass	No Access
Mental Health Clinicians (with mental health security templates)	Soft Stop Break the Glass	Soft Stop Break the Glass
ED Clinicians (with ED security templates)	Soft Stop Break the Glass	Soft Stop Break the Glass



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)

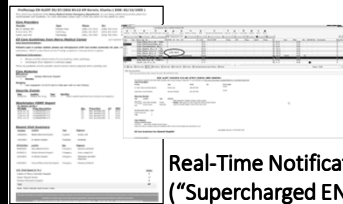
### Governance & Compliance Administration

(e.g., Process, Personnel, Tools, Terms of Use, Subscriber Contracts)

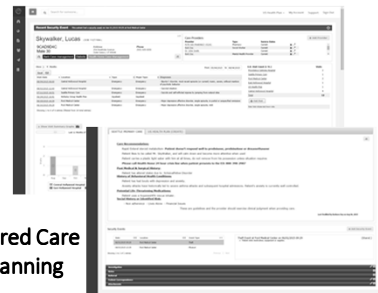
### Technology Infrastructure & Controls

(e.g., MPI, Interfaces, Data Filters, User Permissions, Audit Trail)

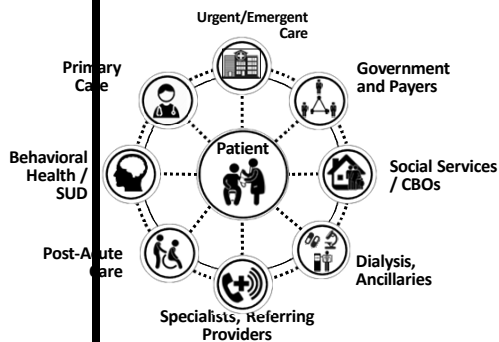
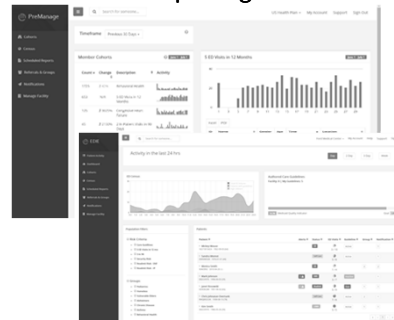
## Tools for Cross-Continuum Care Collaboration



Shared Care Planning



## Dashboards & Reporting



# Who works with Collective Medical?



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

**FOLEY**  
FOLEY & LARDNER LLP

### MEMORANDUM

TO: Travis K. Smith  
President & Chief Operating Officer

FROM: Lawrence W. Vernaglia, Esq.

DATE: March 14, 2017

RE: PreManage Primary Software Service  
New Hampshire State and Federal Law

This memorandum addresses Collective Medical Technologies, Inc.'s ("CMT") use of the PreManage Primary software service to share Protected Health Information ("PHI") about patients among hospitals, health care providers, and health plans (collectively "PreManage Subscribers") under Federal law and the laws of New Hampshire.

#### I. SHORT ANSWER

PreManage Subscribers may use PreManage Primary to exchange PHI and medical records or information<sup>1</sup> without authorization<sup>2</sup> for purposes of Treatment, Payment for health care services, and certain Health Care Operations purposes (as will be defined below).

### State Specific Sensitive Information Policies

#### 0730.6 SENSITIVE INFORMATION POLICY (NEW HAMPSHIRE) PRIVACY POLICIES Collective Medical Technologies, Inc.

##### Objective

This New Hampshire Sensitive Information Policy 0730.6 ("Policy") applies to all Services provided by Collective Medical Technologies, Inc. ("CMT") pursuant to a Master Subscription Agreement or similar instrument whereby Subscribers subscribe to CMT Services ("Underlying Agreement") and may be updated or amended by CMT from time to time in its sole discretion.

A. CMT provides access to remotely hosted applications and underlying technical services in support of the CMT Network ("Services") to support the exchange of information among health care organizations ("Subscribers") within and across certain geographies who have entered into the Underlying Agreement for purposes of coordinating, collaborating and supporting treatment, payment, health care operations and public health activities for the benefit of patients ("CMT Network").

B. "Sensitive Information" is Patient Data which falls into specific categories according to applicable federal or New Hampshire State law, in each case as defined in this Policy.

C. Sensitive Information may only be included in Patient Data uploaded to the CMT Network and requested for disclosure by a Subscriber or User through the CMT Network in compliance with this Policy. Any upload of Sensitive Information using the Services in violation of this Policy is a material breach of the Underlying Agreement and may violate applicable federal and/or state laws, or ethical or licensure obligations of a Subscriber or User.

D. This Policy applies to the use of the Services by all Subscribers and Users in the State of New Hampshire and is in addition to all other policies and requirements for use of the CMT Network. Capitalized terms not defined herein shall have the definitions established in the Underlying Agreement or the CMT Privacy Policy (Policy 0740), as applicable.

##### Policy

#### 1. Psychotherapy Notes

##### 1.1. Definition under HIPAA.

1.1.1. Psychotherapy Notes are notes recorded (in any medium) by a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session, and that are separated from the rest of the individual's medical record.<sup>3</sup>

1.1.2. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the patient's diagnosis, functional status, treatment plan, symptoms, prognosis, and progress to date.<sup>4</sup>

1.2. No Psychotherapy Notes in the Services. Psychotherapy Notes may not be uploaded into or requested through the Services, except where an individual has provided a valid consent or authorization for sharing such information through the Services.

<sup>1</sup> 45 C.F.R. § 164.502.  
<sup>2</sup> Id.

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

### High Level Conclusions for New Hampshire

#### • **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 law is 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)
- >> Therefore, patient information can be shared without consent for TPO 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 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)

## 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: 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
  - Providing Special 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

**0740 SPECIAL CONSENT POLICY**  
PRIVACY POLICIES  
Collective Medical Technologies, Inc.

**Objective**  
This policy describes the terms and requirements for CMT Subscribers who elect to use the Special Consent Form in order to enable access and sharing of certain Sensitive Information for Treatment activities for their patients in care.

**Special Consent for Release of Sensitive Information**  
(Provider Name / Login)

**Policy**

**1. Definitions**

1.1. "CMT" means Collective Medical Technologies, Inc. or its affiliates.

1.2. "SUD" means Substance Use Disorder.

1.3. "MHI" means Mental Health Information.

1.4. "HIV/AIDS" means Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome.

1.5. "STD" means Sexually Transmitted Disease.

1.6. "SI" means Sensitive Information.

1.7. "Special Consent Form" means the form provided by CMT for patients to provide consent for the release of SI.

1.8. "Special Consent Policy" means the policy provided by CMT for subscribers to use the Special Consent Form.

1.9. "Special Consent Implementation Instructions" means the instructions provided by CMT for subscribers to use the Special Consent Form.

1.10. "Special Consent Training Materials" means the training materials provided by CMT for subscribers to use the Special Consent Form.

**Purpose for Release**  
The purpose of this form is to request and authorize (patient) to electronically consent and disclose the sensitive information described below to past, present or future members of my Care Team through CMT's ProManage and the Collective Medical Network for purposes of enabling members of my Care Team to provide Treatment to me. (See reverse side for answers to some Frequently Asked Questions)

**Consent to Release Sensitive Information**  
I hereby request and authorize (patient) to disclose my sensitive information and records as described below through the CMT's electronic health information exchange (interoperable) operated by Collective Medical Technologies, Inc. to the members of my Care Team identified below who are connected to or participate in the Collective Medical Network. This consent and request applies to information and records concerning diagnosis and treatment of me as a minor, if applicable.

**Amount and Kind of Sensitive Information to be Disclosed** (Check box or type in the following text)  
☐ Option A: Full Care Documentation. Any of the following types of sensitive information or records which are available in (patient's) electronic record (e.g., clinical notes, discharge summaries, care plans, lab results, medications, etc.) to my Care Team for purposes of providing me Treatment, including:  
• Substance use disorder program (including medications, treatment plans, clinical assessments or tests, symptoms, diagnoses, progress notes)  
• HIV/AIDS or sexually transmitted disease (STD) diagnosis or treatment information and records  
• Mental, behavioral health and developmental disability diagnosis and treatment information and records, whether on an inpatient or outpatient, or voluntary or involuntary basis  
• Adult day program service information

☐ Option B: Limited Sensitive Information. Only my sensitive information limited to identifying (1) the type of providers who are members of my Care Team, with an exception that specialists in substance use disorder or adult treatment or related services, mental health (inpatient or outpatient), HIV or sexually transmitted diseases, developmental disability services, adult day programs and Social Services Provider (SSP) (2) the dates, locations and types of encounters with such providers (e.g., inpatient diagnosis, completion, service, or location codes or information)

**To Whom My Sensitive Information May be Disclosed**  
The sensitive information and records described above may be disclosed to all of the past, present, and future members of my Care Team (including health care providers, behavioral health providers, and Social Service Providers) who access my sensitive information in order to enable them to provide Treatment to me as part of my overall care plan.

**Consent and Refusal**  
1.9. "I am authorizing (patient) to disclose the sensitive information I have designated above, for the purposes and to the extent described in this Consent form."  
• My decision to sign this form is voluntary, and I understand that I may refuse to sign this Consent form. My refusal to sign will not affect my ability to obtain Treatment or payment or eligibility for benefits.  
• As required under federal law (42 CFR Part 2.5.2.13(d)), upon my request (patient) will provide me with a list of entities to which my sensitive information has been disclosed under this Consent.  
• I understand that I have a right to receive a copy of this consent.  
• I understand that I may revoke (i.e., take back) my Consent in writing at any time. My revocation will take effect upon receipt by (patient), except to the extent that others have already acted in reliance upon this Consent.  
• My Consent will expire either upon my death, or if (patient) decide to revoke it.

Client Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Legal Representative (if any): \_\_\_\_\_ Signature: \_\_\_\_\_  
Reason (Client is unable to sign) (if applicable): \_\_\_\_\_  
Provider/Supervisor/Client: ☐ Patient ☐ Care Team Coordinator ☐ Health Care Provider of Attorney  
☐ Other Legally Authorized Representative under applicable state law (specify): \_\_\_\_\_

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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?

