



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

SUBSTANCE USE DISORDER TREATMENT CONFIDENTIALITY BOOT CAMP

A combination of in-person guided meetings, webinars, and integrated delivery network team-based homework to provide technical assistance to integrated delivery networks in a compressed period of time.

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INTRODUCTION

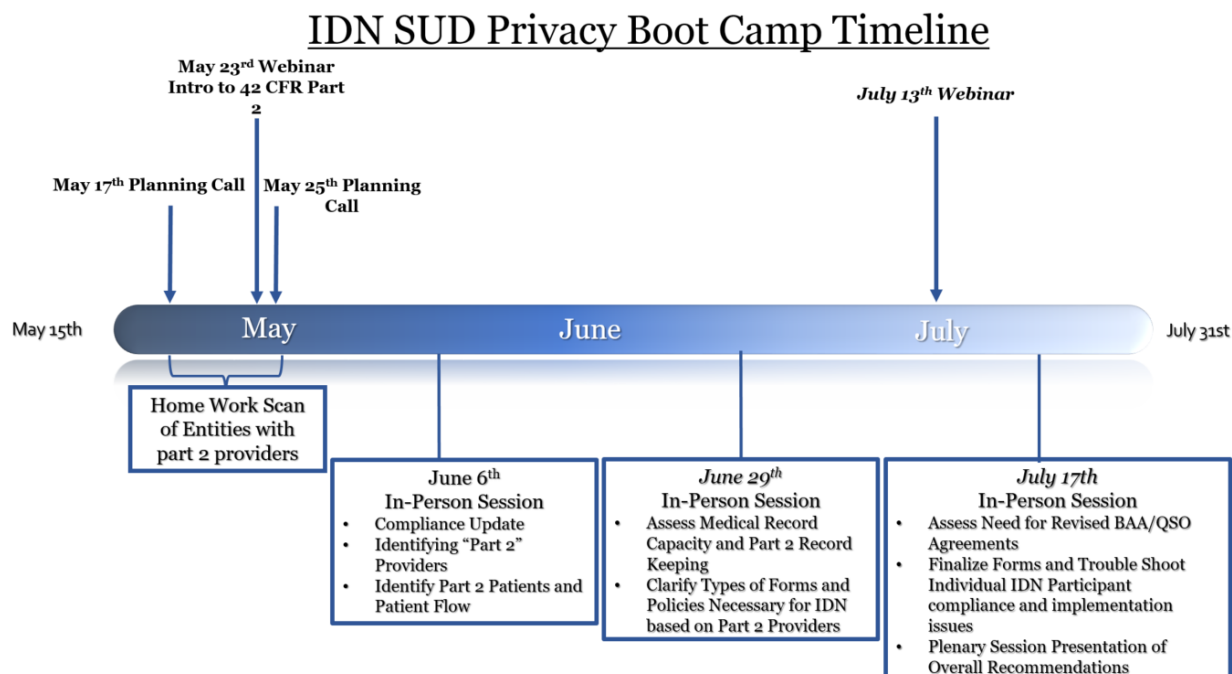
The Health Law and Policy Programs at UNH School of Law, Institute for Health Policy and Practice, and the NH Citizens Health Initiative have contracted with several of the New Hampshire Building Capacity for Transformation Delivery System Reform Incentive Payment (DSRIP) Integrated Delivery Networks (IDN) to provide technical assistance to the IDNs as they develop confidentiality tools related to substance use disorder services projects.

A UNH Team assisted the IDNs by providing an educational summary of federal and state confidentiality requirements, focusing on 42 CFR Part 2, and hosting IDN interdisciplinary teams in three Substance Use Disorder (SUD) Treatment Confidentiality Boot Camp sessions providing technical assistance to assist each IDN partner with their SUD confidentiality project goals. The “boot camp” consisted of several guided meetings with assigned homework to follow, leading to the ultimate development of processes, plans, and draft forms and policies to implement Part 2 confidentiality. The process incorporated learning from the Citizens Health Initiative’s existing New Hampshire Behavioral Health Integration Learning Collaborative.

The Project was implemented during half-day working sessions between May 15 – July 30, based upon the availability of IDN interdisciplinary teams and as arranged in collaboration with the IDNs. The IDNs committed to including project leaders with knowledge about and authority to investigate issues regarding projects, patient flow, and privacy. The project teams were multi-disciplinary. IDN participants were encouraged to review issues, forms, and ideas with their individual legal counsel at any point. ***The technical assistance provided as part of this project is not and does not take the place of legal advice.***

DESCRIPTION OF WORK, TIMELINE, AND TEAMS

Timeline



Establish IDN Teams

Each participating IDN identified an IDN team liaison who assisted with communications, coordination, and attendance of staff within their IDN and across their own regional IDN providers. Team liaisons helped coordinate follow up between meetings.

Participating IDNs committed to full participation at all in-person meetings beginning at the inception of the project. IDN team liaisons helped the IDN partner select each IDN's multi-disciplinary Boot Camp team members with responsibility for administration and delivery of IDN SUD services. This multi-disciplinary Boot Camp team assisted participating IDNs with the development and implementation of SUD specific confidentiality protections, specifically the development and adoption of compliant practices consistent with newly amended 42 CFR Part 2. The multi-disciplinary Boot Camp team included at least some of the following:

- Behavioral health providers, those who do and do not provide SUD services
- Risk managers
- Health information management/privacy managers
- Practice managers
- Primary care providers
- Others as necessary.

Each IDN's multi-disciplinary team was responsible for addressing:

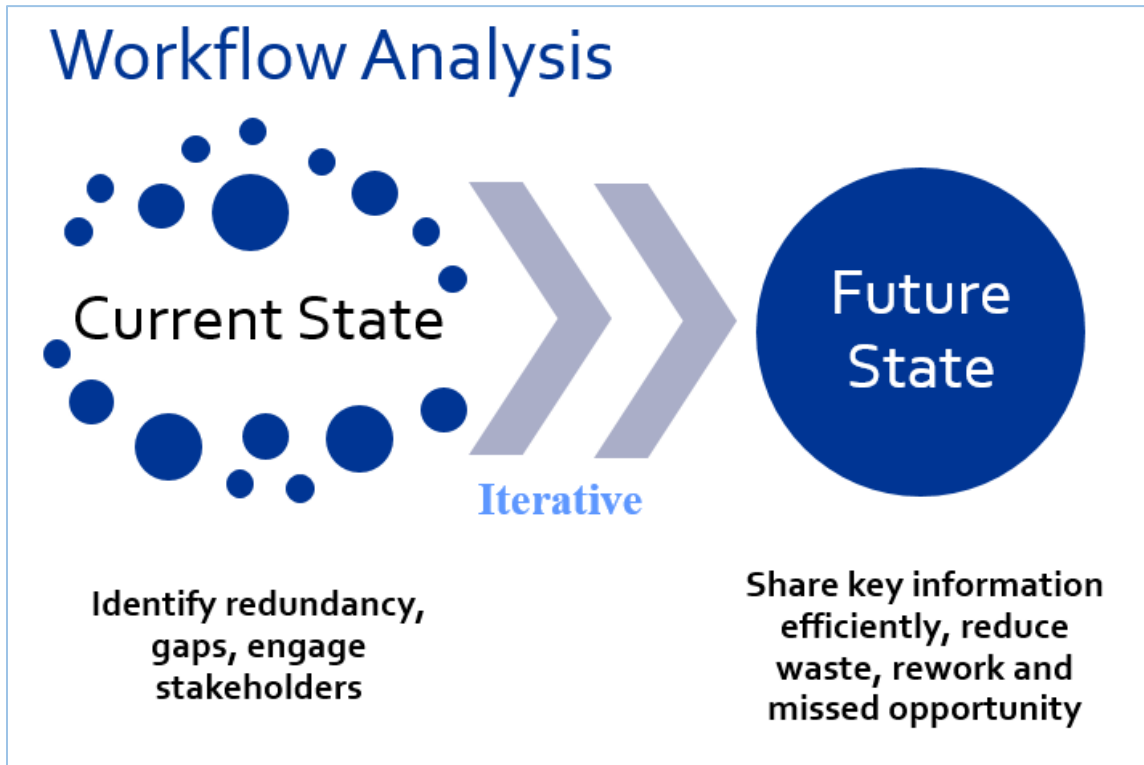
- Project summaries
- Identification of participating entities
- Patient flow
- Electronic Health Record capacities
- System culture
- Desired goals of integrating care
- Policies and procedures
- Other.

Patient Centered Compliance

| Goal | Multi-Disciplinary Team | Strategy |
|--|--|---|
| <p>Culture of Care: Develop and implement a plan to meet the confidentiality requirements of 42 CFR Part 2 and state law in an integrated health care setting with a system wide Electronic Health Record.</p> | <p>Risk Behavioral Health Providers Substance Use Providers HIM/IT Practice Managers Legal</p> | <p>Identify SUD providers Review SUD Patient flow Review current confidentiality practices Review current forms used with SUD patients Update patient flow Revise and update forms Integrate into electronic health</p> |

Worksheet Template: Identify Your Team:

| Name | Role | Organization | Contact Info |
|------|---|--------------|--------------|
| | IDN Boot Camp Lead | | |
| | Health System/Provider | | |
| | BH Provider Rep(s) | | |
| | SUD Provider Rep(s) | | |
| | Health Information Management/Privacy Manager | | |
| | Practice Manager(s) | | |
| | Primary Care | | |
| | | | |
| | | | |



WHAT IS PART 2?

42 CFR Part 2 are the federal substance use disorder (SUD) confidentiality regulations issued by the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). These regulations protect the confidentiality of SUD treatment records.

The Part 2 rules were recently amended with the first substantial update to the Confidentiality of Alcohol and Drug Abuse Patient Records (Part 2) regulations since 1987. The changes to Part 2 are designed to:

- Encourage care integration and information exchange,
- Address healthcare technology changes,
- Address prohibition against re-disclosures and accounting for disclosures,
- Address research uses of data, and
- Address security of records.

The proposed amendments were published on February 9, 2016 with a comment period that ended on April 9, 2016. The final rule was published on January 18, 2017 to be effective February 17, 2017, but the Trump administration delayed effectiveness until March 2017.

Purpose of 42 CFR Part 2 (Part 2)

The purpose of Part 2 is to protect patients from any unintended bias associated with substance use disorders. The heightened confidentiality protections of Part 2 protect SUD patients who seek treatment from the potentially harmful consequences of having their patient records available to others who do not need access to them.¹ The goal is to encourage people to seek SUD treatment, rather than not, because they can do so without fear of their information being shared.²

To accomplish this goal, Part 2 strictly prohibits the disclosure and use of SUD patient records except with the patient's specific written consent or under certain limited exceptions.³ The lawful recipient of SUD records is also prohibited from re-disclosing the information except with written patient consent or when another Part 2 exception applies.

¹ Confidentiality of Substance Use Disorder Patient Records, 42 C.F.R. § 2.2(b)(2) (2017).

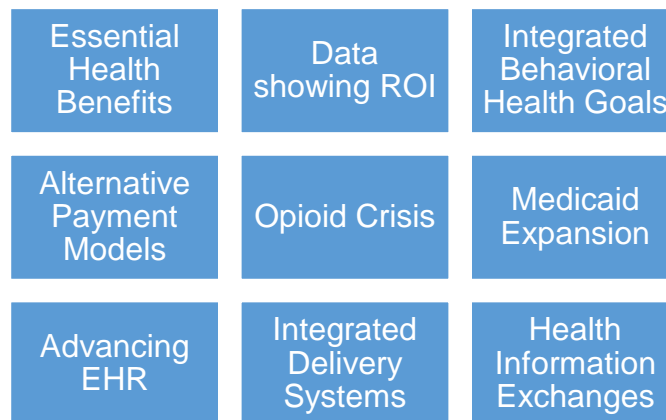
² 42 C.F.R. § 2.2(b)(2) (2017).

³ *Id.*

Why is Part 2 an issue now?

The Part 2 rules protect SUD patient information, but in order for providers to provide good quality care, it is important to understand the circumstances that allow for disclosure.

The heightened confidentiality of substance use disorder records in Part 2 is in conflict with the theory that mind and body should be treated as one with no stigma associated with behavioral health. Despite this conflict, the recent changes to Part 2 were designed to accommodate integrated delivery models and to “better align them with advances in the U.S. health care delivery system” while retaining the necessary privacy protections.⁴ “SAMHSA wants to ensure that patients with substance use disorders have the ability to participate in, and benefit from health system delivery improvements, including from new integrated health care models while providing appropriate privacy safeguards.”⁵



Providers, payers, and data users have heightened awareness of Part 2 protections in 2017 due to a number of recent developments. First, the new updated Part 2 rules went into effect in March of 2017. Second, recent changes to health insurance coverage as a result of the Affordable Care Act means many more individuals now have coverage for “essential health benefits” including SUDs. Therefore, patients with health insurance, including those in the New Hampshire Health Protection Program and traditional Medicaid (including managed care), have better access to SUD treatments. More treating providers have access to confidential SUD treatment records and need to be aware of Part 2 protections. Finally, the opioid crisis has focused New Hampshire on the need for treatment and services, and the need for more integrated care for patients, again, heightening our need to be careful of SUD patient privacy rights.

⁴ Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052, 6053 (Jan. 18, 2017) (to be codified at 42 C.F.R. Pt. 2).

⁵ 82 Fed. Reg. at 6053.

OVERVIEW OF APPLICABLE PRIVACY AND CONFIDENTIALITY LAWS

State and federal laws and regulations work together to provide protection of patient health information and govern the confidentiality of patient information.

The chart below provides a brief overview of New Hampshire and federal laws and regulations that govern confidentiality in New Hampshire. All providers should already be familiar with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).⁶ Other privacy regulations may not be as familiar, like the Confidentiality and Drug Abuse Patient Records, 42 CFR Part 2 (Part 2), that have undergone recent changes. This Boot Camp and accompanying Work Book is meant to help the IDNs understand the amended Part 2 and implement appropriate policies and practices now that the regulation is finalized.

| Jurisdiction | Statute/Regulation | Scope |
|--------------|---------------------|---|
| | 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. |
| | RSA 332-I:1 | Medical information in 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. |
| | RSA 135-C:19-a | Requires and/or permits the disclosure of certain information by treating providers and community mental health centers to designated receiving facilities (DRFs) regarding patients who are seriously mentally ill. ⁷ |

⁶ Health Insurance Portability and Accountability Act, 45 C.F.R. §§ 160, 162, and 164 (2009).

⁷ Practitioners treating seriously mentally ill patients, especially those admitted to DRFs, should familiarize themselves with the disclosure statutes and exceptions, including RSA 135-C:19-a.

WHO IS A PART 2 PROVIDER/PROGRAM?

Let's start by identifying who is a Part 2 "program". Remember, the Part 2 regulations impose restrictions upon the disclosure and use of SUD patient records, which are maintained by a Part 2 program.⁸ Once it is clear who is governed by this law, it becomes easier to understand how it differs from HIPAA and how it affects those Part 2 providers. In most instances, Part 2 is more restrictive than HIPAA.

A Part 2 program can be any of the following individuals or entities:⁹

- A Medical personnel or staff member who:
 - **Holds themselves out as providing** and does provide SUD treatment, diagnosis, or referral for treatment; or
 - Practices in a general medical facility whose **primary function is** SUD treatment, diagnosis, or referral for treatment and is identified as such; or
 - Is a NH Licensed Alcohol and Drug Counselor (LADC) providing LADC services;
- An entity (other than a general medical facility) that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment; or
- A unit within a general medical facility that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment.

Note: A good question to ask is whether you hold yourself out as providing and do provide SUD services to patients. If you do, chances are you are a Part 2 provider and your records for SUD patients are protected by the heightened confidentiality obligations of Part 2.

Example: Buprenorphine providers are not categorically included in the definition of a "Part 2 program," unless the provider meets the "holds themselves out as providing" or the "primary function" test.

Example: A family practitioner in a family practice screens a patient using SBIRT and refers the patient to a SUD provider for follow-up assessment. Conducting SBIRT does not make the practitioner a Part 2 program.

⁸ 42 C.F.R. § 2.2(a) (2017).

⁹ 42 C.F.R. § 2.11 (2017).

Note: The term “holds itself/themselves out as” is not actually defined anywhere in the law, but the Substance Abuse and Mental Health Services Administration (SAMHSA) commented on this phrase in its Frequently Asked Questions page regarding 42 CFR Part 2. SAMHSA states the phrase:

“...could mean a number of things, including but not limited to state licensing procedures, advertising or the posting of notices in the offices, certifications in addiction medicine, listings in registries, internet statements, consultation activities for non-“program” practitioners, information presented to patients or their families, or **any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment or referral for treatment.**” (Emphasis added)

SAMHSA, *Applying the Substance Abuse Confidentiality Regulations*, <https://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-faqs>, last visited May 17, 2017.

See also 82 Fed. Reg. at 6065-6066.

*Part 2 applies to providers or programs that meet one of the definitions of a Part 2 program AND are federally assisted.*¹⁰

Federally Assisted Programs Are:¹¹

- Recipients of federal financial assistance;
 - Federal financial assistance is assistance of any kind, even if it does not directly fund the SUD treatment, diagnosis, or referral for treatment services.
- Licensed, certified, registered, or authorized by the federal government to conduct business;
- Tax-exempt through the IRS; *or*
- Conducted by the federal government or a state or local government that receives federal funds, which could be used for SUD programs.
- **Exception:** Part 2 does not apply to the Department of Veterans Affairs¹²

¹⁰ 42 C.F.R. § 2.11 (2017).

¹¹ 42 C.F.R. § 2.12(b) (2017).

¹² 42 C.F.R. § 2.12(c) (2017).

DIFFERENCES BETWEEN PART 2 AND HIPAA¹³

Now that we can identify Part 2 providers/programs, let's take some time to differentiate Part 2 from HIPAA. You are probably already familiar with HIPAA, but Part 2 works very differently so it is important to understand the differences between the two federal laws before moving forward.

| | HIPAA | Part 2 |
|-------------------------------------|---|---|
| Who is Covered? | <ol style="list-style-type: none"> 1. Health care providers, both physical and behavioral health 2. Health Plans 3. Health care clearinghouses 4. Business Associates | <ol style="list-style-type: none"> 1. An individual or entity (or a unit in a general medical facility or practice) that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment; OR 2. Medical personnel or staff in a general medical facility or practice whose primary function is to provide such services and who are identified as SUD providers; AND 3. Are federally funded <p>[Note: providing SBIRT services does not necessarily make a provider a Part 2 provider]</p> |
| | HIPAA | Part 2 |
| What information is covered? | <ul style="list-style-type: none"> • All individually identifiable health information • Psychotherapy notes documenting or analyzing a conversation during a private counseling session or group session must be maintained separately. | <p>Information, whether or not recorded, which:</p> <ul style="list-style-type: none"> • Would identify a patient as a SUD patient either directly or by verification. • Is any SUD patient information created, received or acquired by a <i>Part 2 program</i> for the purpose of treating alcohol or drug abuse, making a diagnosis for treatment, or making a referral for that treatment. |

¹³ 42 C.F.R. § 2 (2017); 45 C.F.R. § 160, 162, and 164, (2009).

| | HIPAA | Part 2 |
|---------------------------------|---|---|
| When is a disclosure permitted? | <ul style="list-style-type: none"> • With a patient’s valid verbal or written authorization. • After a patient receives notice of the provider’s privacy policy, a covered provider may disclose health information without authorization for the purposes of treatment, payment, health care operations, and other purposes as consent authorizes. | <ul style="list-style-type: none"> • When express written consent is given • For internal communications • For research • As part of an authorized record audit • When reporting child abuse/neglect • When the information is de-identified • By court order • In the event of a crime on program premises • In a medical emergency • Pursuant to a qualified service organization agreement <p>[Note: re-disclosure is not allowed without consent of the patient.]</p> |

Part 2 does not allow disclosures mandated by other state or federal laws unless a specific exception applies.

Example: A state law requires all licensed health care providers to make their records available to state public health authorities for purposes of tracking communicable diseases. A Part 2 program is neither permitted nor required to disclose its Part 2 records for these purposes. The Part 2 rules do not contain an exception for public health disclosures.

Note: Part 2 does not allow a Part 2 program to disclose Part 2 records for payment, treatment, or health care operations without consent.

Note: Unlike HIPAA, oral consent to disclose information is NOT permitted by Part 2. However, both written consents with signature and on-line consents with electronic signatures are allowed.

Confidentiality and Minors

Both HIPAA and Part 2 leave defining a minor, and whether a minor can obtain health care or alcohol/drug treatment without parental consent, entirely up to State Law.

In New Hampshire a minor 12 years old or older may seek and be treated for drug dependency or any problem related to the use of drugs without parental consent.¹⁴

Other issues regarding minors in NH

- The age of majority in NH is 18.¹⁵
- NH law provides that a health care provider can only perform an HIV test with the consent of the individual being tested.¹⁶
 - Example: If a 15-year-old is seeking any HIV test, that 15-year-old must consent to the test even if the parent does not consent.
 - Results of a test may only be given to the individual tested.¹⁷
 - If the individual tested is under 18 or lacks the mental capacity to understand a positive HIV test, the provider may disclose to the parent or guardian.¹⁸
- A provider is not liable for failing to obtain consent when treating a patient in an emergency no matter the age of the patient.¹⁹
- A minor who is 14 years old or older may seek and be treated for a sexually transmitted disease without the consent of a parent or guardian.²⁰

¹⁴ N.H. Rev. Stat. Ann. § 318-B:12-a (2009).

¹⁵ N.H. Rev. Stat. Ann. § 21-B:1 (1973).

¹⁶ N.H. Rev. Stat. Ann. § 141-F:5 (2010).

¹⁷ N.H. Rev. Stat. Ann. § 141-F:7, II (1995).

¹⁸ N.H. Rev. Stat. Ann. § 141-F:7, III (1995).

¹⁹ N.H. Rev. Stat. Ann. § 153-A:18 (1999).

²⁰ N.H. Rev. Stat. Ann. § 141-C:18 (1995).

WHAT PATIENT INFORMATION IS PROTECTED BY PART 2?

It is important to identify a Part 2 program because the Part 2 programs are subject to the heightened confidentiality requirements of Part 2. It is also important to understand what records of a Part 2 program are protected.

Part 2 protects against the “**disclosure and use**” of SUD “**patient records**” which are maintained in connection with the performance of any federally assisted alcohol and “**drug abuse program.**”²¹

Important definitions:

- A “**patient**” means any individual who has applied for or been given a diagnosis, treatment, or referral for treatment for a SUD **at a Part 2 program** (or someone who is identified as having a SUD after an arrest or charge).²²
- “**Records**” means any information relating to a patient received, created, or acquired by a Part 2 program, regardless of whether it is recorded or not.²³
- “**Patient identifying information**” includes anything that identifies the patient, such as name, address, Social Security number, or other information that allows for the identification of the patient.²⁴ (It does not include a patient number, assuming the patient number does not contain patient identifying information like a Social Security number or a driver’s license number).
- “**Treatment**” means the care or management of a patient suffering from a SUD, a condition identified as having been caused by the SUD, or both.²⁵

Note: If a patient’s SUD diagnosis or referral for treatment is NOT provided by a Part 2 program, that patient’s diagnosis or referral is not necessarily covered by the Part 2 confidentiality provisions.

²¹ 42 C.F.R. §2.12(a) (2017).

²² 42 C.F.R. § 2.11 (2017).

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

- **“Treating provider relationship”** “means that regardless of whether there has been an actual in-person encounter:
 - a patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual or entity, and
 - the individual or entity undertakes or agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient *for any condition.*”²⁶ (emphasis added)

Example: The internal medicine practice of Your Health System conducts SBIRT screening and referrals, but does not provide SUD treatment, and refers a patient with SUD issues to the SUD Treatment Unit at the Community Mental Health Center. The patient’s record maintained by the internal medicine practice, including the screening and referral, must comply with HIPAA and Your Health System’s privacy practices **but not** Part 2. However, the SUD Treatment Unit’s records will be protected by Part 2.

Example: Part 2 confidentiality regulations do not apply to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless such personnel meet the definition of a Part 2 program or provider.

Example: A pregnant patient of Your Community is screened by the OB nursing staff and is found to be at risk for substance abuse. The screening and referral are not considered Part 2 records. Later, a provider from a well-advertised SUD Treatment Unit provides an assessment and recommendation for treatment, and schedules a follow-up visit. At that point, the records developed by the SUD Treatment Unit are protected by Part 2 and subject to heightened confidentiality.



Question

- Who is a Part 2 Program?



Question

- Who is a Part 2 patient?



Question

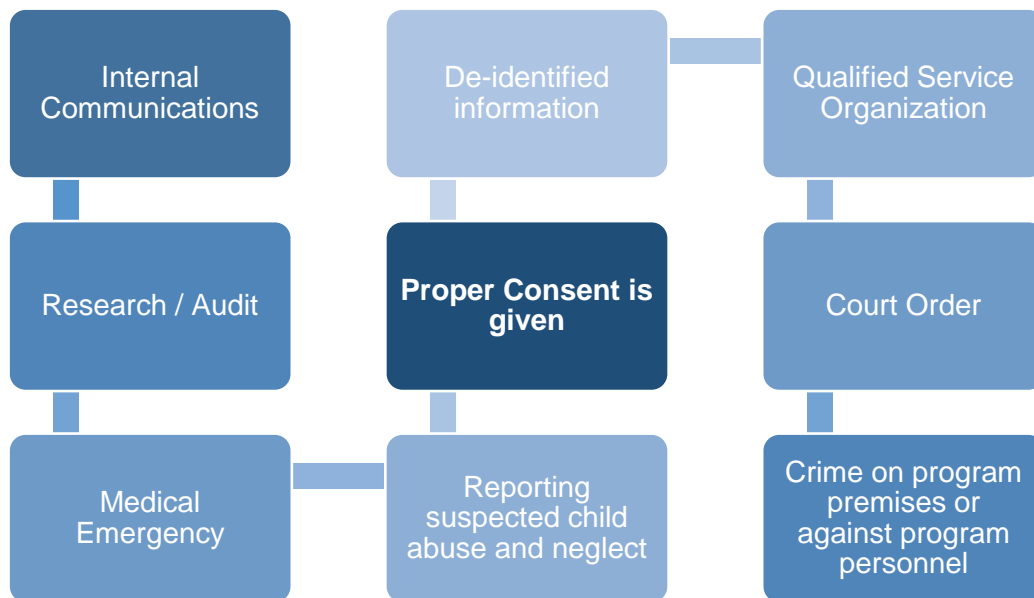
- Are Part 2 records being disclosed or re-disclosed?

²⁶ 42 C.F.R. § 2.11 (2017).

WHEN CAN A PATIENT'S PART 2 RECORDS BE USED OR DISCLOSED?

With a better understanding of the purpose of the law, how it differs from HIPAA, and who is considered a Part 2 Provider/Program and Patient, we next look at when Part 2 patient records CAN be disclosed. Good patient centered care and integrated patient care often depend upon the sharing of information! Remember, Part 2 regulations only permit disclosure of Part 2 records by a Part 2 program IF certain circumstance are present. The most relevant exceptions for integrated providers are disclosures pursuant to a written patient consent, disclosures to a qualified services organization, and disclosures in an emergency.

The general rule under Part 2 is that SUD treatment records and information, including the identity of a SUD patient, cannot be disclosed. The limited exceptions to the general rule are shown here and then explained in further detail below.



Proper Patient Consent

See Draft Form B in Appendix

- A patient can give consent to share their SUD treatment information. A Part 2 program may disclose Part 2 patient information if the patient has given valid **written** consent. For Part 2, consent is **ONLY** valid if it is in writing and meets the special requirements of Part 2. Written patient consents under Part 2 require more detail than an authorization under HIPAA. (See more on these requirements below)

Internal Communications

- Part 2 regulations do not apply to communications within a Part 2 program or between a program and an entity that has **direct administrative control** over that program, however, disclosure must be limited to those who have a “need for the information in connection with their duties that arise out of the diagnosis, treatment, or referral for treatment of patients with substance use disorders.”²⁷

Example: A patient tells his substance use counselor, at the Federally Qualified Health Center, that he has liver disease. The counselor can disclose the information to his supervisor, the care coordinator, social worker, and nurse to coordinate treatment needs.

Example: A Part 2 program provider may discuss a compliance issue with the practice’s risk manager.

Note: Remember any information disclosed with consent cannot be re-disclosed without further consent or an applicable exception. In the above situation, the compliance team would not be able to re-disclose the information unless it was reporting the information back to the Part 2 program.

²⁷ 42 C.F.R. § 2.12(c)(3) (2017).

Research and Audit

- **Research:** Part 2 information may be disclosed, without patient consent, for the “purpose of conducting scientific research,”²⁸ if certain protections are in place. Part 2 information must be “rendered non-identifiable” in research reports.²⁹ Records must still be maintained in compliance with other relevant federal, state, and local laws.³⁰
- **Audit:** Part 2 data may also be disclosed, without patient consent, for on-site audits or evaluations.³¹ Disclosures may be made to government agencies that help to fund or regulate the Part 2 program, private entities that help fund the program or provide third-party payments which are conducting quality control reviews, or others who are conducting an audit or evaluation of the program. Generally, entities must agree in writing to protect SUD patient records.³²

Reporting Suspected Child Abuse and Neglect

- Part 2 providers must comply with relevant suspected child abuse and neglect laws and Part 2 allows for the disclosure of information for this purpose.³³ Information may be disclosed for the initial abuse or neglect report, but restrictions on disclosure will still apply to SUD patient records that might be needed for future civil or criminal proceedings arising out of the initial report.³⁴

De-identified information

- Part 2 is specifically meant to protect SUD patients from being identified as having or having had a SUD.³⁵ Information that **cannot** be used to identify the patient as a current or past SUD patient may be disclosed as “de-identified” information. The new rules incorporate the detailed definition of “de-identified” applied by the HIPAA standards.

²⁸ 42 C.F.R. § 2.52 (2017).

²⁹ *Id.*

³⁰ *Id.*

³¹ 42 C.F.R. § 2.53 (2017).

³² *Id.*

³³ 42 C.F.R. § 2.12(c)(6) (2017).

³⁴ *Id.*

³⁵ 42 C.F.R. § 2.12(a)(1) (2017).

Court Order

- A Part 2 program may only disclose SUD patient information without consent by a court order if the court order complies with the heightened protections described in the law.³⁶ Some of these requirements include:
 - Giving the Part 2 program (and the patient for noncriminal purposes) notice and opportunity to be heard before the court when a court order is requested;³⁷
 - The use of fictitious names, confidential proceedings, sealed records, and limited disclosure of information to protect the patient’s SUD information;³⁸ and
 - Heightened criteria for obtaining a court order which requires the court to find “good cause” for the order. The criteria include finding that “the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services,” including requiring that court orders for criminal cases be for crimes that are “extremely serious.”³⁹

Crime on Program Premises or Against Program Personnel

- A Part 2 program can disclose certain information to law enforcement, without patient consent, if it relates to a patient committing or threatening to commit a crime on the program premises or against program personnel.⁴⁰ Information that may be disclosed includes a report of the incident, patient status, name, address, and last known whereabouts of the person who committed or is threatening to commit the crime.⁴¹

Example: After work, Counselor at a Part 2 program cannot find his car in the parking lot and there is shattered glass in the parking spot where he left his car. Earlier in the day, Patient X argued with Counselor and threatened to “mess” him up. Patient Y said he saw Patient X trying to break into the car. Part 2 allows the program to report to the police that the car has been stolen, the threat made by Patient X, Patient X’s name, address, status as a patient at the program, and last known whereabouts. The program cannot, however, disclose any information about Patient Y without her written consent.

Legal Action Center, *Tool #2, SBIRT and the Federal Alcohol and Drug Confidentiality Rules – The Basic Requirements*, 6 (2017), https://lac.org/wp-content/uploads/2017/03/SBIRT_Tool2.pdf

³⁶ 42 C.F.R. § 2.64 (2017).

³⁷ 42 C.F.R. §§ 2.64 and 2.65 (2017).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ 42 C.F.R. § 2.12(c)(5) (2017).

⁴¹ *Id.*

Medical Emergency

- Patient identifying information may be disclosed by a Part 2 program to medical personnel **to the extent necessary to meet a bona fide medical emergency** in which the patient's prior consent cannot be obtained.⁴²
- **Condition:** The Part 2 program must document whom the information was disclosed to and who made the disclosure, the date and time of the disclosure, and the nature of the emergency (why the information was disclosed) in the patient's record.⁴³



Example: If a Part 2 provider is meeting with a patient whom the provider believes might be dangerously intoxicated or overdosing, the provider can call for emergency services. If the patient loses consciousness or cannot give consent, the Part 2 provider can disclose the information to the emergency medical personnel, and the specific disclosure details must be documented later.

Legal Action Center, *Tool #2, SBIRT and the Federal Alcohol and Drug Confidentiality Rules – The Basic Requirements*, 4 (2017), https://lac.org/wp-content/uploads/2017/03/SBIRT_Tool2.pdf

Example: An emergency room physician is treating a patient in a medical emergency and contacts the patient's treating provider to determine if the patient is on any medications. The treating provider appropriately discloses that the patient is on suboxone, as suboxone would impact anesthesia for the patient.

Qualified Services Organizations

See Draft Form D in Appendix

A Qualified Services Organization (QSO) can share Part 2 information with a Part 2 program pursuant to a valid Qualified Services Agreement. A QSO is like a business associate, but be aware the definition of a QSO under Part 2 is much more limited than the delineation of a business associate under HIPAA. They are entities that provide services to the Part 2 program pursuant to a written agreement.⁴⁴ QSOs can provide the following services:

- data processing
- bill collecting
- dosage preparation
- lab analysis or
- professional services including
 - legal
 - accounting
 - medical staffing
 - **population health management** or
 - services to prevent or treat child abuse.⁴⁵

⁴² 42 C.F.R. § 2.51 (2017).

⁴³ *Id.*

⁴⁴ 42 C.F.R. § 2.11 (2017).

⁴⁵ *Id.*

How has this changed in the updated Part 2 law? The new Part 2 includes “population health management, medical staffing, or other professional services” in the language describing QSOs. This broadens the definition of a QSO and allows for disclosure to these entities pursuant to written agreement or patient consent.

The QSO must enter into a written agreement with the Part 2 program and the agreement must acknowledge the QSO’s obligations to comply with the Part 2 regulations.⁴⁶ The Part 2 program can then share necessary information with the QSO. This means the Part 2 restrictions on disclosures do not apply to communications between a Part 2 program and a QSO, but only to the extent the information disclosed is **necessary** for the QSO to provide agreed upon services to the Part 2 program.⁴⁷ QSOs can include a third-party entity such as an electronic health record vendor, Health Information Exchange network, etc.⁴⁸

Example: Part 2 Unit enters into a QSO with affiliated Accountable Care Organization (ACO) staff to assist in the review of patient outcomes and quality indicators. Patient consent is not required if the ACO staff agrees to maintain information consistent with Part 2 requirements.

Note: A QSO CANNOT be used to “avoid obtaining patient consent in the treatment context.” (82 Fed. Reg. at 6067). For example, a practice cannot share Part 2 information with a specialist who is not part of the practice simply by entering into a QSO agreement. However, if the specialist provides services under a staffing agreement and treats patients at and through the practice part-time, a QSO is appropriate. SAMHSA warns, however, that a QSO agreement cannot be used to circumvent patient consent and disclose information to other treating providers outside the Part 2 program or unit such as PCPs, care managers, or medication management providers. (*Id.*) Disclosures by a Part 2 program to other practitioners outside the program usually requires patient consent.

Example: A Part 2 program can enter into a QSO agreement with a *locum tenens* physician or community provider covering call for the practice.

A Part 2 program can provide information to the QSO to the extent necessary for it to perform its services and the QSO can send that information back to the Part 2 program, but the information cannot be disclosed to a third party. In this instance a “third party” would be

⁴⁶ *Id.*

⁴⁷ 42 C.F.R. §§ 2.11 and 2.12(c)(4) (2017).

⁴⁸ Substance Abuse and Mental Health Services Administration, *Frequently Asked Questions - Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)*, <https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf> (last visited Aug. 17, 2017).

someone not a member of the QSO agreement because there can only be 2 entities within such an agreement. Multi-party QSO agreements are prohibited.⁴⁹

Alternatively, a QSO agreement CAN be used to disclose information to an organization providing population health management services.⁵⁰ However, these disclosures “would be limited to a specific office(s) or unit(s)/entity(ies) that is/are tasked with carrying out such services for the organization.”⁵¹ Thus, the information cannot be shared with the entire organization or its participants.

PART 2 COMPLIANCE REQUIREMENTS

Next, we will look more closely at the technical compliance steps required by Part 2 including: what types of policies and procedures a practice should have, when notice must be given, what is required for proper notice, what a consent must include, and what a non-re-disclosure notice must look like.

If we break all of this down, there are 5 basic Part 2 requirements that need to be adhered to; those requirements are:

- I. Security Policies;
- II. Notice to Patients of Part 2 Rights;
- III. Patient consent forms that are compliant with Part 2;
- IV. Non re-disclosure notices when Part 2 information is disclosed; and
- V. Qualified Service Organization Agreements when necessary

QSOs will not be discussed further. Please refer back to pages 22-24 and see Draft Form D in Appendix for more information.



Question

- Notice?
- Policies and procedures?



Question

- Consent?
- To whom?



Question

- Notice of non-re-disclosed language with every disclosure?

⁴⁹ Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 6067. Note, while multi-party QSOs are prohibited, multi-party consents are permitted.

⁵⁰ 82 Fed. Reg. at 6067.

⁵¹ *Id.*

I. Security Policies and Procedures

All Part 2 programs or holders of Part 2 information MUST have formal policies and procedures in place to reasonably protect against unauthorized uses and disclosures of patient identifying information.⁵² Policies and procedures must aim “to protect against reasonably anticipated threats or hazards to the security of patient identifying information.”⁵³ These policies and procedures should be included in a practices general privacy policies and procedures.

| | |
|-----------------------------------|---|
| Paper Records⁵⁴ | Policies and procedures for paper records must address the following: <ul style="list-style-type: none">• Transferring and removing records;• Destroying records, including sanitizing the hard copy media associated with patient printouts, to render the patient identifying information non-retrievable;• Maintaining records in a secure room, locked file cabinet, safe, or other similar container, or storage facility when not in use;• Using and accessing workstations, secure rooms, locked file cabinets, safes or other similar containers, and storage facilities that use or store such information; and• Rendering patient identifying information non-identifiable in a manner that creates a very low risk of re-identification. |
|-----------------------------------|---|

| | |
|--|---|
| Electronic Records⁵⁵ | Policies and procedures for electronic records must address the following: <ul style="list-style-type: none">• Creating, receiving, maintaining, and transmitting records;• Destroying records, including sanitizing the electronic media on which records are stored, to render the patient identifying information non-retrievable;• Using and accessing electronic records or other electronic media containing patient identifying information; and• Rendering the patient identifying information non-identifiable in a manner that creates a very low risk of re-identification. |
|--|---|

⁵² 42 C.F.R. § 2.16 (2017).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

II. Notice of Patient Rights under Part 2

See Draft Form A in Appendix

Notice to patients of the federal confidentiality requirements MUST be given at the time of admission to the Part 2 program, or as soon thereafter as the patient has capacity.⁵⁶ Notice of the federal law and regulations protecting privacy, a summary of the federal law and regulations, and the “required elements” set forth in Section 2.22 must be included.⁵⁷ The notice can include state law information as well.

Notice must be in writing (either paper or electronic), and must:⁵⁸

- Communicate to the patient that their SUD patient records are protected by federal law and regulations, and
- Include a summary of the federal law and regulations consistent with Part 2.

Required Notice of Patient’s Rights: Elements of Section 2.22

- A description of the limited circumstances that allow the patients information to be disclosed either by acknowledging their presence or identifying them as having or having had a SUD;
- A statement that violation of Part 2 is a crime, suspected violations may be reported, and contact information for reporting violations;
- A statement that information related to the commission of a crime on the premises or against personnel by a patient is not protected and may be disclosed;
- A statement that reports of suspected child abuse and neglect are not protected and may be disclosed;
- A citation to the federal law and regulations; and
- MAY include a summary of state law and additional consistent policies.

⁵⁶ 42 C.F.R. § 2.16 (2017).

⁵⁷ 42 C.F.R. § 2.22 (2017).

⁵⁸ 42 C.F.R. §§ 2.22 and 2.11 (2017); 82 Fed. Reg. at 6077.

III. Compliant Patient Consents

See Draft Form B in Appendix

A Part 2 program may disclose patient information if the patient has given valid **written** consent. For Part 2, consent is **ONLY** valid if it is in writing. A valid written consent form **must** include the following elements:⁵⁹

- **From Whom:** Identify the Part 2 program as the entity making the disclosure;
- **What Kind:** Describe “how much” and “what kind” of treatment records will be disclosed;
- **Purpose:** Describe the purpose of the disclosure;
- **To Whom:** Clarify “to whom” the disclosure will be made (Important, see details below);
- **Right to Revoke:** Let the patient know of his/her right to revoke;
- **Expiration:** Identify a date the consent expires – (this can be longer than a year!); and
- **Signature:** Be signed and dated by the patient - (this can be an electronic signature).

How has this changed in the updated Part 2 law?

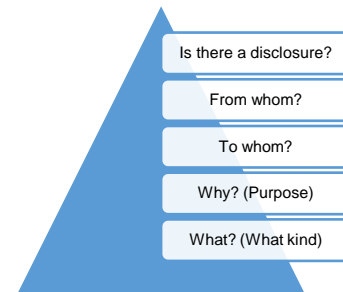
The new Part 2 regulations changed the “To Whom” requirements to allow for general designations of treating providers. A patient may now give written consent to allow disclosure information to “all my treating providers” at a specifically named practice or medical facility. For example, a consent may designate “to an HIE and all my treating providers,” or an ACO and “all my treating providers.” **See below for more details.**

Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 6081.



⁵⁹ 42 C.F.R. § 2.31 (2017).

- **From Whom:** Integrated providers must identify the Part 2 program providers in their delivery network. The Part 2 program providers are the ones that create protected Part 2 information. Part 2 providers are responsible for securing consents and otherwise protecting the patient’s Part 2 information. The Part 2 program or other entity making the disclosure must be identified in the written consent.



- **What Kind:** The patient must be told “how much” and “what kind” of SUD records will be disclosed. It must be clear to the patient what SUD information will be included. Disclosing providers should consider what needs to be disclosed for purposes of integrated care and treatment.
- **Purpose:** The patient must be told for what purpose the information will be disclosed. Providers should also assess why the information must be shared.
- **To Whom:** Identifying “to whom” the disclosures will be made is an important part for Part 2 confidentiality compliance. Part 2 providers must assess patient flows and care patterns to best determine in advance “to whom” information should be shared in an integrated care setting.
 - The consent form must provide information about “to whom” the patient information will be disclosed.
 - The form **CAN name the ENTITY:**⁶⁰
 - If disclosure is to a treating provider
 - If disclosure is to treating providers through an intermediary or a Health Information Exchange (HIE)
 - *However*, the intermediary or HIE must provide the patient with a list of the entities to whom Part 2 records are provided if requested.
 - If disclosure is to a third party payer

Example: I consent to disclosing my patient record including my mental health and SUD information to my treating providers at Primary Care Practice X and Hospital Y.

- The form **MUST name the INDIVIDUAL:**
 - If the recipient entity **does not** have a treating provider relationship with the patient.⁶¹

Example: I consent to disclosure and confirmation of my attendance at and adherence to my treatment plan with Andy White my parole officer and Patricia Black my care manager at City Supported Housing.

⁶⁰ 42 C.F.R. § 2.31 (a)(4) (2017).

⁶¹ 42 C.F.R. § 2.31(a)(4)(iii)(B) (2017).

- **Right to Revoke:** The patient must be informed that they have a right to revoke their consent.
- **Setting expiration dates for consent:** The consent form must have a date, event, or condition which will trigger the expiration of the consent, if it has not already been revoked.⁶² The form cannot just say that consent is valid until revoked.⁶³ It must specify an event, condition, or date. However, an expiration date stated as “upon my death” is proper and consent may last longer than a year.⁶⁴
- **Signature:** The consent form must be signed by the patient and electronic signatures are acceptable.

The patient’s right to a list of entities to whom information has been disclosed. (42 C.F.R. § 2.31 (2017).)

Patients may consent to disclose information to treating providers at certain generally designated entities. For example, “I authorize disclosure of my substance use disorder records to my treating providers through the information exchange.” The information exchange is then the “intermediary.”

The patient must be informed that “upon their request” and consistent with Part 2, “they must be provided a list of entities to which their information has been disclosed.” (42 C.F.R. § 2.31 (2017). *

Patient Right to List of Disclosures (42 C.F.R. § 2.13 (2017).)

- The intermediary or “Health Information Exchange,” (not the Part 2 program) is responsible for giving the patient a list of entities to whom it disclosed Part 2 records.
 - Upon written request by the patient, the intermediary must provide, within 30 days of the request:
 - A list of entities to whom information was disclosed
 - Descriptions of what information was disclosed and when
 - Dating back for the last 2 years

** There are special rules in New Hampshire regarding disclosure of protected health information through Health Information Exchanges/Organizations. If you use an HIE/HIO you should familiarize yourself with the requirements of N.H. Rev. Stat. Ann. § 332-1:3 (2014).*

⁶² 42 C.F.R. § 2.31(a)(4)(iii)(B) (2017).

⁶³ 82 Fed. Reg. at 6078.

⁶⁴ *Id.*

IV. Prohibition against Re-Disclosure

See Draft Form C in Appendix

EVERY disclosure made pursuant to a consent MUST include the special non-disclosure language that follows:⁶⁵

ALCOHOL OR DRUG ABUSE TREATMENT REDISLCOSURE PROHIBITED

“This information has been disclosed to you from records protected by federal confidentiality rules, 42 CFR Part 2. The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR Part 2. A general authorization of 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 in connection with a crime committed on the premises or against a SUD provider, or consistent with 42 CFR Part 2 section 2.65.”

Note: Persons or entities who have received SUD patient information are not allowed to re-disclose that information to someone else without specific consent or unless an applicable exception applies.

The regulators have promised to review this complicated and lengthy “Prohibition Against Re-Disclosure” language to determine whether a shorter form is appropriate. Incorporating this language each time there is a use or disclosure pursuant to a consent is a challenge in the integrated setting, but can and must be incorporated appropriately into practice flow patterns.




Question

- Notice?
- Polices and procedures?



Question

- Consent?
- To whom?



Question

- Notice of non-re-disclosed language with every disclosure?

⁶⁵ 42 C.F.R. § 2.32 (2017).

COMPLIANCE TIPS

Note: Carefully review the instructions and annotations to the Forms attached.

- Who are your Part 2 providers or “units” who create confidential records?
- Who are your Part 2 patients who must sign Part 2 consents?
- Assess your practice patterns in order to determine “to whom” and “from whom” consent needs:
 - What entities/providers do Part 2 providers share information with?
 - What behavioral health care entities/providers do providers need information from?
- Review your policies and patient consent forms and adapt to integrated care model.
- Provide patients with appropriate Notice of federal confidentiality requirements at the time of treatment if possible.⁶⁶
- How will you ensure non-re-disclosure language provided each time Part 2 information is disclosed?
- Assess your electronic health record (EHR) capabilities.

Classifying “To Whom?”

- Is the disclosure of Part 2 information by a Part 2 program to the individual protected because:
 - Internal Communications?
 - By Consent?
 - QSO?
 - Other exception?
- Is the individual/entity part of the Part 2 Program?
- If a treating provider, are the providers or care coordinators providing services as part of the Part 2 program or are they employed by a separate entity?
- Is the individual or entity providing staffing or other services to the Part 2 Program?
- Is the individual/entity providing the type of services to the Part 2 program listed in the rules?
- Does the individual/entity need to see Part 2 information?

We have now discussed the major changes to Part 2. We hope you have a better understanding now of how the law has changed and what your entity must do to comply with the new law and regulations. The rest of this workbook contains helpful resources to assist you in your process of making sure your forms and procedures comply with the new Part 2 in your integrated care setting.

⁶⁶ 42 C.F.R. § 2.22 (2017).

PRE-WORK AND BOOT CAMP SESSIONS

Pre-Work: Conduct IDN Project Scan

Task: Identify IDN Project Plans where projects necessitate, or are anticipated to necessitate, the provision or sharing of substance use treatment records of DSRIP attributed patients.

- Treating and non-treating professionals or entities who are participating directly in the Project.
- Anticipated role of the participating entities/individuals.
- What information will be shared amongst Project team entities/professionals including specifically what SUD treatment/diagnosis/referral records will be shared?

Worksheet Template: Provider Scan

| Business Entity | Medical Provider | BH Provider | Part 2 Provider | Community Provider | |
|------------------------------------|------------------|-------------|-----------------|--------------------|--|
| Sample: Your Hospital System, Inc. | X | | X | | |
| Sample: Your CMHC, Inc. | | X | | | |
| | | | | | |
| | | | | | |
| | | | | | |

Purpose of Scan: To develop appropriate detail for purposes of Part 2 “Scan” in order to identify Part 2 providers, Part 2 records, and Part 2 patient flow. We need the answers to these questions in order to:

- Determine when privacy “packet” (consents/privacy notice) needs to be reviewed with SUD patient and by whom
- Determine how to complete the model “to whom” language of the patient consents
- Determine purpose for which records will be shared for purposes of Part 2 compliance
- Determine who needs to receive the obligatory non-re-disclosure notice.

APPENDIX

Guidelines for completing process flow of IDN Projects

Process Flow Map

Guidelines for completing Part 2 Consents

From/To Whom Chart for Disclosures

Classifying Your Organization's Help and Support

Instructions for FORM Development

Form B with Instructions

Form A- Sample Notice of Privacy Practice

Form B- SUD Services: Authorization and Consent to Disclose

Form C- Prohibition on Re-disclosure Language

Form D- QSO Agreement

GUIDELINES FOR COMPLETING PROCESS FLOW OF IDN PROJECTS

Answer each of the questions below while visually creating a process flow map (see template below) to identify Part 2 patients and providers/entities.

1. Identify what Part 2 Substance Use Disorder (SUD) Service you are *improving, expanding or delivering* through this project.



➤ Identify the goal of this project.

2. Identify a Part 2 Patient in this Project. **For this exercise, we will be using Aster.**
Aster represents a person who through entering into this project is identified as an individual with a substance use disorder.
3. Identify who will recommend **Aster** for this project service (i.e. PCP, county courts, etc.). **Use a box per entity in the corresponding section.**
 - a. Are they a treating provider?
 - b. Are they a SUD/Part 2 Provider?
 - c. Are they a community organization?

Using the key and supplies provided to you, identify the entities you classified for the above questions. If the recommender is NOT a treating provider, identify by name. Follow the instructions for further detail.

4. Identify what entities or professionals could provide the enhanced SUD Service to **Aster**.
 - a. What SUD/Part 2 information needs to be shared by this entity with the recommending entities or individuals? **Enter in notes section.**
 - b. Two-way information sharing or one-way sharing? **Identify relationship with drawing arrows between entities.**

5. Identify where **Aster** could go next after “completing” the enhanced service.
 - a. What SUD/Part 2 information needs to be shared by this entity? **Enter in notes section.**
 - b. Two-way information sharing or one-way sharing? **Identify relationship with drawing arrows between entities.**

GUIDELINES FOR COMPLETING PART 2 CONSENTS



1. What are you doing together as IDN partners with other individuals or entities that necessitates disclosure of patient behavioral health information?
[E.g., think through the context for the patient treatment experience and disclosures]

2. Which SUD/Part 2 or lawful holder of SUD/Part 2 information in your Project patient flow will be reviewing confidentiality issues with the patient and when? (i.e. securing the consent, reviewing privacy notice, etc.)

[Entity(s)/professional making the disclosure]:

3. What type of SUD/Part 2 information will be disclosed to other providers, entities or individuals about the patient's care?

[List]

4. **To whom** will the disclosures be made?

a. *Treating Providers*: Name the entities to the extent the entities include the patient's treating providers:

b. *Non-Treating Providers*: Name the entities or individuals who are NOT treating providers to whom SUD/Part 2 information will be disclosed? If you do not know the name, provide the most accurate title you can.

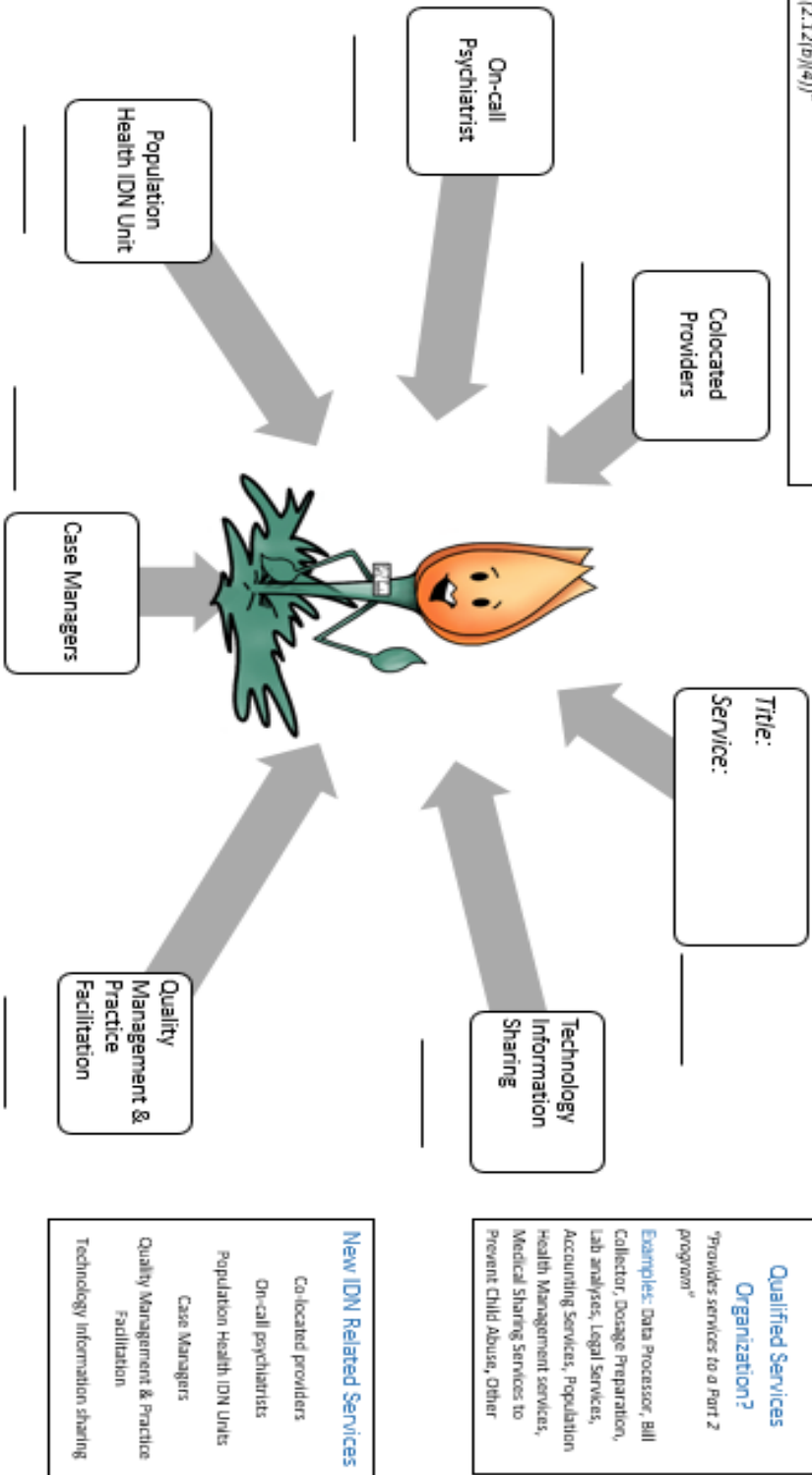
c. Name the intermediary, such as an information exchange, if you may be using to share the information?

d. Will any of the providers, entities and/or individuals who receive the SUD/Part 2 information need to re-disclose the information to others? Why and how?

5. Which entity or individuals will be involved in population health/evidence-based outcome analysis with regard to the SUD patients included in this project? Briefly describe what they will be doing and for whom.

Classifying Your Organization's Help and Support: OSO? Treating Provider? Community Support?

"Part 2 Providers may disclose SUD information to a OSO pursuant to a OSO agreement to the extent the information is needed to provide the services (2.12(b)(4))"



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INSTRUCTIONS FOR FORM DEVELOPMENT EXERCISE

1. Draft Forms:

Please review the PowerPoint presentations and Workbook for further information about the requirements of 42 CFR Part 2, as amended. The rules require:

1. *Formal Policies and Procedures to secure Part 2 information (2.16)*
2. *Notice of Privacy Rights (adapted and updated from Legal Action Center form published pre-2017) (Draft Form A attached)*
3. *Consent/Authorization to Disclose (Draft Form B attached)*
4. *Prohibition on Re-disclosure language – to be attached to Part 2 information that is disclosed pursuant to a consent (adapted from 42 CFR Part 2) (Draft Form C attached)*
5. *Qualified Services Organization Agreement template language (adapted and updated from Legal Action Center forms published under rules pre-2017) (Draft Form D attached)*

2. Notice of Privacy Rights (Draft Form A):

- a. To be provided to patients as soon as practicable by a Part 2 Program provider.
- b. Draft Form A includes basic requirements of the statute.

3. Consent/Authorization (Draft Form B):

- a. The basic elements of a 42 CFR Part 2 consent are listed below and a general form template with instructions is attached for your use and adaptation. Many Part 2 providers have authorization forms and consents already in use that may be modified to incorporate updated language. The consent/authorization language should be consistent with your program's philosophy, the IDNs purpose, whole person patient care and privacy compliance. Confidentiality should not overwhelm good patient care – it should be part of it:

- Name of Patient
- Name of Part 2 Program making the Disclosure
- Identification of TO WHOM the disclosure will be made
 - Treating providers
 - Community Care Agencies or other non-treating providers
 - Payers
 - Health Information Exchange (if needed)
 - friends and family members (if needed)

For Use and Review by IDNs Participating in UNH Privacy Boot Camp

SAMHSA has promised but has not yet published sub-regulatory guidance or draft Forms consistent with the 42 CFR Part 2 regulations published January 2017. Any Form should be reviewed with and revised by your provider's leadership/compliance team and counsel as necessary.

- Identify WHAT will be disclosed
- Identify the PURPOSE for the disclosure
- Right to revoke
- Effective date and expiration date
- Reminder of 42 CFR Part 2 Rights in general

We recommend you try to fill out a consent form together using the template provided. Compare this to the forms you are currently using. Modify and update as necessary.

4. Prohibition on Re-Disclosure Statement (Draft Form C):

- a. To be provided to any recipient of Part 2/SUD information when disclosed by a Part 2 provider or re-disclosed by an authorized recipient pursuant to a consent.
- b. Draft Form C includes language directly from Part 2 regulations.

5. Qualified Service Organization Agreement (Draft Form D):

- a. See PowerPoint exercise from July 17, 2017.
- b. Draft Form D includes examples of suggested language required by 42 CFR Part 2.

SUBSTANCE USE DISORDER SERVICES:

AUTHORIZATION AND CONSENT TO DISCLOSE PROTECTED HEALTH INFORMATION^{67,68}

DRAFT FORM B WITH INSTRUCTIONS

Name: _____ Date of Birth: _____

Medical Record # (if known): _____

[Introduction FROM WHOM: Describe IDN integrated treatment model and identify the Part 2 Program making the disclosures. An example is provided below:]⁶⁹

I understand my care providers at ***[Name of SUD/Part 2 ENTITY making disclosure]*** _____ *[If part of hospital system, include affiliated entities if necessary, i.e., "I am a patient of Mount Ida Primary care, Mount Ida Capital partners and affiliated entities"]* will be providing and helping to coordinate aspects of my care and treatment and will therefore need to share certain private health information about my referral, diagnosis and/or treatment for substance use disorder [and mental health] with my treatment team, with other treating providers, with other individuals or entities involved in my care and/or recovery, with entities responsible for payment and with others listed below as authorized by me or by law.

⁶⁷ **Acknowledgement:** UNH Health Law and Policy appreciates the collaboration of the Legal Action Center (Deborah Reid, JD), the New Hampshire Center for Excellence (Amy Pepin) and New Hampshire attorneys also assisting providers in 42 CFR Part 2 compliance, including, but not limited to Courtney Grey Tanner, JD, MSW, NH Providers' Association, Sabrina Dunlap, JD, HinkleyAllen and Jason Gregoire, JD, Sheehan Phinney Bass & Green.

⁶⁸ NOTE: This Sample Consent Form may be used separately from or combined with a provider's HIPAA form, however, HIPAA differs from 42 CFR Part 2 in that HIPAA applies to all "covered entities" disclosing private health information, whereas Part 2 applies to Part 2 Programs.

⁶⁹ NOTE: The 42 CFR Part 2 rules apply heightened confidentiality restrictions to disclosures and re-disclosure of SUD/Part 2 information by Part 2 Programs (SUD Providers). This Sample Consent Form is intended for use with SUD patients referred for SUD services from SUD/Part 2 providers. Non-SUD health care providers may make disclosures consistent with applicable privacy rules or regulations to the extent they apply, such as HIPAA.

For Use and Review by IDNs Participating in UNH Privacy Boot Camp

SAMHSA has promised but has not yet published sub-regulatory guidance or draft Forms consistent with the 42 CFR Part 2 regulations published January 2017. Any Form should be reviewed with and revised by your provider's leadership/compliance team and counsel as necessary.

[Section 1: For Disclosures to Treating Providers⁷⁰]

[WHAT]:

I authorize [my Part 2 Program treatment team]⁷¹ to access, use, disclose and communicate both verbally and in writing, private substance use disorder and mental health information [which is maintained as part of my integrated electronic health record]⁷², including:
[Check all that apply]⁷³

- My health care record
- Intake, progress and discharge reports and notes
- Evaluations and assessments by my providers
- Test, lab and radiology results
- Referrals for treatment
- Medications
- Case management and treatment plans (including addendums)
- Other:(specify) _____
- Other:(specify) _____

⁷⁰ NOTE: Consent must be obtained from a patient in order for a Part 2 Program to share SUD/Part 2 information with treating providers (other than those in the Part 2 Program or unit). A "treating provider" is an individual or entity that provides health related assistance to a patient by way of diagnosis, evaluation or treatment.

⁷¹ NOTE: There is no consent required for sharing a SUD patient's identity and SUD/Part 2 information amongst the Part 2/SUD Program's own treating providers.

⁷² NOTE: Part 2 Programs that are part of a larger health system and use a unified EHR should work with their compliance team and EHR vendor to manage the consent and prohibition against re-disclosure notice process.

⁷³ NOTE: In developing your consent form, you may summarize if all treating providers will have access to the medical record for purposes of their treatment.

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[TO WHOM and PURPOSE]

I understand disclosures and re-disclosures both verbally and in writing may be made to and from my past, current and/or future treating providers for the purpose of *my ongoing treatment and recovery and helping me manage my care*, including but not limited to:⁷⁴ [LIST OF TREATING PROVIDER ENTITIES]

[Check all that apply]⁷⁵

- My Care Coordinator(s) at⁷⁶: _____
- [IDN Treating Provider Entity 1]
- [IDN Treating Provider Entity 2]
- [IDN Treatment Provider Entity 3]
- [IDN Treatment Provider Entity 4]
- [IDN Treatment Provider Entity 5]
- [IDN Treatment Provider Entity 6]
- [IDN Treatment Provider Entity 7]
- [My treating providers through the [Health Information Exchange]]: (Name/Title of Supervisor of HIE) _____
- Other: (specify) _____
- Other: (specify) _____

⁷⁴ NOTE: The new Part 2 rules explain that Part 2 Providers can seek consent to disclose generally to "treating providers" through an "intermediary." The intermediary, whether it be a medical facility or Health Information Exchange (HIE), must keep track of disclosures and provide the list to the patient upon request. Part 2 Programs can include a specific consent to disclose to treating providers through a HIE and provide the explanation in the Notice of Privacy Practices. If the intermediary is a clinic or hospital, the clinic or hospital must keep track of disclosures. If the intermediary is a HIE, as a non-treating provider intermediary, the person responsible for the HIE must be named.

⁷⁵ NOTE: IDN teams should consider listing by entity name the treating providers that are part of a typical SUD patient's "patient flow" as documented in the first day of Boot Camp. When filling out the consent form, the treating providers can be checked. If the SUD/Part 2 program is part of an integrated medical system, the Part 2 Program affiliates should be listed.

⁷⁶ NOTE: Care coordinators do not have to be listed at all if they are part of the Part 2 Program team, or the care coordinator can be described and listed as a treating provider or as a non-treating provider identified by name depending upon how the care coordination function is set up by the IDN or group of providers.

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[Section 2: List of Community Care Agencies and Other Non-Treating Providers]⁷⁷:

[WHAT]:

I also authorize [my treatment team] to access, use, disclose and communicate both verbally and in writing the following private substance use disorder and mental health information [which is maintained as part of my integrated electronic health record], including:⁷⁸
[Check all that apply]

- My medical events, care management plan and medication list
- My attendance at my recovery program
- Information confirming my compliance with my care and recovery plan
- Other: _____
- Other: _____

[TO WHOM and PURPOSE]⁷⁹

I understand that disclosures and re-disclosures may be made both verbally and in writing to and from the following individuals involved in my well-being and recovery:

[LIST OF NAMES AND TITLES of individuals at COMMUNITY CARE AGENCIES or other non-treating providers to whom SUD/Part 2 Program Information will be disclosed]

- Agency: (Title/Name of Individual/Tel #) _____
- Agency: (Title/Name of Individual/Tel #) _____
- Agency: (Title/Name of Individual/Tel #) _____
- Agency: (Title/Name of Individual/Tel #) _____
- Other: _____
- Other: _____

⁷⁷ NOTE: "Community Care Agencies" are simply those partners who will be part of the patient's care "flow" in the IDNs who do not provide medical care, such as police departments, DCYF, housing services, vocational rehab, etc. Consents to share SUD/Part 2 information with community care agencies must identify the name of the person to whom the disclosure will be made.

⁷⁸ NOTE: Create either an opt in or opt out list of the specific information your Part 2/SUD program might share with Community Care Entity

⁷⁹ NOTE: If possible, to be consistent with the Part 2 rules, the purpose of the disclosure should correspond with the name of the individual to which it is disclosed, e.g., "Laconia PD, Officer True" for "confirming compliance with court ordered treatment, probation or parole".

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For the purpose of: [check all that apply]

- Monitoring and supporting my ongoing recovery
- Assessing/evaluating my readiness/ability to participate in housing/employment/vocational training
- Confirming compliance with court ordered treatment, probation or parole
- For the purpose of the care and treatment of my children
- Other: _____
- Other: _____

[Section 3: For Payment]:⁸⁰

I authorize [my treatment team] to use, disclose and communicate both verbally and in writing any and all information about my care and treatment to and from my health insurance company or other entity responsible for my medical bills for the purpose of eligibility and payment. *[Either insert the name of the payer or refer to your program's policy regarding notification of payment]:*

[OPTIONAL]

Authorization to Discuss Health Status with Family, Friends and/or Advocates

If I am not present or available, I authorize [ENTITY] affiliated treating providers and staff to discuss my relevant health information, including my substance use disorder [and mental health] treatment, with the family members, friends and/or advocates named below.

Authorized individuals (please provide full names):

| | |
|-------------|-------------|
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |

⁸⁰ NOTE: Your Part 2 Program may simply modify its existing form or policy requesting information about payer sources, confirming the ability to disclose SUD information to the payer on the form consistent with 42 CFR Part 2.

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Acknowledgement of Rights

I understand that my substance use disorder treatment records are protected under the federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I understand that if my treating providers disclose my substance use disorder treatment records pursuant to this consent, the recipient will be provided a notice of non-disclosure.

I also understand that I may revoke this consent, orally or in writing by contacting [APPROPRIATE ENTITY INFORMATION MANAGEMENT OFFICE _____] at [PHONE NUMBER _____] at any time except to the extent that action has been taken in reliance on it. We are unable to take back any disclosures we have already made with your consent and we are required to retain as records of the care we provide to you.

If not already revoked, this consent will expire on _____ [Example: One year/specified date/upon my death.]

Upon request, I can inspect or obtain a copy of the information I am authorizing to be released.

[I understand that I may be denied services if I refuse to consent to a disclosure for purposes of my treatment [or payment]. I will not be denied services if I refuse to consent to a disclosure for other purposes.]⁸¹

If I have any questions about disclosure of my private health information, I can contact _____ at [PHONE NUMBER].

I understand I can ask for a copy of this authorization and consent form.

Signature of Patient or legal representative or guardian

Date and Time

Authority/Relationship of representative to patient
(Attach copy of documentation of authority)

⁸¹ This provision is not necessary and may be different depending upon the type of provider offering services.

NOTICE OF PRIVACY PRACTICES FOR SUBSTANCE USE PATIENTS **DRAFT FORM A**

As a patient receiving substance use disorder prevention and treatment services by our Substance Use Disorder Treatment staff at [PART 2 PROGRAM ENTITY/ENTITIES] or an affiliated provider, your treatment records have additional privacy protections under federal law. Private information regarding your health and substance use disorder care is protected by two federal laws including HIPAA, and what we refer to as "Part 2." The full description of these laws are: the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 42 U.S.C. § 1320d *et seq.*, 45 C.F.R. Parts 160 & 164, and the Confidentiality of Substance Use Disorder Patient Records, 42 U.S.C. § 290dd, 42 C.F.R. Part 2 ("Part 2"). Specifically, Part 2 includes confidentiality provisions relating to the access, use, and disclosure of substance use disorder patient records. These protections go above and beyond the protections described in our [ENTITY] Notice of Privacy Practices.

Under Part 2, you must give written consent before information identifying you as a patient who needs or is receiving substance use disorder prevention and treatment is disclosed, including to entities or individuals who are paying your insurance claims. We ask you to help us care for you and support your treatment goals by providing a written consent that allows your providers to receive from, and disclose to, other treating providers, your identity and information in order to provide you the care you need, to obtain payment for care and treatment, and to allow for communication with other professionals, friends, and advocates involved in your treatment or recovery.

Under federal law, we may disclose information about your care and treatment for substance use disorder services *without* your written consent for the following reasons:

- 1) The disclosure is allowed by court order;
- 2) The disclosure is made to medical personnel in a medical emergency;
- 3) The disclosure is made to appropriate authorities to report suspected child abuse or neglect;
- 4) The disclosure is made to a qualified service organization/business associate;
- 5) The disclosure is made to qualified personnel for research, audit or program evaluation; or
- 6) The disclosure is made in connection with a suspected crime committed on the premises or a crime against any person who works for us or about any threat to commit such a crime.

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For example, [ENTITY/ENTITIES] or an affiliated provider can disclose information *without your consent* in order to provide services in a medical emergency to ensure your emergency is treated effectively.

In addition, with your consent, the [Part 2 Program] will disclose [your treatment and recovery information] [your medical events, a shared care plan, and your medication list] to your treating providers using a confidential and secure information exchange [identify HIE]. You have a right to request a list of the treating providers who have received your substance use disorder treatment information exchanged by [the HIE] pursuant to 42 CFR Part 2. If you would like additional information or a list of treating providers who have received your information, please contact:

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Violation of Part 2 is a crime and suspected violations may be reported to appropriate authorities, including the US Attorney in the judicial district where the violation occurs.

If you have any questions about disclosure of your private health information, you can contact [APPROPRIATE ENTITY INFORMATION MANAGEMENT OFFICE] at [PHONE NUMBER].

Acknowledgement of Receipt of the [ENTITY] Notice of Privacy Practices by Substance Use Patients

I acknowledge that I have received and reviewed the [ENTITY] Notice of Privacy Practices for Substance Use Patients, which includes particular information relating to the disclosure and use of information relating to substance use treatment (entitled Notice of Privacy Practice Substance Use Patients).

Name/DOB: _____/_____ Date: _____

⁸² NOTE: SAMHSA will be issuing sub-regulatory guidance on the responsibility of an intermediary to provide a "list" of disclosures, including clinics or practices who are sharing information with treating providers pursuant to a general consent. The obligations of an HIE to provide a list are clearly indicated in the comments to the rule and therefore included in this draft FORM for Notice of Privacy Rights. General or multi-specialty practice entities who receive Part 2 information pursuant to a consent pursuant to the "treating provider" designation may also have an obligation to notify the patient upon request which treating providers at the receiving entity access the patient's SUD records under the new Part 2 rules. Please consult with your attorneys or compliance team regarding this obligation and regulatory guidance as it is provided by SAMHSA in the near future.

SUBSTANCE USE DISORDER SERVICES:

AUTHORIZATION AND CONSENT TO DISCLOSE PROTECTED HEALTH INFORMATION⁸³

DRAFT FORM B

Name: _____ Date of Birth: _____

Medical Record # (if known): _____

I understand my care providers at **[Name of SUD/Part 2 ENTITY making disclosure]** _____ [If part of hospital system, include affiliated entities if necessary, i.e., "I am a patient of Mount Ida Primary care, Mount Ida Capital partners and affiliated entities"] will be providing and helping to coordinate aspects of my care and treatment and will therefore need to share certain private health information about my referral, diagnosis and/or treatment for substance use disorder [and mental health] with my treatment team, with other treating providers, with other individuals or entities involved in my care and/or recovery, with entities responsible for payment and with others listed below as authorized by me or by law.

I authorize [my Part 2 Program treatment team] to access, use, disclose and communicate both verbally and in writing, private substance use disorder and mental health information [which is maintained as part of my integrated electronic health record], including:
[Check all the apply]

- | | |
|---|--|
| <input type="checkbox"/> My health care record | <input type="checkbox"/> Medications |
| <input type="checkbox"/> Intake, progress and discharge reports and notes | <input type="checkbox"/> Case management and treatment plans (including addendums) |
| <input type="checkbox"/> Evaluations and assessments by my providers | <input type="checkbox"/> Other: (specify) _____ |
| <input type="checkbox"/> Test, lab and radiology results | <input type="checkbox"/> Other: (specify) _____ |
| <input type="checkbox"/> Referrals for treatment | _____ |

⁸³ **Acknowledgement:** UNH Health Law and Policy appreciates the collaboration of the Legal Action Center (Deborah Reid, JD), the New Hampshire Center for Excellence (Amy Pepin) and New Hampshire attorneys also assisting providers in 42 CFR Part 2 compliance, including, but not limited to Courtney Grey Tanner, JD, MSW, NH Providers' Association, Sabrina Dunlap, JD, HinkleyAllen and Jason Gregoire, JD, Sheehan Phinney Bass & Green.

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I understand disclosures and re-disclosures both verbally and in writing may be made to and from my past, current and/or future treating providers for the purpose of *my ongoing treatment and recovery and helping me manage my care*, including but not limited to:
[Check all that apply]

- My Care Coordinator(s) at: _____
- [IDN Treating Provider Entity 1]
- [IDN Treating Provider Entity 2]
- [IDN Treatment Provider Entity 3]
- [IDN Treatment Provider Entity 4]
- [IDN Treatment Provider Entity 5]
- [IDN Treatment Provider Entity 6]
- [IDN Treatment Provider Entity 7]
- [My treating providers through the [Health Information Exchange]]: (Name/Title of Supervisor of HIE) _____
- Other: (specify) _____
- Other: (specify) _____

I also authorize [my treatment team] to access, use, disclose and communicate both verbally and in writing the following private substance use disorder and mental health information [which is maintained as part of my integrated electronic health record], including:
[check all that apply]

- My medical events, care management plan and medication list
- My attendance at my recovery program
- Information confirming my compliance with my care and recovery plan
- Other: _____
- Other: _____

I understand that disclosures and re-disclosures may be made both verbally and in writing to and from the following individuals involved in my well-being and recovery:

- Agency: (Title/Name of Individual/Tel #) _____
- Agency: (Title/Name of Individual/Tel #) _____
- Agency: (Title/Name of Individual/Tel #) _____
- Agency: (Title/Name of Individual/Tel #) _____
- Other: _____
- Other: _____

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For the purpose of: [check all that apply]

- Monitoring and supporting my ongoing recovery
- Assessing/evaluating my readiness/ability to participate in housing/employment/vocational training
- Confirming compliance with court ordered treatment, probation or parole
- For the purpose of the care and treatment of my children
- Other:* _____
- Other:* _____

I authorize [my treatment team] to use, disclose and communicate both verbally and in writing any and all information about my care and treatment to and from my health insurance company or other entity responsible for my medical bills for the purpose of eligibility and payment. *[Either insert the name of the payer or refer to your program's policy regarding notification of payment]:*

Authorization to Discuss Health Status with Family, Friends or Advocates Members

If I am not present or available, I authorize [ENTITY] affiliated treating providers and staff to discuss my relevant health information, including my substance use disorder [and mental health] treatment, with the family members, friends and/or advocates named below.

Authorized individuals (please provide full names):

| | |
|-------------|-------------|
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |
| Name: _____ | Tel # _____ |

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Acknowledgement of Rights

I understand that my substance use disorder treatment records are protected under the federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I understand that if my treating providers disclose my substance use disorder treatment records pursuant to this consent, the recipient will be provided a notice of non-disclosure.

I also understand that I may revoke this consent, orally or in writing by contacting [APPROPRIATE ENTITY INFORMATION MANAGEMENT OFFICE _____] at [PHONE NUMBER _____] at any time except to the extent that action has been taken in reliance on it. We are unable to take back any disclosures we have already made with your consent and we are required to retain as records of the care we provide to you.

If not already revoked, this consent will expire on _____ [Example: One year/specified date/upon my death.]

Upon request, I can inspect or obtain a copy of the information I am authorizing to be released.

[I understand that I may be denied services if I refuse to consent to a disclosure for purposes of my treatment [or payment]. I will not be denied services if I refuse to consent to a disclosure for other purposes.]⁸⁴

If I have any questions about disclosure of my private health information, I can contact _____ at [PHONE NUMBER].

I understand I can ask for a copy of this authorization and consent form.

Signature of Patient or legal representative or guardian

Date and Time

Authority/Relationship of representative to patient
(Attach copy of documentation of authority)

⁸⁴ This provision is not necessary and may be different depending upon the type of provider offering services.

INSTRUCTIONS

How will the Prohibition of Re-disclosure language be communicated to recipients of any Part 2 Program/SUD records disclosed pursuant to a patient consent?

PROHIBITION ON RE-DISCLOSURE DRAFT FORM C

Each disclosure made with the patient's written consent must be accompanied by the following written statement (42 CFR § 2.32):

"This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosure of this information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as 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 Sections 2.12(c)(5) and 2.65."

**QUALIFIED SERVICE ORGANIZATION/BUSINESS ASSOCIATE
AGREEMENT (QSO/BA AGREEMENT)⁸⁵
DRAFT FORM D**

[Insert entity name] and the [insert program name] hereby enter into an agreement whereby the [insert entity name] agrees to provide:

(Nature of services to be provided to the program)

Furthermore, [insert entity name]:

1. acknowledges that in receiving, transmitting, transporting, storing, processing, or otherwise dealing with any information received from [insert program name] identifying or otherwise relating to the patients in the [insert program name] ('protected information'), it is fully bound by the provision of the federal regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 142, 160, 162 and 164;
2. agrees to resist any efforts in judicial proceedings to obtain access to the protected information except as expressly provided for in the regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, as amended;
3. agrees that it will not use or disclose protected health information except as permitted or required by the Agreement or by law;
4. agrees that, when the [insert entity name] uses, discloses, or request protected health information it will limit the use, disclosure, or request to the minimum necessary;
5. agrees that if the [insert entity name] enters into a contract with any agent, including a subcontractor, the agent will agree to comply with 42 C.F.R. Part 2 and HIPAA, and, if the [insert entity name] learns of a pattern or practice by the agent that is a material breach of the contract with the [insert entity name], to take reasonable steps to cure the breach or terminate the contract, if feasible;

⁸⁵ This Form has been modified from a version published by the Legal Action Center, "QSO/BA Agreement.- Form 6"

6. agrees to comply with HIPAA's security provisions with regard to electronic protected health information, and to use appropriate safe guards (*can define with more specificity*) to prevent the unauthorized use or disclosure of the protected information;
7. agrees to report breaches of protected information to the [insert program name];
8. agrees to report to the [insert program name] any use or disclosure of the protected information not provided for in this Agreement of which it becomes aware (*insert negotiated time and manner terms*);
9. agrees to ensure that any agent, including a subcontractor, to whom the Center provides protected information received from the [insert program name], or creates or receives on behalf of the [insert program name], agrees to the same restrictions and conditions that apply through this Agreement to the [insert entity name] with respect to such information;
10. agrees to provide access to the protected information at the request of the [insert program name], or to an individual as directed by the [insert program name], in order to meet the requirements of 45 C.F.R. § 164.524 which provides patients with the right to access and copy their own protected information (*insert negotiated time and manner terms*);
11. agrees to make any amendments to the protected information as directed or agreed to by the [insert program name] pursuant to 45 C.F.R. § 164.524 (*insert negotiated time and manner terms*);
12. agrees to make available its internal practices, books, and records, including policies and procedures, relating to the use and disclosure or protected information received from the [insert program name], or created or received by the [insert entity name] on behalf of the [insert program name], to the [insert program name] or to the Secretary of the Department of Health and Human Services for purposes of the Secretary determining the [insert program name]'s compliance with HIPAA (*insert negotiated time and manner terms*);
13. agrees to document disclosures of protected information, and information related to such disclosures, as would be required for the [insert program name] to respond to a request by an individual for an accounting of disclosures in accordance with 45 C.F.R. § 164.528 (*insert negotiated time and manner terms*);

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14. agrees to provide the [insert program name] or an individual in accordance with paragraph (9) of this agreement to permit the [insert program name] to respond to a request by an individual for an accounting of disclosures in accordance with 45 C.F. R. 45 C.F.R. § 164.528 (insert negotiated time and manner terms).

Termination

1. The [insert program name] may terminate this agreement if it determines that the [insert entity name] has violated any material term.
2. Upon termination of this Agreement for any reason, the [insert entity name] shall return or destroy all protected information received from the [insert program name], or created or received by the [insert entity name] on behalf of the [insert program name]. This provision shall apply to protected information that is in the possession of subcontractors or agents of the [insert entity name]. The [insert entity name] shall retain no copies of the protect information.
3. In the event that the [insert entity name] determines that returning or destroying the protected information is infeasible, the [insert entity name] shall notify the [insert program name] of the conditions that make return or destruction infeasible (insert negotiated time and manner terms);
4. Upon notification that the return or destruction of the protected information is infeasible, the [insert entity name] shall extend the protections of this Agreement to such protected information and limit further uses and disclosures of the information to those purposes that make the return or destruction infeasible, as long as, the [insert entity name] maintains the information.

Executed this _____ day of _____, 20 _____

President
[Entity Name & Address]

Program Director
[Program Name &

Notes: