

SHARING

Substance Use Disorder Information

A GUIDE FOR WASHINGTON STATE





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Disclaimer

This guidance is designed to clarify the state and federal laws that limit the use and disclosure of substance use disorder information, and it is intended to increase the common level of understanding in Washington's health care community. However, it is non-binding, is for informational purposes only and should not be construed as legal advice from Washington State or the Health Care Authority. Compliance with and interpretation of health care privacy laws is complex. Readers are encouraged to consult an attorney prior to operationalizing policies and procedures that control the use and disclosure of protected information.

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A word from Dr. Fotinos

Twenty years ago most people thought addiction to drugs or alcohol was a choice, a weakness of character. This thinking led to discrimination and a law enforcement focused approach to treatment. In order to protect people from discrimination strict Federal privacy rules were put in place. While well intended, the rules are complicated and hard to understand. This has led to barriers in sharing important health information across different disciplines of care.

Today we know addiction is not a choice. Brain science has helped us understand the complicated brain changes that occur in people who suffer from addiction to alcohol or drugs, also called substance use disorders. Despite this knowledge, people with substance use disorders and their families continue to carry shame and are afraid to talk about how their lives are being affected. This is particularly true with the current opioid epidemic.

The very good news is that there are effective medical treatments for opioid use disorder. There are also behavioral therapies that can help people with other substance use disorders. This makes it more important than ever for health care providers to think about and address 'whole person' health. This toolkit is meant to help medical, mental health, chemical dependency professionals and patients understand how a person's information can be safely shared and protected. Better information sharing across health care disciplines will help assure medications are prescribed safely, duplicate tests and treatments are avoided, and that health care providers can work together to help support their patients. Substance use disorders are medical conditions that are treatable, perhaps when healthcare providers become better at asking about substance use and sharing this information with other health related disciplines, there will be less shame and trying to keep hidden, treatable conditions.

Dr. Charissa Fotinos
HCA deputy chief medical officer

Introduction

People benefit when their health care providers have access to complete information and can provide whole-person care. But a complex set of privacy laws and regulations apply to Washington providers that sometimes cause confusion and prevent appropriate information from being available. Whether information can be exchanged may vary based on:

- What type of health information is being exchanged;
- The setting where care was provided;
- Who is disclosing the information; and
- Who is receiving the information.

Substance use disorder (SUD) information is often subject to stringent regulations in 42 Code of Federal Regulations (CFR) Part 2 (sometimes just referred to as "Part 2"). Not all SUD information is subject to Part 2; SUD information is only subject to Part 2 when created or disclosed by an entity that is subject to Part 2 (referred to as a "Part 2 Program").

Part 2 is based on legislation passed in the 1970s that was designed to address the risk of stigma and discrimination, and encourage people to seek services. The regulations have been updated recently, but because they are based on legislation that is over four decades old they are inconsistent with other health care privacy laws and do not reflect current health technology capabilities or the movement toward integrated, whole-person care.

Faced with a complex set of privacy laws, providers may take one of two opposing approaches.

They may overprotect the information and not share at all, or they may accidentally share more information than is allowed by law. Neither approach benefits people in need of services.

There are continued efforts to modify the statutes and regulations that protect SUD information, but the Health Care Authority believes it is important to implement current law as effectively as possible now without waiting for uncertain future changes. The goal of this document is to begin to break down barriers to information exchange and integrated care with guidance that establishes an accepted and commonly understood interpretation of when and how information can be appropriately shared. Specific goals include:

- Promoting shared understanding of when information can be shared with or without consent;
- Enabling greater consistency in how consent is requested and provided; and
- Facilitating whole-person care, and promoting care coordination and patient safety, by allowing providers more access to comprehensive health care information.

These resources were created in collaboration with other state agencies and valuable review was provided by a wide range of partners in the health care community. Continued engagement from those participants and others in the health care community is essential to ensure we continue making progress that allows us to better serve Washington residents.

Executive Summary

The rest of this document includes detailed information about the health care privacy laws that apply to the exchange of SUD information. This summary is intended to highlight key points, and help you navigate the document.

Scope

This document is intended to focus on substance use disorder information covered by 42 CFR Part 2. However, it is important to recognize that there are many different statutes and regulations that establish protections for different types of health care information. In particular:

- The Health Insurance Portability and Accountability Act (HIPAA), and its implementing regulations, establish the minimum protections for all types of health care information.
- State law in chapter 70.02 RCW establishes standards that largely, but not always, mirror HIPAA .
- State law in chapter 70.02 RCW also establishes more stringent protections for mental health and sexually transmitted infection information.
- Federal law in 42 USC 290dd-2, and its implementing regulations in 42 CFR Part 2, control the use and disclosure of applicable substance use disorder information.

More information about these different laws is provided beginning on page 9.

Generally applicable guidance

Although different laws apply to different types of information, some basic principles apply broadly to all types of health care information. These

principles include:

- The minimum necessary standard requires that in most circumstances, even when information is allowed to be used, shared, or requested, only the minimum amount necessary to accomplish a particular purpose should be used, shared, or requested.
- Information that has had all identifiable information properly removed is no longer subject to legal protection.

More information about these topics is provided beginning on page 12.

Who is subject to 42 CFR Part 2

42 CFR Part 2 only applies to SUD information created by particular providers, called Part 2 Programs. A provider that provides SUD services is a Part 2 Program if it holds itself out as offering SUD services, and is federally assisted. The definition of federally assisted is extremely broad and will include most providers, unless the provider is exclusively private-pay. The definition of “holds itself out” is less clear:

- It is likely satisfied if the program advertises that it provides SUD services, or is a separate unit that specializes in SUD services as part of a larger facility.
- An individual physician can be a Part 2 Program, but it is unlikely that providing occasional medication-assisted treatment alone would make a physician subject to Part 2.



Even for a Part 2 Program, it is possible some of its records are not subject to 42 CFR Part 2, such as if it provides both mental health and SUD treatment.

People or organizations other than the Part 2 Program can also become subject to Part 2's restriction. For example, when SUD information is shared pursuant to consent, Part 2's restrictions carry through to the recipient of the information.

More information about Part 2's applicability is provided beginning on page 16.

Disclosures with consent

SUD information can be shared consistent with a person's consent. The requirements for a valid written consent under 42 CFR Part 2 are more specific than the requirements under HIPAA. For example:

- Consent must describe both who can share information, and who can receive it;
- Consent can allow sharing with "all treating providers" through an intermediary, such as a Health Information Exchange (HIE), but the HIE must be identified and additional restrictions attach to how disclosures must be tracked; and
- The information must be accompanied by a statement to the recipient that the information remains subject to the restrictions in 42 CFR Part 2.

More information about sharing SUD information pursuant to consent is provided beginning on page 20.

Disclosures without consent

42 CFR Part 2 contains far fewer situations than HIPAA where information can be shared without consent, but it does include some. For example, information can be shared:

- In response to a medical emergency,
- For appropriately approved research projects,
- For limited public health purposes, or
- With "qualified service organizations" that provide certain administrative functions.

More information about situations where information can be shared without consent, and the prerequisites to sharing, is provided beginning on page 27.

Common exchange scenarios

Many people and organizations may be involved with a person's care, including different providers, contractors of those providers, and third-party payers. This document includes detailed scenarios that walk through how those different people and organizations can exchange information beginning on page 45.

Provider and patient educational materials

Much of this document is intended to be a resource for providers to understand when SUD information can be used, shared, or requested. It also includes materials that can be used to facilitate gathering consent, including:

- A template consent form that incorporates recent changes to 42 CFR Part 2,
- A sample script that could be used by a clinician at the point of care to explain consent, and
- A patient brochure that describes consent and the legal protections for SUD information.

These resources begin on page 55.

Scope and Summary of Privacy Laws

The Health Insurance Portability and Accountability Act (HIPAA) sets the minimum standards for protecting health information.¹ If other laws establish more stringent protections, then those more stringent laws apply.² For example, if a Washington statute does not allow information to be shared in a particular circumstance, then it cannot be shared even if HIPAA would have allowed the information to be shared.

There are several types of information that are subject to heightened protections. SUD information created or disclosed by Part 2 Providers is protected by federal law, and mental health and sexually transmitted infection (STI) information are protected by state law.

Each privacy law begins with the same basic assumption: information can never be used or disclosed without a person's consent. The laws

then provide lists of exceptions to that general rule. Much of the complexity and confusion surrounding the exchange of health information arises from differences with respect to which exceptions apply to which types of information.

This guidance is focused on the intersection of laws that govern SUD information. But some basic understanding of the laws that apply to other types of information is helpful. Just as different types of information are subject to different health care privacy laws, the types of people or organizations that are subject to each law varies. For example, not all organizations subject to HIPAA must comply with state law in chapter 70.02, and some health care privacy laws have exemptions for workers' compensation programs.³ With the exception of providing details on who 42 CFR Part 2 applies to, this guidance is not intended to address which laws apply to which people or organizations.

Laws That Apply to All Types of Health Information

Federal

HIPAA Privacy Rule (45 C.F.R. § 164.500 et seq.)

The HIPAA Privacy Rule establishes national standards to protect medical records and other patient-identifying health information and applies to health plans, healthcare clearinghouses, and most health care providers.⁴ The entities that HIPAA applies to are called "covered entities." Some contractors of covered entities, called "business associates," must also comply with HIPAA.⁵ The Privacy Rule requires appropriate safeguards to protect the privacy of patient-identifying health information, and sets limits and conditions on the uses and disclosures of information without consent.⁶ Generally, exceptions are allowed for treatment, payment, and healthcare operations.⁷ Other exceptions are laid out in the rule as well. The Privacy Rule also gives patients' rights over their health information, including rights to access and to request corrections.

¹ 45 CFR § 160.203.

⁵ 45 CFR § 160.102.

² 45 CFR § 160.203(b).

⁶ 45 CFR Part 164, Subpart

³ See, e.g., 45 CFR § 164.514(l).

E.

⁴ 45 CFR § 160.102.

⁷ 45 CFR § 164.506.



HIPAA Security Rule **(45 C.F.R. § 164.300 et seq.)**

The HIPAA Security Rule establishes security standards to protect individuals' electronic patient-identifying information that is created, received, used, or maintained by a covered entity or its business associate(s). The Security Rule requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of electronic health information.

Washington State

Chapter 70.02 RCW

This chapter of Washington law, known as Washington's Uniform Health Care Information Act, creates privacy standards for health care providers and third-party payers. Its requirements largely, but not entirely, mirror national standards in HIPAA, but as described below it also includes enhanced protections for mental health and sexually transmitted infection information.

Laws that Apply to Substance Use Disorder Information

Federal

42 CFR Part 2

42 CFR Part 2 applies to federally assisted treatment programs that hold themselves out as providing, and actually provide, substance use disorder diagnosis, treatment, or referral for treatment (Part 2 Programs). "Holding themselves out" means obtaining certifications or publishing advertisements for substance use disorder treatment services. These regulations apply to information that would identify a person as having a SUD who is treated by a Part 2 Program and allow very limited disclosures of information without consent. With the exception of disclosing information in response to a medical emergency, disclosures outside the program are not allowed for treatment functions without explicit consent.

⁸ 45 CFR §§ 164.522-528.

⁹ 45 CFR Part 164, Subpart C.

¹⁰ 42 CFR Part 2, Subpart D.

Laws that Apply to Mental Health Information

Washington State

Chapter 70.02 RCW

Chapter 70.02 RCW includes enhanced protections for information related to mental health treatment, including the fact of admission for treatment provided by a mental health professional.¹¹ This information may be shared between providers for legitimate treatment purposes, such as care coordination or referral from one provider to another.¹² Other disclosures should be examined on a case-by-case basis.

Laws that Apply to Sexually Transmitted Infection Information

Washington State

Chapter 70.02 RCW

Chapter 70.02 RCW includes enhanced protections for information related to tests, test results, diagnoses, or treatment for sexually transmitted infections.¹³ This information may be shared between providers without written consent for legitimate treatment purposes, such as care coordination or referral from one provider to another.¹⁴ Other disclosures should be examined on a case-by-case basis.

¹¹ RCW 70.02.010(22); 70.02.230.

¹² RCW 70.02.230(2)(u).

¹³ RCW 70.02.010(23); 70.02.220

¹⁴ RCW 70.02.220(5).



Generally Applicable Guidance

Although there are many considerations that help determine whether information may be shared in a specific circumstance, some basic health care privacy principles apply broadly to most scenarios. The concepts below typically apply to all types of health information, including SUD, mental health, and STI information.

Minimum Necessary Standard

The minimum necessary standard is both a best practice and a legal requirement. Under this standard, even uses or disclosures that are allowed by law must be limited to the minimum amount of information necessary to accomplish the intended purpose. Importantly, it applies regardless of whether the information is being requested, used, or disclosed.

In addition to the explicit minimum necessary standard in HIPAA, the concept is included in both

42 CFR Part 2¹⁵ and chapter 70.02 RCW, which allows disclosures “to the extent a recipient needs to know the information.”¹⁶

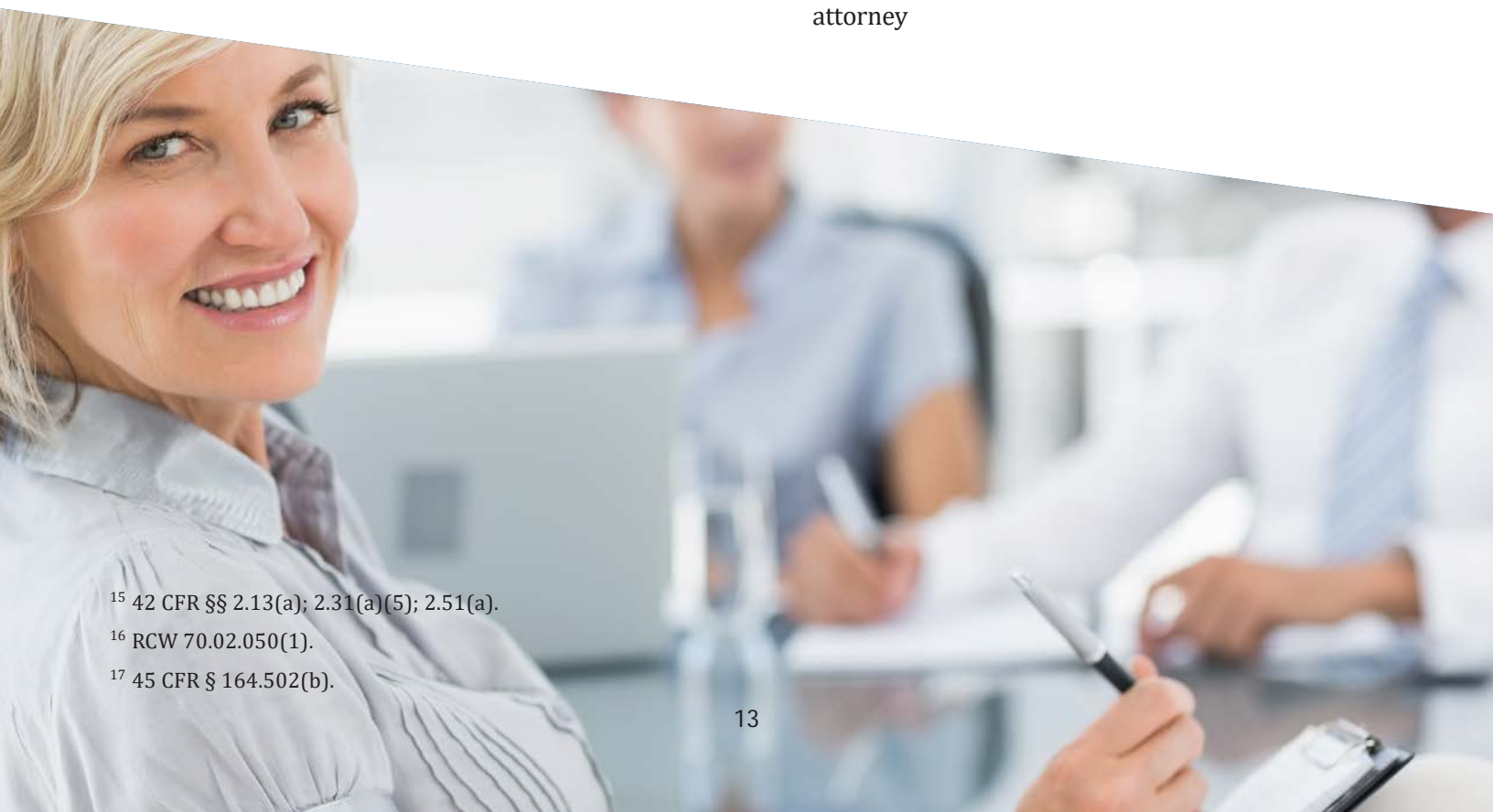
Although 42 CFR Part 2 and chapter 70.02 RCW do not include explicit exceptions to the minimum necessary standard, HIPAA clearly states there are some scenarios where the standard does not apply:¹⁷

- Disclosures to or requests by a health provider for treatment purposes
- Disclosures made to the patient who is the subject of the record
- Uses or disclosures made pursuant to a valid patient consent
- Disclosures to the Secretary of the U.S. Department of Health and Human Services
- Uses or disclosures required by law, such as a statute that requires reporting suspected abuse or a court order to share information with an attorney

¹⁵ 42 CFR §§ 2.13(a); 2.31(a)(5); 2.51(a).

¹⁶ RCW 70.02.050(1).

¹⁷ 45 CFR § 164.502(b).



Each of these exceptions, however, may be subject to other limitations on uses and disclosures. For example, a disclosure pursuant to written consent must comply with the terms of the consent. Similarly, a disclosure required by law must be tailored to what the law or court order requires to be disclosed.

Psychotherapy Notes

Psychotherapy notes are a specific subset of information that includes notes created by a mental health professional documenting a conversation during a counseling session, that are kept separate from the rest of a person's medical record and are subject to different standards for disclosure.¹⁸ These notes may be used for treatment purposes by the provider who created the notes. In most other circumstances, the notes cannot be used or disclosed without patient consent.¹⁹ The consent must specifically identify release of psychotherapy notes. Patients may provide consent to share medical records, while still excluding the sharing of psychotherapy notes.

De-identified Information and Limited Data Sets

Information that has identifying information removed may be used or shared with fewer restrictions than identifiable information. Fully de-identified information and limited data sets are two types of information that have had identifiable information removed. They have had different amounts of information removed and are subject to different levels of protection.

¹⁸ 45 CFR § 164.501; RCW 70.02.010(37).

¹⁹ 45 CFR § 164.508(a)(2); RCW 70.02.230(2)(u)(B)(iii).

²⁰ 45 CFR § 164.514(a).

²¹ 42 CFR § 2.11.

De-identified Information

Fully de-identified information is information that has identifiers removed so that the patient who is the subject of the information cannot be reasonably identified. Fully de-identified information is not protected by health care privacy laws. This principle is explicit in HIPAA,²⁰ and the concept is also included in 42 CFR Part 2 and chapter 70.02 RCW.

42 CFR Part 2 applies to information created by Part 2 Providers that could reveal "the identity of a patient . . . with reasonable accuracy."²¹ The Substance Abuse and Mental Health Services Administration (SAMHSA) has indicated that it intends for the Part 2 definition to align with the HIPAA identifiers discussed below.²² Chapter 70.02 RCW applies to information that "identifies or can readily be associated with the identity of a patient."²³ HIPAA sets more specific requirements. Information can be de-identified using one of two standards. The first is called the expert certification standard, and requires:

- 1) Obtaining a determination by a qualified expert that the risk of re-identification is very small; or
- 2) Removing specified identifying information, in combination with an absence of actual knowledge that the information could be used to re-identify an individual

This qualified expert must have "appropriate knowledge of and experience with generally accepted statistical and scientific principles

²² FR Vol. 82, No.11, p.6064, January 18, 2017.

²³ RCW 70.02.010(17).

²⁴ 45 CFR § 164.514(b).

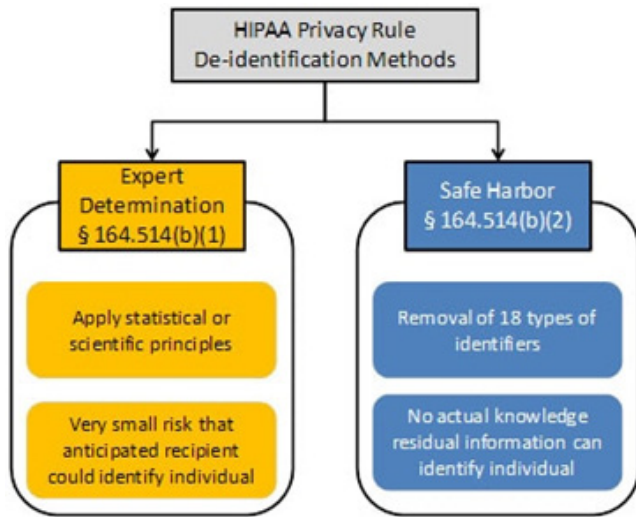
and methods for rendering information not individually identifiable.”

The second method is called the safe harbor method. It cannot be used if there is actual knowledge that a person could still use the information to identify a person, and it requires all of the following information about the person, relatives, employers, and household members to be removed:²⁵

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code.

It’s important to understand that removing identifiers is not necessarily limited to the above list, and as the final bullet provides, any unique identifying characteristic could be considered an identifier necessary to remove.

²⁵ 45 CFR § 164.514(b)(2).



Limited Data Sets

Fully de-identifying, especially using the safe harbor method, leads to significant information loss that will limit the usefulness of the health information. A limited data set is information with most, but not all, identifiers removed. It therefore may be more useful. Limited data sets can be disclosed only for research, public health, or health care operations purposes and must be accompanied by a data use agreement.²⁶ The following information about the individual, relatives, employers, and household members must be removed:²⁷

- Names
- Street address
- Telephone and fax numbers

- Electronic mail addresses
- Social Security Numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- License / certification numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images

Unlike the safe harbor method, a limited data set may include some indirectly identifying information such as dates and geographic information (except street address). However, a limited data set is not fully de-identified and is still considered protected health information.²⁸

²⁶ 45 CFR § 164.514(e)(3-4).

²⁷ 45 CFR § 164.514(e)(2).

²⁸ 45 CFR § 164.514(e)(3-4).

Who is Subject to 42 CFR Part 2?

An entity or provider is subject to 42 CFR Part 2 if it (1) meets the definition of a “program” and (2) is federally assisted.²⁹

For-profit programs and private practitioners who only accept private insurance or self-pay patients that do not receive federal assistance of any kind are not subject to 42 CFR Part 2 unless they are required to comply under state licensing or certification standards.

Am I a program?

An individual or entity is a “program” if they provide or make referrals for SUD services, and “hold themselves out” out as offering SUD services.³⁰ An individual or entity “holds itself out” if they do anything that would lead someone to reasonably think that they provide SUD diagnosis, treatment, or referral for treatment. Examples of activities that could qualify include:

- State or federal government authorization (e.g. licensure, certification, or registration) to provide SUD services,
- Advertisements, notices, or other postings or presentations about SUD services, or
- Offering consultation for non- “program” practitioners.

A program can be either an individual or an entity, and can include:³¹

- An individual or entity that is not part of a general medical facility,
- An identified unit within a general medical facility, or
- Individual personnel or staff in a general medical facility whose primary function is providing SUD services.

In other words, it is possible for a facility with multiple provider functions to have certain isolated providers or groups who are subject to Part 2, while the facility as a whole is not subject to Part 2. For example, a large facility may have primary care providers and a separate unit that provides SUD services. The SUD unit is subject to Part 2, but the rest of the facility is not. If a patient were to receive both primary care and SUD treatment, the SUD providers are still subject to Part 2 and could not share information with the patient’s primary care provider without consent.

An individual provider who works in a general medical facility (not in a standalone SUD facility or an identified SUD unit) could also be a Part 2 program, but only if the provider’s primary function is to provide SUD services. For example, a primary care physician who provides

²⁹ 42 CFR § 2.12(a).

³⁰ 42 CFR § 2.11.

³¹ 42 CFR § 2.11.

medication-assisted treatment would only meet the requirement if providing services to persons with SUD is their primary function. The fact that the physician sometimes provides SUD services as part of their practice does not on its own make the physician a Part 2 program.

Am I Federally Assisted?

While there are for-profit programs and private practitioners that may not receive federal assistance of any kind, most SUD treatment programs are federally assisted. The definition is broad, and you should consult with legal counsel if you are unsure if you are federally assisted.

Examples of federal assistance include:³²

- The program is conducted directly by the federal government.
- The program is authorized, licensed, certified, or registered by the federal government, which could include:
 - Participation in the Medicare or Medicaid program,
 - Authorization to conduct maintenance treatment or withdrawal management, or
 - Registration with the Drug Enforcement Agency to dispense a controlled substance in the treatment of substance use disorders.

- The program receives federal funds in any form, even if the funds do not directly pay for the substance use disorder services.
- Income tax deductions are allowed for contributions to the program, or the contribution is granted tax exempt status.

Recipients and Lawful Holders

Part 2 directly regulates providers who meet the requirements explained above. But confidentiality restrictions also apply to other individuals or entities who receive protected SUD information from a Part 2 program pursuant to a properly completed consent form or under one of the other limited exceptions that allow disclosure without consent. The people or entities that receive information pursuant to consent or another exception are called lawful holders.

When a recipient like a primary care treating provider, a third-party payer, or an HIE receives SUD information pursuant to consent, it must protect that information to the same extent as the Part 2 program.³³ When the recipient receives information under one of Part 2's exception, the specific restrictions will depend on which exception allowed the recipient to obtain the information. For example, a researcher cannot re-disclose information to anyone other than the entity that provided the information,³⁴ and an auditor may have to sign an agreement limiting its acceptable uses and disclosures.³⁵

³² 42 CFR § 2.12(b).

³³ 42 CFR § 2.32.

³⁴ 42 CFR § 2.52.

³⁵ 42 CFR § 2.53.

What records are protected?

The fact that a facility or individual provider is subject to 42 CFR Part 2 does not mean that all of the records held by that facility or provider are subject to the standard in Part 2. Only information that would directly or indirectly identify a person as having an SUD is protected.³⁶ The examples below show how Part 2 applicability for particular records may vary depending on the setting where services are provided.

Part 2 program provides only SUD services

If a facility only provides SUD services, then all of its patient records will be subject to 42 CFR Part 2. This is true even if some of those records do not include specific SUD treatment or diagnosis information. The reason is that even those records, in combination with the fact that the facility provides only SUD services, reveals that a person receiving treatment is being treated for an SUD.

Part 2 program provides co-located SUD and mental health services

When a facility does not solely provide SUD services, then Part 2 applicability will depend on the specific services and treatment provided. For this type of facility, Part 2 will apply to records about patients receiving SUD services. This includes records that show treatment for co-occurring mental health and substance use disorders. But Part 2 will not apply to information about people receiving only mental health services.

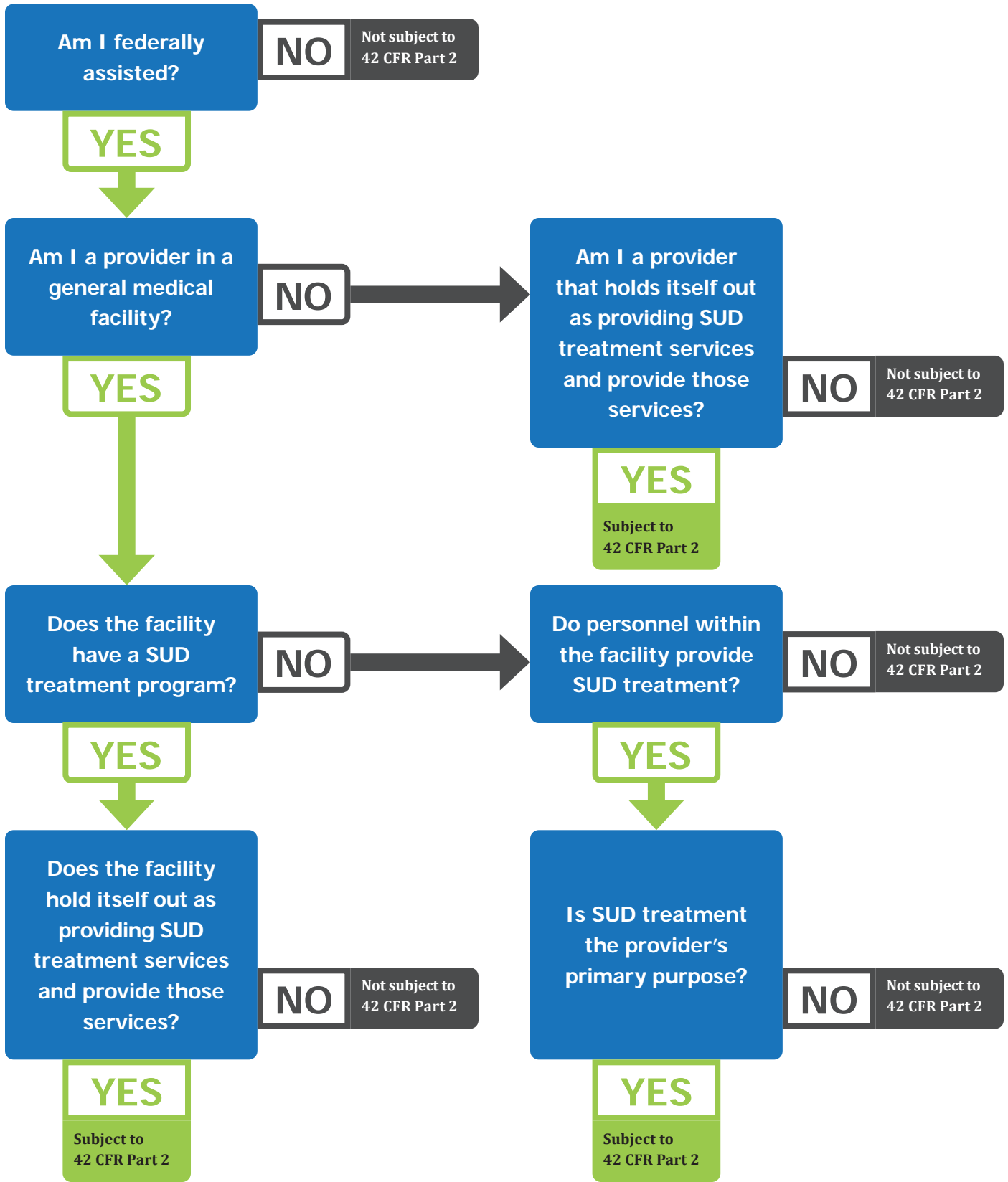
In this type of facility, it can be difficult to efficiently segment information that is subject to different standards. But it is important to recognize that mental health information is not subject to the standards in 42 CFR Part 2 and can be shared without consent for treatment purposes, including care coordination, as allowed under HIPAA.³⁷



³⁶ 42 CFR § 2.12(a)(1).

³⁷ RCW 70.02.230(2)(u).

Am I a Part 2 Program?



Disclosures with Consent

Health care privacy laws focus primarily on uses and disclosures without patient consent. But they also give patients control over their information and allow a wide range of uses and disclosures with patient consent. In most situations, specific consent is required for SUD information to be disclosed for treatment, payment, or health care operations purposes.

The consent must be documented in writing and important restrictions apply to how the information may be re-disclosed after the initial disclosure.

Consent Requirements

A written consent for the disclosure of SUD information must include nine specific elements.³⁸ Many of these elements are straightforward and need little explanation. Others have been complicated by recent changes to 42 CFR Part 2, but when properly implemented allow for more efficient information exchange. These requirements all work together to define what and when information can be shared.

A consent form that meets these requirements will also satisfy the requirements in HIPAA and chapter 70.02 RCW.

- 1) The name of the patient

The consent must identify whose information may be disclosed.

- 2) Who may make the disclosure

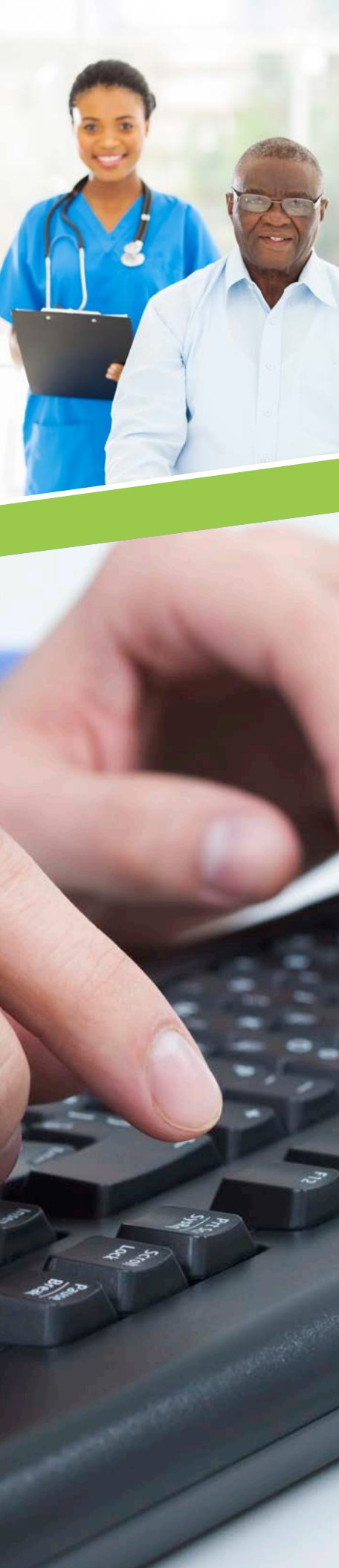
This requirement is commonly referred to as the “from whom” element of consent. It explains who is allowed to disclose information. This element may be satisfied with either a specific or general designation.

A specific designation lists the name (or names) of the specific program, entities, or individuals who may disclose the information. This type of designation minimizes how information is shared and allows patient control. It also comes with some practical limitations. For example, if the intent is for reciprocal sharing between two programs, care must be taken to ensure the consent allows both programs to disclose information. And if the disclosing program changes its name following a merger or restructuring, the consent will no longer be valid.

Alternatively, the consent may include a general designation of who may disclose information, such as “any drug or alcohol treatment program.”

The appropriate designation depends on the intended purpose of the consent. If the intent is to facilitate sharing between Part 2 programs or to facilitate sharing information via an intermediary, such as an HIE, then a general designation will be more efficient and create more opportunities for information exchange that supports care coordination. If the purpose is more focused, such as to release information to a third-party payer to receive payment, then a specific designation is more appropriate.

³⁸ 42 CFR § 2.31(a).



3) What information may be disclosed

The consent must explain how much and what kind of information may be disclosed, including an explicit description of the SUD information that may be disclosed. For example, it may explain that all SUD treatment history may be disclosed, including medications, lab test results, diagnoses, and clinical notes. Or it may specify that only claims data may be transmitted. To ensure that the consent can be followed, it is important that the information is described in a manner that reflects how the information is actually maintained and how it can be divided.

4) Who can receive the information

This requirement is commonly referred to as the “to whom” element of consent. As with the “from whom” requirement, this information can be in the form of a specific or general designation. The requirements for general designations have been introduced in recent changes to allow greater sharing for treatment purposes, particularly in the context of HIE. However, these changes have also added complexity.

In general, determining whether a consent form is valid requires considering:

- Whether there is a treating provider relationship with the recipient,
- Whether the recipient is a third-party payer,
- Whether the consent designates an individual or an entity, and
- Whether the information is shared with an intermediary (such as an HIE).

The level of detail required for different scenarios is shown on the next page.

Intermediary	Relationship with patient	To whom requirements	Explanation
None	Any, may or may not be a provider	Specific designation of individual or entity	Information can always be shared with a specifically identified individual or entity.
None	Treating provider	Specific designation of entity	When the recipient is a treating provider, identifying the entity is sufficient.
None	Third-party payer	Specific designation of entity	When the recipient is a third-party payer, identifying the entity is sufficient.
Intermediary HIE	Any	Specific designation of individual and intermediary entity	Consent to share with a specific individual through an intermediary should identify the intermediary entity. The intermediary does not have to be identified if they are a qualified service organization of the Part 2 program.
Intermediary HIE	Single treating provider	Specific designation of entity and intermediary entity	Consent to share with a specific entity through an intermediary should identify the intermediary entity. The intermediary does not have to be identified if they are a qualified service organization of the Part 2 program.
Intermediary HIE	Multiple treating providers	General designation of individuals or entities with a treating provider relationship and specific designation of intermediary entity	<p>Consent to share through an intermediary can include a general designation to allow sharing with a broader group of recipients, such as all treating providers. This is a recent change aimed at increased efficiency for electronic exchange of information.</p> <p>The intermediary needs to be identified regardless of whether it is a qualified service organization of the Part 2 program.</p>

In addition, a consent that includes a general designation must also include a statement indicating that the patient understands that they may request and receive a list of entities that have received information pursuant to the general designation. More information about this requirement is included in the “Documenting Disclosures” section later in this document.

5) Why the information is being disclosed

The consent must include the purpose of the disclosure. Any disclosures pursuant to the consent must be tailored to the minimum amount of information necessary to fulfill that purpose. For example, if a third-party payer is authorized to receive information to process a claim for payment, it would typically not be necessary to share all SUD information.

6) An explanation of the right to revoke consent

The consent must explain that the patient may revoke consent at any time prior to its expiration,³⁹ and explain how to revoke consent. Consent pursuant to 42 CFR Part 2 can be revoked orally, but SAMHSA recommends obtaining revocation in writing or documenting an oral revocation in a person’s record.

Consent cannot be revoked to the extent it has already been acted upon. For example:

- If treatment is provided in reliance on written consent that allows disclosure to receive payment from a third-party payer, then consent cannot be revoked to prevent a provider from submitting a claim for payment;⁴⁰ and
- Revoking consent does not have any impact on information that has already been appropriately shared pursuant to the consent.

7) When the consent expires

It is not sufficient for a consent form to say that it is valid until revoked. Instead, it must include a specific expiration date, event, or condition. Consent that expires “one year from the date of my signature” would be valid, as would consent that expires “upon my death.”⁴¹

8) The patient’s signature

The consent must include the patient’s signature, or the signature of a person authorized to act on behalf of the patient. The signature may be an electronic signature.⁴²

³⁹ 42 CFR § 2.31(a)(6).

⁴⁰ 42 CFR § 2.31(a)(6).

⁴¹ FR Vol. 82, No. 11, p.27.

⁴² The requirements for a valid electronic signature in Washington are beyond the scope of this guidance.

If the consent is signed by someone other than the patient, it should include an explanation of the relationship between the person signing and the patient. If the person receiving services has been determined by a court to be incompetent, then a court-appointed guardian or other legally authorized person can sign.

If the patient is a minor, then whether the minor can provide consent depends on whether they could consent to receive treatment without parental consent. If the minor cannot receive treatment without consent from a parent or guardian, then both the minor and the minor's parent or guardian must provide consent.⁴³

In Washington, a minor under the age of 13 cannot receive SUD treatment without parental consent. Whether a minor who is 13 or older may consent to receive services depends on a variety of factors, including whether the services are inpatient or outpatient, whether the minor is emancipated, whether minor is capable of making a rational choice to receive treatment, and whether the Department of Social and Health Services has determined the minor is a child in need of services.

When a parent or guardian signs on behalf of a person receiving services, the relationship should be documented and confirmed.

- 9) The date the written consent is signed

The consent must include the date it is signed. This establishes when information can begin to be disclosed.

Re-disclosure

Under HIPAA and chapter 70.02 RCW, legal protections for information do not automatically attach when the information is shared. For instance, if a HIPAA-covered entity shares health information (and the entity sharing information is not a Part 2 program) with another covered entity pursuant to consent, the information is still protected by HIPAA because the recipient is subject to HIPAA. But if the consent allows disclosure to a person who is not subject to HIPAA, then the recipient is not required to follow HIPAA when further sharing the information.

42 CFR Part 2 operates differently. SUD information received pursuant to consent cannot be re-disclosed unless:

- 1) The consent allows the additional disclosure,
- 2) Separate written consent is obtained that allows the additional disclosure, or
- 3) The additional disclosure is otherwise allowed by 42 CFR Part 2 without consent.

⁴³ 42 CFR §§ 2.31(a)(8); 2.14(b).

To put the recipient of SUD information on notice of this limitation, each disclosure pursuant to consent must include one of these two statements:⁴⁴

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

- or -

42 CFR part 2 prohibits unauthorized disclosure of these records.

Documenting Disclosures

Even when made pursuant to consent, some disclosures must be documented so that a list of disclosures can be provided at the patient's request. This requirement only applies to disclosures pursuant to a consent that uses a general "to whom" designation. Specifically, the requirement to document and provide a list of disclosures applies when:⁴⁵

- The disclosures are made by an intermediary, such as an HIE; and
- The disclosures are pursuant to a general "to whom" designation, such as "all individuals or entities that have a treating provider relationship" with the patient.

A patient's request for a list of disclosures must be in writing and is limited to disclosures within the last two years. The information that must be provided in response includes:

- The names of the recipients;
- The date of the disclosures; and
- A brief description of the information disclosed.

⁴⁴ 42 CFR § 2.32.

⁴⁵ 42 CFR §§ 2.13(d); 2.31(a)(4).

The list must be provided within 30 days of receiving the written request.⁴⁶ This requirement is separate and distinct from the “accounting of disclosures” process in HIPAA. The accounting of disclosures requirement has different timelines and requires documentation of different types of disclosures. For example, disclosures pursuant to consent are explicitly excluded from the HIPAA accounting of disclosures process.

Sample Consent

HCA recognizes that providers, payers, and other organizations have created and implemented consent gathering processes and forms. However, there are also occasional questions about whether particular forms meet all of the requirements in 42 CFR Part 2, and many organizations’ forms have not been updated to incorporate recent changes to 42 CFR Part 2.

Appendix 1 includes a sample consent form that incorporates recent changes to 42 CFR Part 2 and is focused on gathering consent to facilitate care coordination. Organizations are not required to use the form, but it is intended to be a flexible resource that be used as in a variety of circumstances, without being tied to a specific provider or HIE. An organization may also choose to tailor it for a specific use, or incorporate elements into the organization’s existing templates.

⁴³ 42 CFR §§ 2.31(a)(8); 2.14(b).

Uses and Disclosures Without Consent

There are many circumstances where consent is required to share SUD information, even though sharing would otherwise be allowed by HIPAA and other health care privacy laws. But consent is not required for all uses and disclosures. This section includes summaries of some of the most common exceptions where information can be used or disclosed without consent.

The exceptions are grouped into familiar categories, such as treatment, payment, health care operations, public health reporting, and research. Each situation includes a summary of the conditions for use or disclosure under 42 CFR Part 2, and a comparison to the requirements in HIPAA and chapter 70.02 RCW.

Even though consent is not required for these disclosures, there may be other complicated requirements that apply. This information is only a summary and is not a substitute for careful consideration of the applicable regulatory provisions or legal advice.

Qualified Service Organization Agreements

This section outlines how providers can use qualified service organization agreements (QSOAs) to allow appropriate behavioral health information sharing. This includes substance use information between a part 2 provider and a qualified service organization.

HIPAA generally permits protected health information disclosure without patient consent for treatment, payment or health care operations. 42 CFR Part 2 is not as permissive and requires patient consent for such disclosure. However, restrictions on disclosures under 42 CFR Part 2 do not apply to communications between a part 2 program and a qualified service organization (QSO) involving information needed by the QSO to provide services to the program (42 CFR 2.12(c)(4)).

A qualified service organization (QSO) means a person/entity that:

- 1) Provides services to a part 2 program, and
- 2) Has entered into a written agreement with a part 2 program under which that person:
 - c) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by 42 CFR Part 2; and
 - d) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Services that QSOs provide include (but are not limited to) population health management, bill collection, laboratory analyses, professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy.

QSOAs under Part 2 are similar to business associate agreements under HIPAA. Both types of agreements serve

as mechanisms that allow for disclosure of information between a part 2 program and an organization that provides services to the program, including HIEs.

A part 2 program should only disclose information to the QSO that is necessary for the QSO to perform its duties under the QSOA. Also, the QSOA does not permit a QSO to re-disclose information to a third party unless that third party is a contract agent of the QSO, helping them provide services described in the QSOA, and only as long as the agent only further discloses the information back to the QSO or to the part 2 program from which the information originated. For additional information, see Number 10 of the 2010 Frequently Asked Questions published by SAMHSA and the Office of the National Coordinator.

42 CFR Part 2 requires the following terms in a written QSOA:

- Acknowledgement that receiving, storing, processing or otherwise dealing with any patient records from the part 2 program is fully bound by the regulations in 42 CFR Part 2; and
- Agreement to resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment or referral for treatment except as permitted by 42 CFR Part 2.

Other common terms in a QSOA, though not required by 42 CFR Part 2, might include HIPAA-required terms for business associates under HIPAA.

Treatment

Information that is subject to 42 CFR Part 2 cannot normally be shared for treatment purposes without consent, which presents a significant barrier to care coordination and providing whole-person care. But the information can be shared in response to a medical emergency, and can be shared between providers in the same Part 2 program. The second situation is important because it allows sharing between providers who are treating co-occurring mental health and substance use disorders within the same Part 2 program.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Examples of permissible treatment activities	<p>“Treatment” means the care of a patient suffering from a substance use disorder, a condition which is identified as having been caused by the substance use disorder, or both, in order to reduce or eliminate the adverse effects upon the patient.</p> <p>42 CFR § 2.11</p>	<p>“Treatment” generally means the provision, coordination, or management of health care and related services among health care providers or by a health care provider with a third party, consultation between health care providers regarding a patient, or the referral of a patient from one health care provider to another.</p> <p>45 CFR § 164.501</p>

Payment (consent typically required)

Information that is subject to 42 CFR Part 2 cannot normally be shared for payment purposes without consent. However, information can be shared within a Part 2 program, or an entity that has direct administrative control over the Part 2 program, among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients. Payment functions include a broad range of activities such as determining eligibility for benefits, claims management, or requesting prior authorization. Even submitting a claim for payment requires consent.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Disclosures from Part 2 program to contractors	<p>Information can be shared with a contractor that provides payment-related services to a part 2 program, such as data processing or bill collecting.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The contractor must sign an agreement called a Qualified Service Organization Agreement (QSOA) that limits its uses of the information to the specified payment functions and includes: <ul style="list-style-type: none"> ○ Acknowledgement that the contractor is fully bound by 42 CFR Part 2 ○ A requirement that the QSO will resist in court inappropriate efforts to obtain SUD information <p>Tips:</p> <ul style="list-style-type: none"> • A contractor that meets these requirements is referred to as a “qualified service organization” • This justification for sharing does not apply to treatment-related services, including care coordination <p>42 CFR §§ 2.11; 2.12(c)(4).</p>	<p>Information can be shared with contractors that provide services to or on behalf of a covered entity. These contractors are referred to as “business associates” and must sign a business associate agreement (BAA). HIPAA includes specific requirements for business associate agreements. If a Part 2 program is also a covered entity, then it needs both a QSOA and BAA with the contractor. The requirements for QSOAs and BAAs can be combined into one agreement.</p> <p>45 CFR § 164.504(e).</p>

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Disclosures from lawful holder to contractors	<p>An organization that receives information under a written consent to disclose for payment purposes, such as a third-party payer, can further disclose information to its contractors to perform payment functions.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The contractor must sign an agreement that limits its uses of the information to uses necessary to carry out the purposes specified in the written consent <p>42 CFR §§ 2.33(b); 2.13(a).</p>	<p>The restrictions on a lawful holder’s ability to share information with contractors depends on whether the lawful holder is subject to HIPAA. If a third-party payer is a covered entity under HIPAA, then contractors that provide services to the third-payer payer are business associates and a BAA is required.</p> <p>45 CFR § 164.504(e).</p>
Disclosures related to incapacitated or incompetent person	<p>Information can be disclosed without consent to obtain payment when a person has a medical condition that prevents the person from acting on their own behalf.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Scope of consent must be solely to obtain payment for services • Person must be unable to effectively act on their own • Part 2 program director must act on the person’s behalf to consent to disclosure <p>Tips:</p> <ul style="list-style-type: none"> • This exception does not apply to minors or people who have already been determined to be incompetent by a court <p>42 CFR § 2.15(a)(2).</p>	<p>Information can be used and disclosed for legitimate payment purposes without written consent. 42 CFR Part 2 is more restrictive.</p> <p>45 CFR § 164.506(c); RCW 70.02.050(1).</p>

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Examples of permissible payment and health care operations activities (this list is non-exhaustive—other activities may also be permissible)</p>	<ol style="list-style-type: none"> 1. Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing, and/or related health care data processing; 2. Clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services); 3. Patient safety activities; 4. Activities pertaining to: <ol style="list-style-type: none"> i. The training of student trainees and health care professionals; ii. The assessment of practitioner competencies; iii. The assessment of provider or health plan performance; and/or iv. Training of non-health care professionals; 5. Accreditation, certification, licensing, or credentialing activities; 6. Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care; 7. Third-party liability coverage; 8. Activities related to addressing fraud, waste and/or abuse; 9. Conducting or arranging for medical review, legal services, and/or auditing functions; 10. Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies; 11. Business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations; 	<p>“Payment” encompasses the various activities of health care providers to obtain payment or be reimbursed for their services and of a health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement for the provision of health care. In addition to the general definition, the Privacy Rule provides examples of common payment activities which include, but are not limited to:</p> <ul style="list-style-type: none"> • Determining eligibility or coverage under a plan and adjudicating claims; • Risk adjustments; • Billing and collection activities; • Reviewing health care services for medical necessity, coverage, justification of charges, and the like; • Utilization review activities; and

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
	12. Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers; 13. Resolution of internal grievances; 14. The sale, transfer, merger, consolidation, or dissolution of an organization; 15. Determinations of eligibility or coverage (e.g., coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims; 16. Risk adjusting amounts due based on enrollee health status and demographic characteristics; 17. Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; 18. Care coordination and/or case management services in support of payment or health care operations; and/or 19. Other payment/health care operations activities not expressly prohibited in this provision. 42 CFR § 2.33(b)	<ul style="list-style-type: none"> • Disclosures to consumer reporting agencies (limited to specified identifying information about the individual, his or her payment history, and identifying information about the covered entity). 45 CFR § 164.501

Health Care Operations

Information that is subject to 42 CFR Part 2 cannot normally be shared for health care operations purposes without consent. However, information can be shared within a Part 2 program, or an entity that has direct administrative control over the Part 2 program, among personnel having a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of patients. Health care operations include a broad range of provider activities that do not involve treatment or payment activities. Examples include quality improvement, provider performance review, fraud and abuse detection, or receiving legal services. Information can be shared with contractors to perform health care operations functions on behalf of the Part 2 program.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Disclosures from Part 2 program to contractors	<p>Information can be shared with a contractor that provides health care operations services to a part 2 program, such as legal or accounting services, or population health management</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The contractor must sign an agreement called a Qualified Service Organization Agreement (QSOA) that limits its uses of the information to the specified health care operations functions and includes: <ul style="list-style-type: none"> ○ Acknowledgement that the contractor is fully bound by 42 CFR Part 2 ○ A requirement that the QSO will resist in court inappropriate efforts to obtain SUD information <p>Tips:</p> <ul style="list-style-type: none"> • A contractor that meets these requirements is referred to as a “qualified service organization” • This justification for sharing does not apply to treatment-related services, including care coordination <p>42 CFR §§ 2.11; 2.12(c)(4).</p>	<p>Information can be shared with contractors that provide services to or on behalf of a covered entity. These contractors are referred to as “business associates” and must sign a business associate agreement (BAA). HIPAA includes specific requirements for business associate agreements. If a Part 2 program is also a covered entity, then it needs both a QSOA and BAA with the contractor. The requirements for QSOAs and BAAs can be combined into one agreement.</p> <p>45 CFR § 164.504(e).</p>
Disclosures from lawful holder to contractors	<p>An organization that receives information under a written consent to disclose for health care operations purposes can further disclose information to its contractors subject to the Minimum Necessary Standard and specific only to the contractor’s purposes.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The contractor must sign an agreement that limits its uses of the information to the purposes specified in the written consent <p>42 CFR §§ 2.33(b); 2.13(a).</p>	<p>The restrictions on a lawful holder’s ability to share information with contractors depends on whether the lawful holder is subject to HIPAA. If the entity is a covered entity under HIPAA, then contractors that provide services to the third-payer payer are business associates and a BAA is required.</p> <p>45 CFR § 164.504(e).</p>

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Examples of permissible payment and health care operations activities (this list is non-exhaustive—other activities may also be permissible)</p>	<ol style="list-style-type: none"> 1. Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing, and/or related health care data processing; 2. Clinical professional support services (e.g., quality assessment and improvement initiatives; utilization review and management services); 3. Patient safety activities; 4. Activities pertaining to: <ol style="list-style-type: none"> i. The training of student trainees and health care professionals; ii. The assessment of practitioner competencies; iii. The assessment of provider or health plan performance; and/or iv. Training of non-health care professionals; 5. Accreditation, certification, licensing, or credentialing activities; 6. Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and/or ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care; 7. Third-party liability coverage; 8. Activities related to addressing fraud, waste and/or abuse; 9. Conducting or arranging for medical review, legal services, and/or auditing functions; 10. Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies; 11. Business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations; 	<ul style="list-style-type: none"> • “Health care operations” are certain administrative, financial, legal, and quality improvement activities of a covered entity that are necessary to run its business and to support the core functions of treatment and payment. These activities, which are limited to the activities listed in the definition of “health care operations” at 45 CFR 164.501, include: • Conducting quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, and case management and care coordination; • Reviewing the competence or qualifications of health care professionals, evaluating provider and health plan performance, training health care and non-health care professionals, accreditation, certification, licensing, or credentialing activities; • Underwriting and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to health care claims

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
	<p>12. Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;</p> <p>13. Resolution of internal grievances;</p> <p>14. The sale, transfer, merger, consolidation, or dissolution of an organization;</p> <p>15. Determinations of eligibility or coverage (e.g., coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;</p> <p>16. Risk adjusting amounts due based on enrollee health status and demographic characteristics;</p> <p>17. Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;</p> <p>18. Care coordination and/or case management services in support of payment or health care operations; and/or</p> <p>Other payment/health care operations activities not expressly prohibited in this provision.</p> <p>42 CFR § 2.33(b)</p>	<ul style="list-style-type: none"> • Conducting or arranging for medical review, legal, and auditing services, including fraud and abuse detection and compliance programs; • Business planning and development, such as conducting cost-management and planning analyses related to managing and operating the entity; and • Business management and general administrative activities, including those related to implementing and complying with the Privacy Rule and other Administrative Simplification Rules, customer service, resolution of internal grievances, sale or transfer of assets, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity. General Provisions at 45 CFR 164.506. <p>45 CFR § 164.501</p>

Medical Emergency

Information that is subject to 42 CFR Part 2 can be shared in response to a medical emergency, and can be shared between providers in the same Part 2 Program. This allows sharing between providers who are treating co-occurring mental health and substance use disorders within the same Part 2 program.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Medical emergencies	<p>Information can be shared in response to a medical emergency.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Disclosure must be necessary to respond to bona fide medical emergency • Only applies when informed consent cannot be obtained • The Part 2 program must document who made the disclosure, who received the information, when information was disclosed, and the reason information was disclosed <p>42 CFR § 2.51.</p>	<p>Information can be used and disclosed for legitimate treatment purposes without written consent. 42 CFR Part 2 is more restrictive.</p> <p>Additionally, information can be used and disclosed when, consistent with applicable law and standards of ethical conduct, such use is necessary (in the good faith belief of the covered entity):</p> <ul style="list-style-type: none"> • To prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and the use is to a person reasonably able to prevent or lessen the threat. • For law enforcement authorities to identify or apprehend an individual. <p>45 CFR § 164.501506(c); 45 CFR § 164.512(j); RCW 70.02.050(1).</p>

Communication within a Part 2 Program

Information sharing is allowed between providers who are treating co-occurring mental health and substance use disorders within the same Part 2 program. Information can also be shared within a Part 2 program to perform payment and health care operations functions.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Communication within a Part 2 program for treatment, payment, or operations</p>	<p>Information can be shared within a Part 2 program for legitimate treatment, payment, or health care operations purposes without written consent.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Need for sharing must arise from providing diagnosis, treatment, referral for treatment, payment functions, or health care operations functions • Disclosure only allowed to personnel of Part 2 program or entity with direct administrative control over the program <p>Tips:</p> <ul style="list-style-type: none"> • A Part 2 program may be located within a facility that has other functions that are not considered part of the Part 2 program and are not covered by this exception <p>42 CFR § 2.12(c)(3).</p>	<p>Information can be used and disclosed for legitimate treatment purposes without written consent. 42 CFR Part 2 is more restrictive.</p> <p>45 CFR § 164.506(c); RCW 70.02.050(1).</p>

Access by Person with SUD

As with other health care information, a person has the ability to view and receive their own information.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Access to a person's own information</p>	<p>A competent adult with SUD can view and receive their own information.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • A request to review and receive information can be made by the person with SUD or their personal representative. • The right to view and receive information about a person who has been determined by a court to be incompetent is controlled by their legal guardian or other legally authorized representative. • More complicated rules apply for records about minors, depending on the minor's age and whether the services are inpatient or outpatient <p>42 CFR §§ 2.23(a); 2.14.</p>	<p>Under HIPAA and chapter 70.02 RCW a person has the right to access their own information. Who can exercise that right is dependent on whether the person has been determined to be incompetent, the person's age, and the types of services provided.</p> <p>45 CFR § 164.502(g); 45 CFR § 164.524(a); RCW 70.02.080; RCW 70.02.130.</p>

Public Health Reporting

Although there is no blanket exception that allows SUD information to be used or disclosed for public health purposes, there are several specific situations where reporting is allowed.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Reporting vital statistics	<p>Information about cause of death can be released consistent with laws that require the collection of death or other vital statistics.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The release must be consistent with law that requires collection of the information <p>42 CFR § 2.15(b)(1).</p>	<p>Under HIPAA and Washington law, information can be released to appropriate authorities for a wide range of public health purposes that include reporting and investigating deaths.</p> <p>45 CFR § 164.512(b); RCW 70.02.050(2).</p>
Investigating cause of death	<p>Information can be released consistent with laws that allow investigation into cause of death.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The release must be consistent with the law that allows the investigation <p>42 CFR § 2.15(b)(1).</p>	<p>Under HIPAA and Washington law, information can be released to appropriate authorities for a wide range of public health purposes that include reporting and investigating deaths.</p> <p>45 CFR § 164.512(b); RCW 70.02.050(2).</p>
Reporting child abuse and neglect	<p>Reports of suspected child abuse and neglect can be reported to appropriate authorities.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Reports should be consistent with permitted or mandatory disclosures under state law <p>Tips:</p> <ul style="list-style-type: none"> • The original information held by the Part 2 program is still protected, and restrictions on disclosure still apply to any requested disclosure for civil or criminal proceedings that arise out of the report of abuse or neglect <p>42 CFR § 2.12(c)(6).</p>	<p>Under HIPAA and Washington law, information can be released to appropriate authorities for a wide range of public health purposes that include reporting child abuse or neglect.</p> <p>45 CFR § 164.512(b); RCW 70.02.200.</p>

Research

The requirements that must be met to provide identifiable information to researchers without consent incorporate the requirements in the HIPAA Privacy Rule.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Providing information to researcher</p>	<p>Information can be disclosed to a researcher so long as the research project meets the research requirements in the HIPAA Privacy Rule or the Health and Human Services regulations regarding the protection of human subjects, as applicable.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • HIPAA and/or 45 CFR Part 46 research requirements must be satisfied, depending on which requirements apply • Appropriate waiver of consent must be obtained from institutional review board or privacy board • Researcher cannot send identifiable information to anyone other than who the information originally came from. <p>Tips:</p> <ul style="list-style-type: none"> • Research can also be conducted with explicit consent from the research subjects <p>42 CFR § 2.52.</p>	<p>Information can be disclosed to research so long as the research projects the research requirements in the HIPAA Privacy Rule, which will require approval and waiver of consent from an institutional review board or privacy board.</p> <p>45 CFR § 164.512(i); RCW 70.02.210.</p>

Audit and Evaluation

Audits and evaluations are a specific subset of health care operations that are allowed by 42 CFR Part 2 under very specific circumstances.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Audit or evaluation that does not require copying or removing records</p>	<p>If records are not copied or removed, then in limited circumstances a Part 2 program may allow an audit or evaluation on its premises.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Auditor or evaluator must agree in writing that identifiable information will: <ul style="list-style-type: none"> ○ Not be disclosed to anyone ○ Only be used to carry out the purpose of the audit or evaluation • Auditor or evaluator must be one of: <ul style="list-style-type: none"> ○ A governmental agency authorized to regulate the Part 2 program ○ Any individual or entity that provides financial assistance to the Part 2 program ○ A third-party payer that covers people treated by the Part 2 program ○ A quality improvement organization performing a utilization or quality control review • Part 2 program must: <ul style="list-style-type: none"> ○ Determine the auditor or evaluator is qualified <p>42 CFR § 2.53(a).</p>	<p>Under HIPAA and chapter 70.02 RCW an audit or evaluation could be completed as part of the entity's health care operations.</p> <p>45 CFR § 164.506; RCW 70.02.010; RCW 70.02.050; RCW 70.02.200.</p>

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Audit or evaluation that requires copying or removing records</p>	<p>If records will be removed, additional restrictions apply to allow an audit or evaluation.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Auditor or evaluator must agree in writing that identifiable information will: <ul style="list-style-type: none"> ○ Not be disclosed to anyone ○ Only be used to carry out the purpose of the audit or evaluation ○ Be maintained and destroyed consistent 42 CFR Part 2 security requirements ○ Be retained as required by any applicable records retention laws • Auditor or evaluator must be one of: <ul style="list-style-type: none"> ○ A governmental agency authorized to regulate the Part 2 program ○ Any individual or entity that provides financial assistance to the Part 2 program ○ A third-party payer that covers people treated by the Part 2 program ○ A quality improvement organization performing a utilization or quality control review <p>Tips:</p> <ul style="list-style-type: none"> • Removing records includes anything that would lead to information leaving the Part 2 program, including copying, downloading, or forwarding information <p>42 CFR § 2.53(b).</p>	<p>Under HIPAA and chapter 70.02 RCW an audit or evaluation could be completed as part of the entity’s health care operations.</p> <p>45 CFR § 164.506; RCW 70.02.010; RCW 70.02.050; RCW 70.02.200.</p>
<p>Audits and evaluations mandated by statute or regulation</p>	<p>Patient identifying information may be disclosed to federal, state, or local government agencies, and the contractors, subcontractors, and legal representatives of such agencies, in the course of conducting audits or evaluations mandated by statute or regulation, if those audits or evaluations cannot be carried out using deidentified information.</p> <p>42 CFR 2.53(g)</p>	<p>Under HIPAA and chapter 70.02 RCW an audit or evaluation could be completed as part of the entity’s health care operations.</p>

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Activities included in Audits and Evaluations</p>	<p>Audits and evaluations may include, but are not limited to :</p> <ol style="list-style-type: none"> 1. Activities undertaken by a federal, state, or local governmental agency, or a third-party payer entity, in order to: <ol style="list-style-type: none"> i. Identify actions the agency or third-party payer entity can make, such as changes to its policies or procedures, to improve care and outcomes for patients with SUDs who are treated by part 2 programs; ii. Ensure that resources are managed effectively to care for patients; or iii. Determine the need for adjustments to payment policies to enhance care or coverage for patients with SUD. 2. Reviews of appropriateness of medical care, medical necessity, and utilization of services. <p>42 CFR 2.53(c)</p>	<p>Under HIPAA and chapter 70.02 RCW an audit or evaluation could be completed as part of the entity's health care operations.</p>

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
<p>Medicare, Medicaid, or Children's Health Insurance Program (CHIP) audit or evaluation</p>	<p>Information can be disclosed as part of a Medicare, Medicaid, or CHIP audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services-regulated accountable care organization or similar CMS-regulated organization.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • Auditor or evaluator must agree in writing that identifiable information will: <ul style="list-style-type: none"> ○ Not be disclosed to anyone ○ Only be used to carry out the purpose of the audit or evaluation ○ Be maintained and destroyed consistent 42 CFR Part 2 security requirements ○ Be retained as required by any applicable records retention laws • Audit or evaluation can be any civil or administrative investigation by a federal, state, or local government agency with oversight responsibilities for Medicare, Medicaid, or CHIP <p>Tips:</p> <ul style="list-style-type: none"> • Additional administrative requirements apply for audits or evaluations necessary to meet the requirements for a CMS-regulated accountable care organization or similar CMS-regulated organization. <p>42 CFR § 2.53(c).</p>	<p>Under HIPAA and chapter 70.02 RCW an audit or evaluation could be completed as part of the entity's health care operations.</p> <p>45 CFR § 164.506; RCW 70.02.010; RCW 70.02.050; RCW 70.02.200.</p>

Law Enforcement and Judicial Proceedings

In limited circumstances information can be disclosed to law enforcement or during judicial proceedings. The summary below describes the circumstances when information can be disclosed to law enforcement to report a crime.

Other provisions allow information to be shared for noncriminal judicial proceedings, or to investigate or prosecute criminal activity, pursuant to a properly obtained court order. Keep in mind that a court order authorizing or requiring disclosure is not the same as a mere subpoena or discovery request. The requirements for those disclosures in 42 CFR Part 2, HIPAA, and chapter 70.02 RCW are complicated and beyond the scope of this document.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Reporting a crime	<p>Limited information can be disclosed to law enforcement to report a crime.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The crime must occur at the program, or against the program’s staff • The only information that can be disclosed is: <ul style="list-style-type: none"> ○ The factual circumstances of the incident, ○ The fact that the person is receiving services, ○ The person’s name and address, and ○ The person’s last know whereabouts <p>Tips:</p> <ul style="list-style-type: none"> • A threat to commit a crime at the program or against the program’s staff meets the criteria above <p>42 CFR § 2.12(c)(5).</p>	<p>HIPAA and chapter 70.02 RCW allow disclosures to law enforcement to report a crime that occurs on the premises of the entity, as well as in several other circumstances. If the crime did not occur on premises, 42 CFR Part 2, HIPAA, and chapter 70.02 RCW should all be considered before making a disclosure.</p> <p>Information can also be used and disclosed when providing emergency health care to a law enforcement official if such disclosure is necessary to alert law enforcements to:</p> <p>(a) the commission and nature of a crime;</p> <p>(b) the location of such crime or of the victim of the crime; and</p> <p>(c) the identity, description, and location of the perpetrator of the crime.</p> <p>45 CFR § 164.512(f); 45 CFR § 164.506(c); RCW 70.02.050(1); RCW 70.02.200.</p>

Confirming Enrollment

In limited circumstances the fact that someone is present in a facility can be confirmed.

Exception	Part 2 Requirements	HIPAA and Chapter 70.02 RCW Requirements
Confirming presence in a facility	<p>A Part 2 program can confirm a person’s presence in the facility if the fact that the person has a substance use disorder is not revealed.</p> <p>Conditions for use or disclosure:</p> <ul style="list-style-type: none"> • The facility cannot solely provide SUD services • The confirmation cannot reveal that the person has an SUD • No additional information may be disclosed <p>Tips:</p> <ul style="list-style-type: none"> • Carefully consider your response; stating that 42 CFR Part 2 restricts the disclosure of a person’s information reveals that the person has an SUD • If the facility only provides SUD services, confirming a person’s presence would require that person’s consent. <p>42 CFR § 2.13(c).</p>	<p>A provider can maintain a directory that includes a person’s name, location in the facility, and general description of the person’s condition. But the provider must first give the person an opportunity to object. 42 CFR Part 2 is more restrictive.</p> <p>45 CFR § 164.510(a); RCW 70.02.010; RCW 70.02.200.</p>

42 CFR Part 2 Revised Rule (effective August 14, 2020)

What Has Not Changed Under the New Part 2 Rule: The revised rule does not alter the basic framework for confidentiality protection of substance use disorder (SUD) patient records created by federally assisted SUD treatment programs. Part 2 continues to prohibit law enforcement’s use of SUD patient records in criminal prosecutions against patients, absent a court order. Part 2 also continues to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order.

What Has Changed Under the New Part 2 Rule: The revised rule modifies several major sections of Part 2, as follows:

Applicability and Re-Disclosure

What changed?

Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2, unless any SUD records previously received from a Part 2 program are incorporated into such records. Segmentation or holding a part of any Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.

Why was this changed?

To facilitate coordination of care activities by non-part-2 providers.

Disposition of Records

What changed?

When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee will be able to fulfill the Part 2 requirement for “sanitizing” the device by deleting that message.

Why was this changed?

To ensure that the personal devices of employees will not need to be confiscated or destroyed, in order to sanitize in compliance with Part 2.

Consent Requirements

What changed?

An SUD patient may consent to disclosure of the patient's Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure.

Why was this changed?

To allow patients to apply for benefits and resources more easily, for example, when using online applications that do not identify a specific person as the recipient for a disclosure of Part 2 records.

Disclosures Permitted w/ Written Consent

Disclosures for the purpose of "payment and health care operations" are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision .

Why was this changed?

In order to resolve lingering confusion under Part 2 about what activities count as "payment and health care operations," the list of examples has been moved into the regulation text from the preamble, and expanded to include care coordination and case management activities. Note that this list is non-exhaustive—other activities may also be allowable.

Disclosures to Central Registries and PDMPs

What changed?

Non-OTP (opioid treatment program) and non-central registry treating providers are now eligible to query a central registry, in order to determine whether their patients are already receiving opioid treatment through a member program.

OTPs are permitted to enroll in a state prescription drug monitoring program (PDMP), and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.

Why was this changed?

To prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment.

Medical Emergencies

What changed?

Declared emergencies resulting from natural disasters (e.g., hurricanes) that disrupt treatment facilities and services are considered a "bona fide medical emergency," for the purpose of disclosing SUD records without patient consent under Part 2.

Why was this changed?

To ensure clinically appropriate communications and access to SUD care, in the context of declared emergencies resulting from natural disasters.

Research

What changed?

Disclosures for research under Part 2 are permitted by a HIPAA-covered entity or business associate to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule (re: Research on Human Subjects).

Why was this changed?

To facilitate appropriate disclosures for research, by streamlining overlapping requirements under Part 2, the HIPAA Privacy Rule and the Common Rule.

Audit and Evaluation

What changed?

Clarifies specific situations that fall within the scope of permissible disclosures for audits and/or program evaluation purposes.

Why was this changed?

To resolve current ambiguity under Part 2 about what activities are covered by the audit and evaluation provision.

Undercover Agents and Informants

What changed?

Court-ordered placement of an undercover agent or informant within a Part 2 program is extended to a period of 12 months, and courts are authorized to further extend the period of placement through a new court order.

Why was this changed?

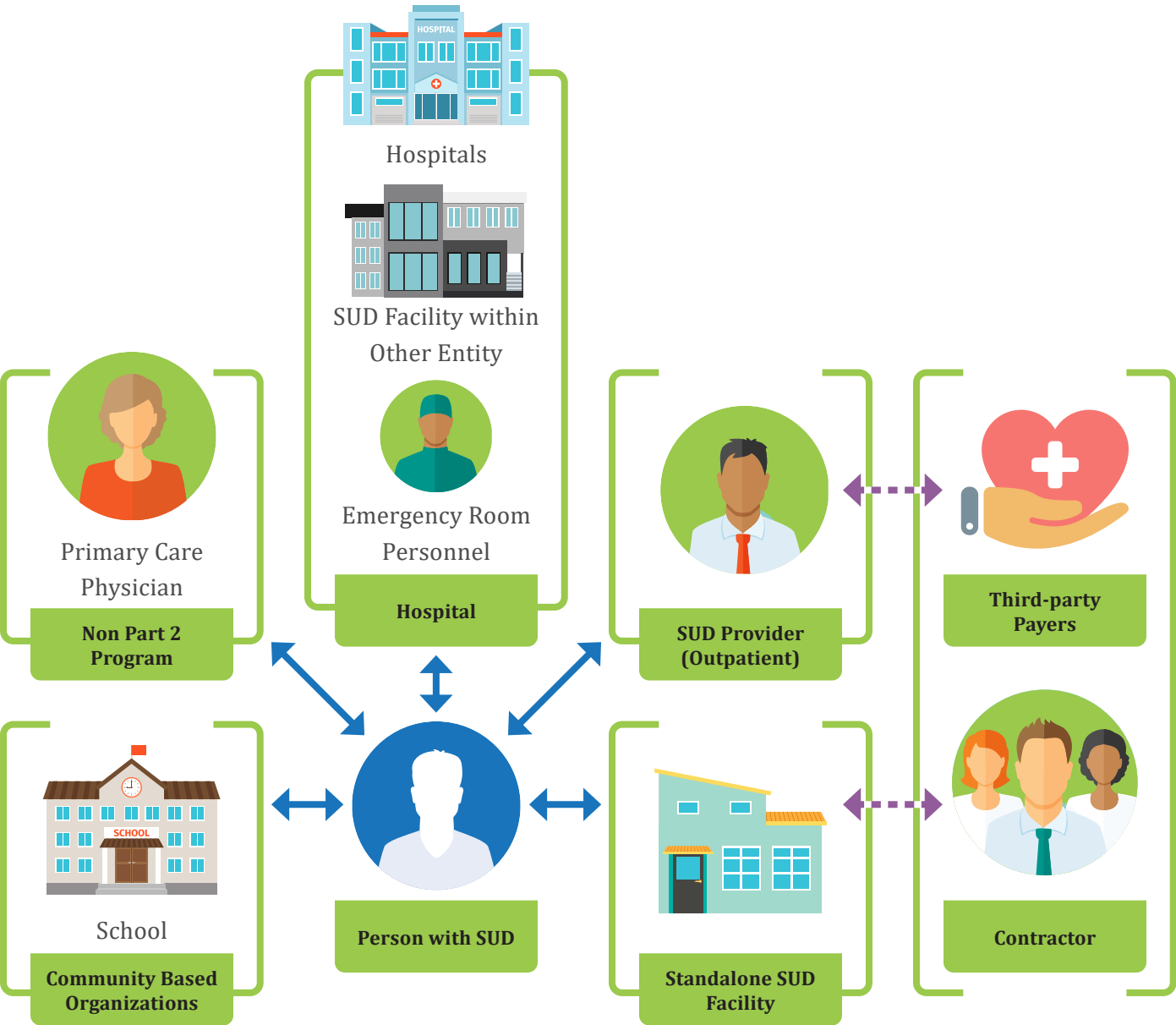
To address law enforcement concerns that the current policy is overly restrictive to some ongoing investigations of Part 2 programs.

Scenarios and Guidance for SUD Data Exchange

The primary beneficiary of the exchange of SUD information is the patient. In order to provide the best care for the whole person, health care professionals and other entities who provide services to people with SUD need to collaborate and communicate. This approach puts the individual at the center of care coordination.

This graphic shows examples of the types of people and entities that may be involved in a person's care, and the following scenarios show when information can be shared amongst these people and entities. The scenarios are grouped into the categories of (1) treatment, and (2) payment and health care operations.

Potential Touchpoints for Persons with SUD



[Quicklinks to the scenarios below:](#)

Treatment Scenarios

- **Scenario 1**
Communication within a Part 2 Program
- **Scenario 2**
Communication between different Part 2 Programs
- **Scenario 3**
Sharing information with a provider not subject to Part 2
- **Scenario 4**
Sharing information with emergency personnel
- **Scenario 5**
Sharing SUD information through an HIE
- **Scenario 6**
Provider not subject to Part 2 sharing with Part 2 Program
- **Scenario 7**
Communication between Part 2 Program and School

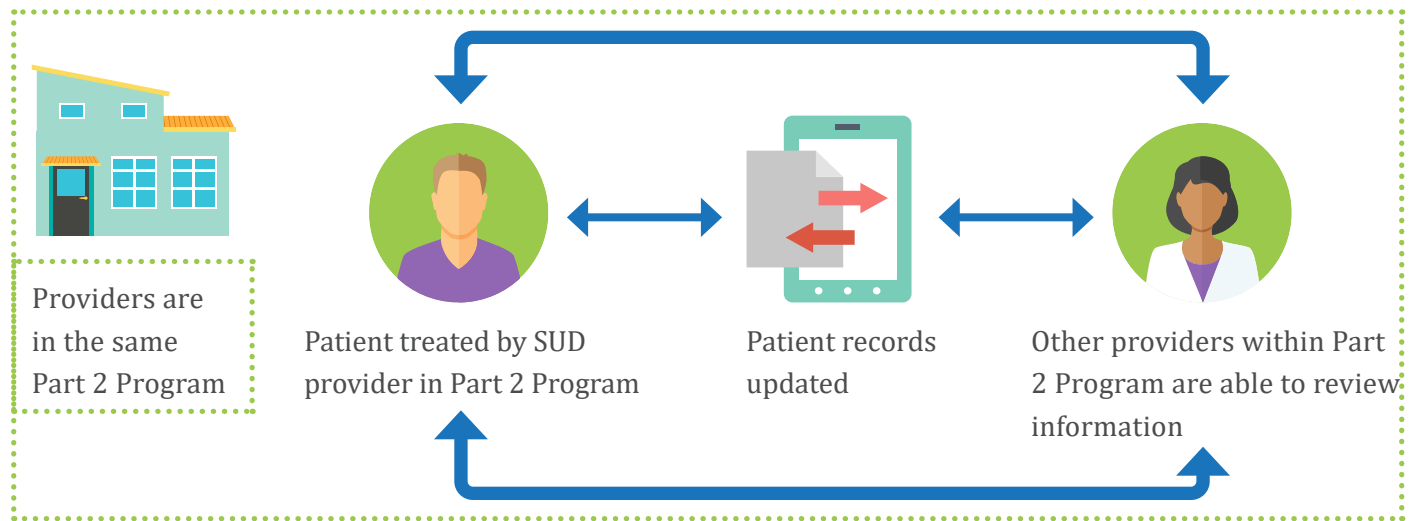
Payment and Health Care Operations Scenarios

- **Scenario 1**
Disclosures from a Part 2 Program to Contractors
- **Scenario 2**
Disclosures to Third-Party Payer

Treatment Scenario 1:

Communication within a Part 2 Program

Key take away: Information can be shared within a Part 2 program for legitimate treatment purposes without written consent



Scenario Description:

- Providers within the same Part 2 program want to share information with each other to coordinate care.

Remember:

- A Part 2 program may be located within a facility that has other functions that are not considered part of the Part 2 program.
- Sharing the same physical location does not mean that all providers are within the Part 2 program.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- Need for sharing must arise from providing diagnosis, treatment, or referral for treatment.
- Disclosure only allowed to personnel of a Part 2 program or entity with direct administrative control over the program.
- See Payment Scenario 1 and Health Care Operations Scenario 1 for specific detail around disclosures within a Part 2 program for payment or health care operations.

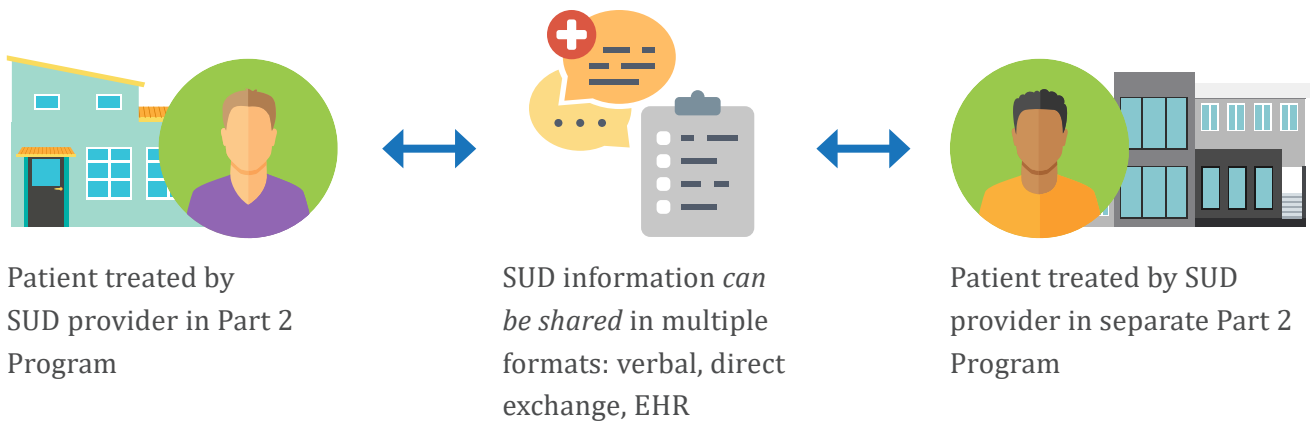
HIPAA and Chapter 70.02 RCW Requirements:

- Information can be used and disclosed for legitimate treatment, payment, and health operations purposes without written consent. 42 CFR Part 2 is more restrictive.

Treatment Scenario 2:

Communication between different Part 2 Programs

Key take away: Information shared between different Part 2 programs requires valid written consent



Scenario Description:

- Separate part 2 programs want to share SUD information with each other.

Remember:

- To share information back and forth, the written consent must indicate that information can be shared both to and from provider.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- Valid written consent.
- Information shared must be tailored to the written consent.

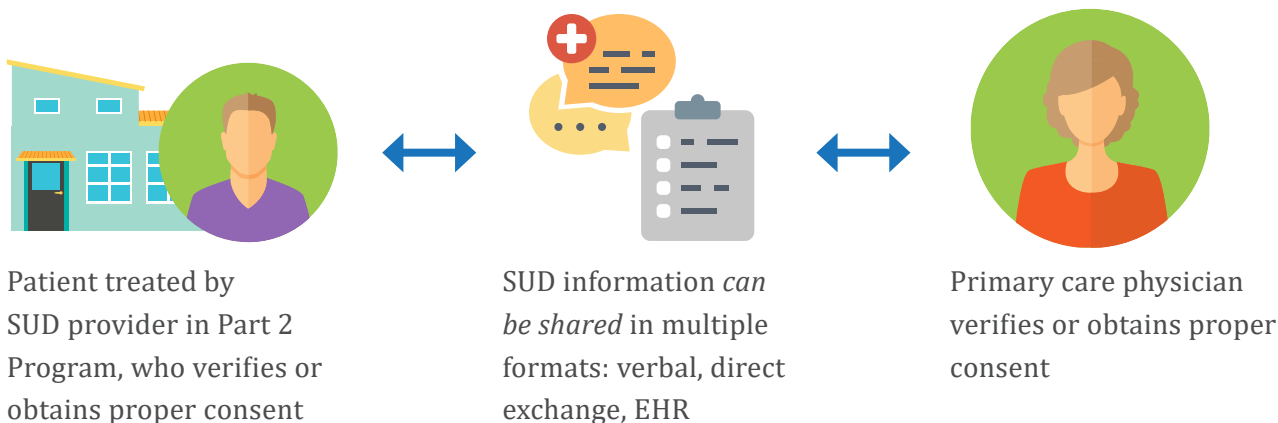
HIPAA and Chapter 70.02 RCW Requirements:

- Information can be used and disclosed for legitimate treatment purposes without written consent. 42 CFR Part 2 is more restrictive.

Treatment Scenario 3:

Sharing information with a provider not subject to Part 2

Key take away: Information shared from Part 2 program to other treating provider requires valid written consent



Scenario Description:

- Part 2 program wants to share information with primary care physician.

Remember:

- The requirements for specificity in the consent vary depending on whether there is a specific or general designation.
- The requirement for written consent does not prevent the primary care physician from sharing with the Part 2 program. See Treatment Scenario 6 for more information.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- Valid written consent.
- Information shared must be tailored to the written consent.

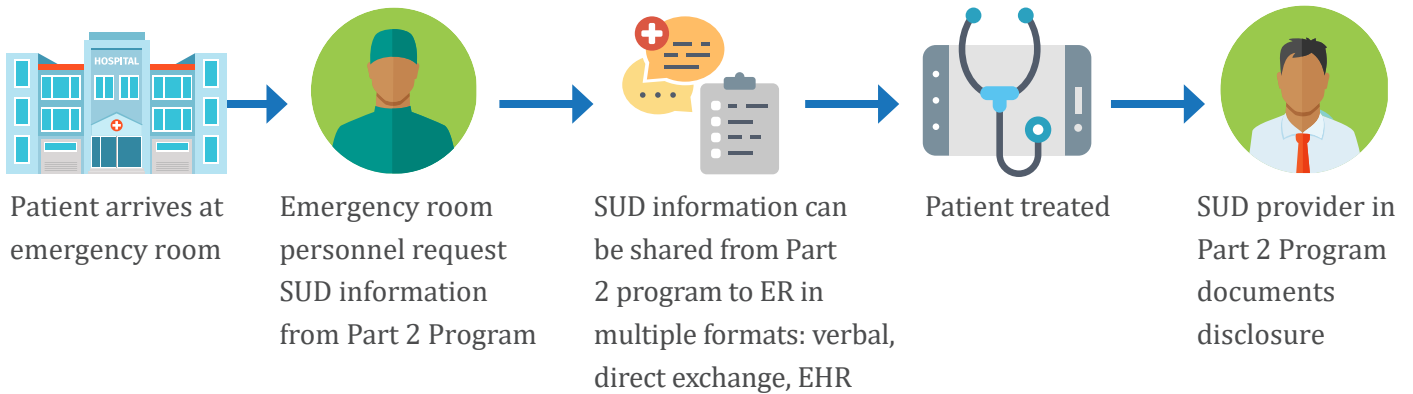
HIPAA and Chapter 70.02 RCW Requirements:

- Information can be used and disclosed for legitimate treatment purposes without written consent. 42 CFR Part 2 is more restrictive.

Treatment Scenario 4:

Sharing information with emergency personnel

Key take away: Part 2 information can be shared without consent with emergency personnel when responding to a legitimate emergency



Scenario Description:

- A person who is experiencing a medical emergency arrives at an emergency facility. The treating provider is aware that the person has previously been treated for SUD by a Part 2 provider, but it is not possible to obtain consent to receive SUD information.

Remember:

- A Part 2 program may be located within a facility that has other functions that are not considered part of the Part 2 program.
- Sharing the same physical location does not mean that all providers are within the Part 2 program.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- Disclosure must be necessary to respond to a legitimate emergency.
- Only applies when informed consent cannot be obtained.
- The Part 2 program that makes the disclosure must document who made the disclosure, why it was made, and when it was made.

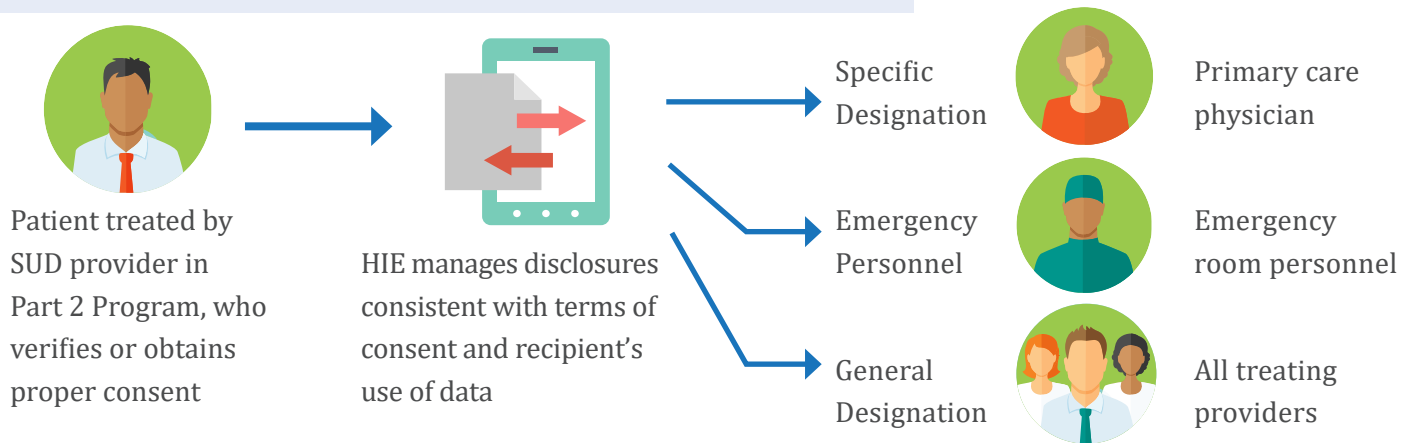
HIPAA and Chapter 70.02 RCW Requirements:

- Information can be used and disclosed for legitimate treatment purposes without written consent. 42 CFR Part 2 is more restrictive.

Treatment Scenario 5:

Sharing SUD information through an HIE

Key take away: Part 2 information can be shared via an HIE. Conditions for sharing depend upon terms of consent and recipient's use of data



Specific Designation

- Part 2 program wants to share information with specific provider through HIE.

Part 2 Conditions:

- Valid written consent that specifies HIE and a specific treating provider; specified treating provider can be either individual provider or the provider entity.
- If the HIE is a qualified service organization of the Part 2 program, the consent only needs to identify the specific treating provider.

Emergency Personnel

- Emergency personnel wants to access information in response to legitimate emergency and it is not possible to obtain consent.

Part 2 Conditions:

- Requirements in Treatment Scenario 4 satisfied .
- HIE is qualified service organization of the Part 2 program, and fulfills role of documenting the disclosure.

General Designation

- Part 2 program wants to share information with all treating providers through HIE.

Part 2 Conditions:

- Valid written consent that specifies HIE and general designation of all treating providers.
- Consent must specify HIE, regardless of whether the HIE is a qualified service organization of the Part 2 program.
- Upon request from the person with SUD, the HIE must provide a list of the entities that received information, the date information was shared, and brief description of what was shared.

Treatment Scenario 6:

Provider not subject to Part 2 sharing with Part 2 Program

Key take away: Information shared by non-Part 2 provider is governed by HIPAA and consent is not required



Information about physical health care requested by Part 2 Program



Records *can be shared* in multiple formats: verbal, direct exchange, EHR



Part 2 Program receives information

Scenario Description:

- Part 2 program wants to receive physical health care records from non-Part 2 provider

Remember:

- The restrictions in 42 CFR Part 2 do not apply to information being sent to a Part 2 program, but Part 2 program should take care when requesting information to not inappropriately reveal that person is being treated for SUD.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- 42 CFR Part 2 does not control disclosures from a non-Part 2 program to a Part 2 program.

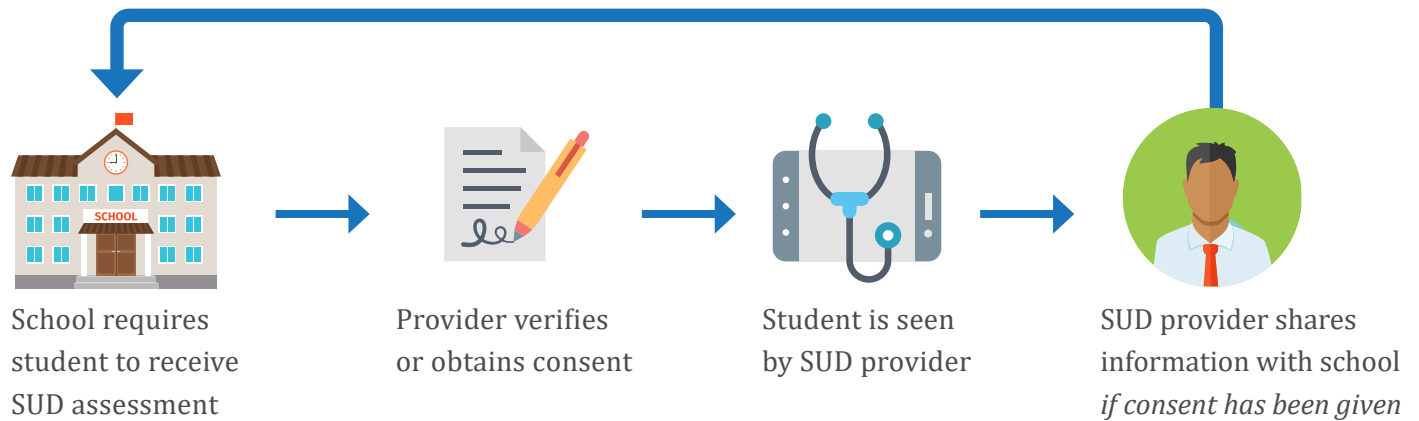
HIPAA and Chapter 70.02 RCW Requirements:

- Information can be used and disclosed for legitimate treatment purposes without written consent.

Treatment Scenario 7:

Communication between Part 2 Program and School

Key take away: Information can be shared between a Part 2 program and student's school with written consent.



Scenario Description:

- School requires SUD assessment and treatment recommendation.
- School wants confirmation from SUD provider.

Remember:

- The school should only receive what it needs to confirm there has been an assessment and recommendation.
- If the information is shared with a multidisciplinary team that includes people other than school employees, all recipients should be listed on the consent.

Conditions for Use or Disclosure of SUD Information:

- Valid written consent.
- Information shared must be tailored to the written consent.
- School becomes a lawful holder and must protect records from further disclosure.

HIPAA and Chapter 70.02 RCW Requirements:

- Information should only be shared with consent.

Payment and Health Care Operations

Scenario 1: Disclosures from a Part 2 Program to Contractors

Key take away: If proper agreements are in place, information can be shared with a contractor that provides payment-related services to a Part 2 program, such as submitting claims or bill collecting



Part 2 Program enters contract for payment or health care operations services



SUD information *can be shared* in multiple formats: verbal, direct exchange, EHR



Qualified Service Organization (QSO)

Scenario Description:

- Part 2 program wants to hire a third-party contractor to perform payment functions, such as submitting claims or bill collecting.

Remember:

- A contractor that meets these requirements is referred to as a “qualified service organization.”
- A Part 2 program can also share information with its own staff to perform these types of payment functions.
- Just like Part 2 programs, lawful holders can use contractors to perform these types of payment functions.

- This justification for sharing does not apply to treatment-related services, including care coordination.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- The contractor must sign an agreement that limits its uses of the information to the specified payment functions.
- The agreement must include an acknowledgement by the contractor that it is fully bound by 42 CFR Part 2.
- The agreement must require the contractor to resist inappropriate efforts to obtain SUD information.

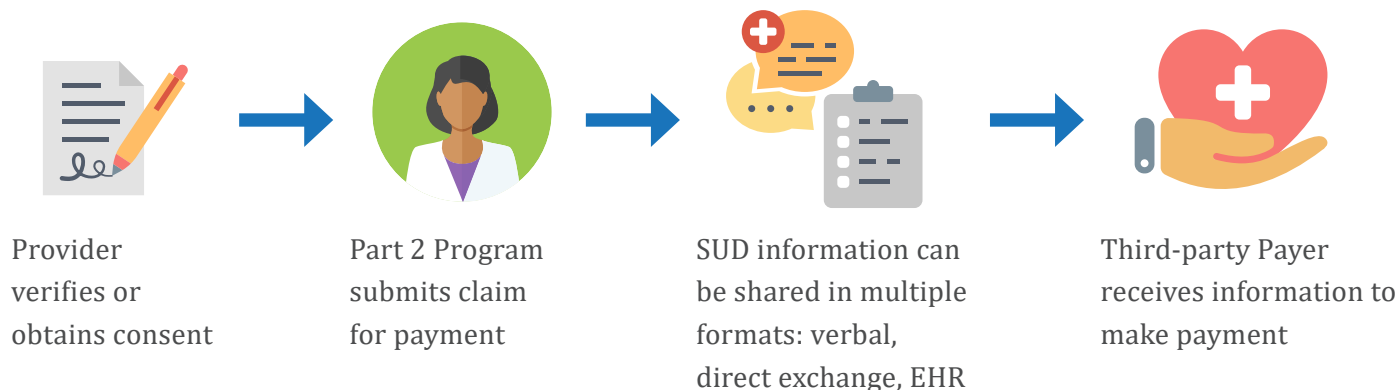
HIPAA and Chapter 70.02 RCW Requirements:

- Information can be shared with contractors that provide services to or on behalf of a covered entity. These contractors are referred to as “business associates” and must sign a business associate agreement. HIPAA includes specific requirements for business associate agreements that should also be included in agreements with a qualified service organization.

Payment and Health Care Operations

Scenario 2: Disclosures to Third-Party Payer

Key take away: Written consent must be obtained before submitting a claim for payment to a third-party payer



Scenario Description:

- Part 2 program wants to submit a claim for payment to a third-party payer.

Remember:

- If a person revokes consent before a claim can be submitted, the Part 2 program can still submit the claim if it relied on the fact that the consent had been signed when it provided treatment.
- If a person is unable to effectively act on their own, a Part 2 program director can consent to disclosure for the sole purpose of obtaining payment.

42 CFR Part 2 Conditions for Use or Disclosure of SUD Information:

- Valid written consent.
- Disclosure must be tailored to the written consent.

HIPAA and Chapter 70.02 RCW Requirements:

- Information can be used and disclosed for legitimate payment purposes without written consent. 42 CFR Part 2 is more restrictive.

Appendix 1 – Consent Form

This sample form is intended to support gathering consent to facilitate care coordination between providers. It is consistent with changes to 42 CFR Part 2 that allow disclosures to all treating providers. The form can be used as is, or tailored to a specific scenario. Any modifications or other uses should be reviewed to ensure consistency with the requirements in Part 2 and consultation with legal counsel is encouraged.

When disclosing information pursuant to consent, one of the following statements must be sent along with the records:

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

- or -

42 CFR part 2 prohibits unauthorized disclosure of these records.

Although the sample consent form includes this language, it is important that this statement be communicated to a recipient separately if the completed consent form itself is not sent with the records.

Consent to Coordinate Care and Treatment

Completion Instructions for Form

Purpose of this form:

Our goal is to provide you with the best care possible. To do this, your health care providers may need to communicate and work together.

Federal laws require that we get your permission to share your substance use disorder treatment records to coordinate your care. However, you do not need to sign this form to receive care or services.

Your treatment records are strictly protected – There are requirements in federal law (42 CFR Part 2) that encourage you to seek treatment for substance use disorder without fear of consequences. These requirements protect the privacy of your treatment records and, in most instances, prohibit sharing your records without your permission.

Who will my information be shared with? – You are in control of who has access to your treatment records. You can provide a general approval, such as “I give my permission to share my substance use disorder treatment information with all individual(s) or organization(s) with whom I have a past, current, or future treating provider relationship.” Or, you can choose to be very specific and share your information with only the individuals or entities that you clearly name, such as “Dr. Jane Smith at ABC Clinic.” You can choose how long you want to share your information and you have the ability to change your mind later.

Definitions

Treating provider – A treating provider includes anyone who has provided you diagnoses, evaluation, treatment, or consultation, for any condition, or anyone you have agreed or legally required to receive diagnoses, evaluation, treatment, or consultation from.

Health Information Exchange – A secure electronic system that sends your treatment medical information and allows doctors, mental health providers, nurses, pharmacists, and other health care providers to appropriately access and securely share this information—improving the speed, quality, safety and cost of your care.

Personal information

Note: Patient identification label may be affixed here in lieu of completing this section.

First name	Middle initial	Last name	Date of Birth (mm/dd/yyyy)	ZIP Code

SECTION 1: What information am I agreeing to share?

I give my permission to share the following information (please select one or both):

- Option 1:** Substance Use Disorder (SUD) treatment records maintained by my providers (including, but not limited to, medications and dosages, lab test results, clinic visits, diagnostic information, discharge summary etc.)
- Option 2:** Claims data related to Substance Use Disorder (SUD) treatment, which include only a summary of my diagnoses and services received
- Option 3** "I select both Option 1 and Option 2"

SECTION 2: Who may share my Substance Use Disorder (SUD) information?

This section identifies which of your providers can share your information.

Please select one or both of the following options:

- Option 1:** "I give permission for all of my past, current, or future treating providers to share my substance use disorder treatment information."
- Option 2:** "I give permission for these specific individual(s) or organization(s) to share my substance use disorder treatment information."

Name of the individual(s) and/or healthcare organization(s) with whom I have (or had) a treating provider relationship:	Enter their contact information:			
	Phone	City	State	ZIP Code

- Option 3:** "I select both Option 1 and Option 2"

SECTION 3: Who do I want to share my information with?

This section identifies who can receive your information.

I give my permission to share the following information (please select one or both):

Option 1: Providers may choose to send and receive patient treatment information through a secure electronic system called a Health Information Exchange (HIE). Doctors, mental health providers, nurses, pharmacists, and other health care providers are only allowed to receive and share your information from an HIE if they have the right permissions to do so.

“I understand that my past or current treating providers may currently use, or plan to use, the following HIE to manage my information: _____.

I agree to share my information through the HIE with all individual(s) or organization(s) that I have a past, current or future treating provider relationship with.”

Option 2: “I give my permission to share my substance use disorder treatment information with these specific individual(s) or organization(s).”

Name of the individual(s) and/ or healthcare organization(s) with whom I have (or had) a treating provider relationship:	Enter their contact information:			
	Phone	City	State	ZIP Code

Option 3: “I select both Option 1 and Option 2”

Note to receiving provider or entity: 42 CFR part 2 prohibits unauthorized disclosure of these records.

SECTION 4: Consent Expiration

I understand that my permission will end: (please select one only)

- On this date:
 One year from the date of my signature, or
 Upon my death.

I understand that I can take back or cancel my permission to share my information at any time. When I take back or cancel my permission, I understand that going forward, my information will no longer be shared.

I understand that any information that may have already been shared before I cancelled my permission cannot be taken back.

To take back or cancel your permission to share your information, please contact:

SECTION 5: Signature

I have read this form or have had it read to me in a language I can understand. I have had my questions about this form answered. **I understand that I do not need to sign this form to receive care or services.**

Print the name of person giving consent or legal representative

Signature of person giving consent or legal representative

Date (mm/dd/yyyy)

Relationship to Individual

- Self Parent Guardian Authorized Representative

Appendix 2 – Provider Script

This script (pages 63 - 64) is meant as a consent aid for providers. The focus of the script is providing a safe, trusting environment for the provider and person receiving services to discuss the benefits of care coordination. This script is not meant to replace the ability of providers to use their professional judgement and established relationships to customize conversational needs. You know the people in your care and the best way to approach sensitive conversations.

Provider Script

When introducing patients to the concept of consent management and its purpose, the following three discussion components are recommended:

- 1) Providing a patient consent conference in a non-judgmental environment.
- 2) Setting the clear intention for improved patient care experience.
- 3) Supporting the patient in self-directed decision making around consent and being in control of that decision.

Below are sample discussion points to facilitate the introduction and request for consent to share SUD information. While positioned from a PCP point of view, the key points are applicable to Behavioral health/SUD providers.

Initiating the patient consent conference

Welcome

- **Thanks for coming in today.** I really appreciate you doing that. I know it's hard sometimes to get to a place where you're able to come in and thank you for sharing your story with me.

This is a safe place

- I want to be sure you understand and know that **this is a safe place.** I appreciate that you've been honest with me and shared your struggle with opiate use disorder with me and **I know it's hard to do**
- My job is to help you figure out how best to manage that. **And it's at your pace and your time.** But this is something that is a chronic condition. It's not because you want this, not because you have a moral weakness, it's a chronic medical condition and so we're going to work together to address that.

Setting a clear intention for improved patient care experience

Asking for information from other providers

- **One of the things that will be really helpful for me to do, is to find out information, such as the diagnoses and medications you have received, from other providers that you've seen but not specifically what you've talked about with your counselors, or what kind of group sessions you were in.**

- If you want to share something with me, that's fantastic. But that's not necessary to my taking care of you. **What is helpful for me to know is if they have some sort of diagnoses** that you may have not remembered so that I can find out if those may or may not still be present, but **more important is to find out if they treated you with any medications.**

Your privacy is protected

- **When you give me permission to talk to your other providers, you are giving me permission to ask for and share health care information about you.**
- **You are only giving me permission to look at this.** If the police or someone else were to say "hey, so and so, I think they have a chemical dependency problem or have they been to a methadone clinic, can you send me all the records on that?" the answer is "no." **You have legal protections and I cannot share this privileged information that you are agreeing to let me have with anybody else. That is illegal.** So that protection is built in as well.
- **This information will not be shared with your employer or family.**

Supporting self-directed decision making about consent and being in control of their consent

Your permission is voluntary

- **I will take care of you no matter what you tell me.**
- **By giving me permission, you're not giving everybody who might ask for something from me your permission as well.** You tell me who's okay to have this information and who's not.

- **This is your information.** And yes, it might be helpful to me, but if it makes you feel unsafe or worried maybe it's not the right time to do that right now.
- **It's important for us to protect the privacy of everything that everybody tells us.** Your medical condition, what meds you're on, what you come in for today, if you have a history of a substance use disorder, if you have a history of a mental health disorder, it is all equally important for us to protect and let you share what you want with people. **It is not about what we want to share. We will only share what we feel we need to.** That helps to provide care for you and specifically in this case, we need your permission.
- **You decide how long this information can be shared.** Once you give permission, we can't take back information already shared, but we can stop any additional information from being shared.

If someone is not sure about their other providers or not able to share that information

Do you have a case manager in your program?

How would it be or how would it be with you that I talk to your case manager? **That way they may give me information that you don't think is important, but it might be helpful to me.** And that if they are worried about you they can give me a call and get through if you're not able to and I found that **working as a team helps people better.** Is that ok?

Appendix 3 – Brochure

This brochure is intended as a consent aid for people receiving services. It is structured similar to brochures aimed at educating patients on HIPAA regulations or research studies. These brochures can be made available in public spaces in a clinic and are highly encouraged to be used while discussing the benefits of consent. On the back fold

of the brochure, there is space for the provider/ clinic to place their contact information. Along with a copy of the consent, the person should be encouraged to take a brochure home with them to ensure they know who to contact if they decide to cancel their consent or have additional questions.



How long will my information be shared?

You choose! If you agree to share, you can choose when your consent to share information should end. Even after choosing a date, you can take back or cancel your permission at any time.

Of course, information may have already been shared with providers before you cancel or take back your permission.

How do I give my permission?

A short form is all that is needed to consent to share information. We can walk you through it.

What You Should Know About Substance Use Disorder Information Sharing

HCA 82-0182 (4/19)



Why are we asking for this?

Our goal is to provide you with the best and safest care possible.

We are asking for your Substance Use Disorder (SUD) information to be shared with providers with the same level of confidentiality as other health care information.

Sharing this information allows your providers to see you as a whole person. For example, sharing this information:

- Allows your SUD treatment provider to better coordinate with your diabetes doctor.
- Allows the doctor treating your high blood pressure to understand what medications you are receiving from your SUD provider.



Who will my information be shared with?

You are in control of who has access to your treatment records. You have the following options:

- You can choose to provide a general approval to all individuals and entities that you have/might have received treatment from.
- You can choose to be very specific and share your information with only specifically named individuals or entities.

Will this information be shared with my family, landlord or employer?

No, your information will not be shared without your permission.

How do I know my treatment information won't be shared without my permission?

Sharing your information is voluntary. Your treatment records are strictly protected under federal law and, in most instances, will not be shared without your permission.

Under Federal Law 42 CFR Part 2:
You are entitled to seek treatment without fear of legal or social consequences.

The privacy and confidentiality of your records prevents their sharing without your permission.






How long will my information be shared?

You choose! If you agree to share, you can choose when your consent to share information should end. Even after choosing a date, you can take back or cancel your permission at any time.

Of course, information may have already been shared with providers before you cancel or take back your permission.

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- You can choose to provide a general approval to all individuals and entities that you have/might have received treatment from.
- You can choose to be very specific and share your information with only specifically named individuals or entities.

Will this information be shared with my family, landlord or employer?

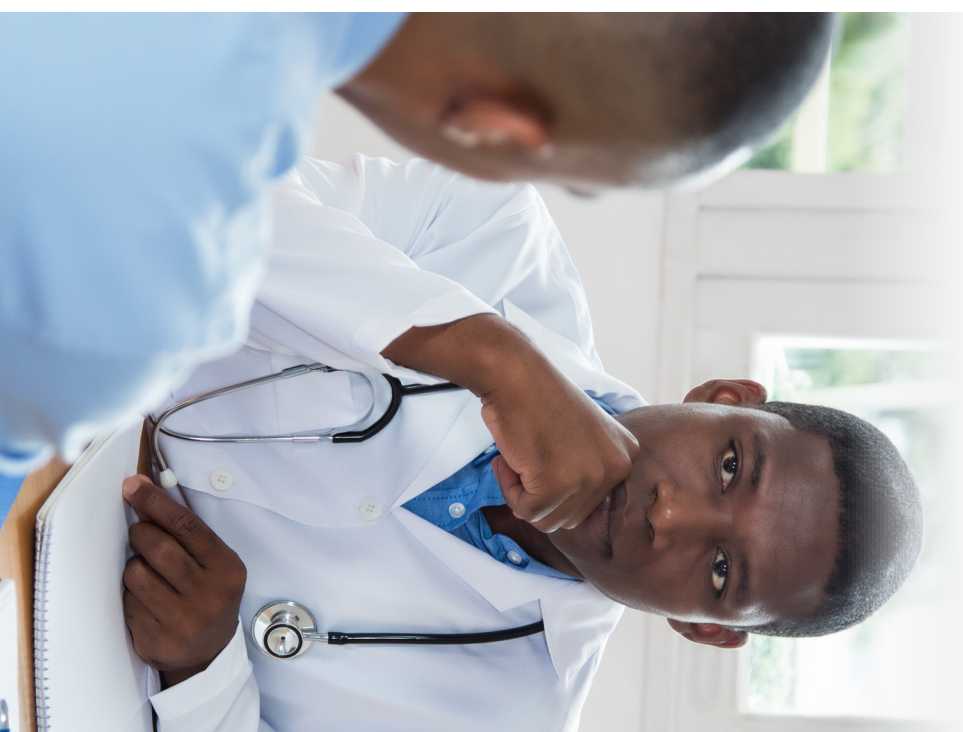
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Appendix 4 – Acknowledgments

This document would not have been possible without collaboration from the state agencies that participated in an SUD Consent Management Workgroup and shared information through interviews, discussion, and review. In addition to HCA, staff from the following state agencies participated and helped develop this guidance:

Department of Children, Youth, and Families

Department of Corrections

Department of Health

Department of Labor & Industries

Department of Social and Health Services

Office of Financial Management

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Finally, HCA was able to draw from excellent resources already created by others, including the [State Health Information Guidance](#) published by the State of California Office of Health Information Integrity.

