Confidentiality Tool Kit for Providers

August 2020
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This tool kit is not legal advice. It is not a substitute for reviewing the law or consulting an attorney.
In 2015, the Oregon Health Authority (OHA) created an internal Behavioral Health Information Sharing Advisory Group to help improve care coordination between physical health and behavioral health providers. This group focused on developing a strategy to support integrated care and services by enabling the electronic sharing of behavioral health information among providers. This is a critical step in supporting the coordinated care model and realizing the goal of better health, better care and lower costs for everyone. This Confidentiality Tool Kit for Providers is one outcome of the Behavioral Health Information Sharing Advisory Group’s work.

This tool kit is for behavioral health service providers, but it may be useful for others. Regulations for confidentiality of health records are subject to change. As a result, be sure to use this resource in conjunction with review of current statutes.

The following resources and examples will help navigate some of the applicable confidentiality laws that may protect a patient’s behavioral health information while allowing appropriate information sharing to coordinate care.
### Summary of selected federal and state laws and regulations addressing confidentiality

<table>
<thead>
<tr>
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<th>General description</th>
<th>Applicability</th>
<th>Information covered</th>
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<tr>
<td>Confidentiality of Substance Use Disorder Patient Records</td>
<td>42 CFR part 2 (42 U.S.C. § 290dd-2)</td>
<td>Confidentiality of substance use disorder patient records</td>
<td>• Lawful holders of patient identifying information and • Federally assisted substance use disorder treatment programs that provide diagnosis, treatment or referral to treatment</td>
<td>Covers patient records, and reference to publicly available information that identifies a person as currently or previously having an alcohol or drug use disorder</td>
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<tr>
<td>Health Insurance Portability and Accountability Act</td>
<td>42 USC 1320d et seq., HIPAA Privacy and Security Rules: 45 CFR Part 160 and 45 CFR Part 164</td>
<td>Federal legislation enacted in 1996 and implementing rules that provide data privacy and security provisions to safeguard medical information</td>
<td>• Applies to covered entities and business associates of covered entities. • Covered entities include health care providers who conduct financial and administrative transactions electronically, health plans, and health care clearinghouses. • A business associate is an entity that creates, receives, maintains or transmits protected health information (PHI) on behalf of a covered entity.</td>
<td>Covers protected health information that identifies an individual or could be used to identify an individual and relates to physical or mental health of an individual, provision of health care and payment for health care</td>
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<td>Oregon Revised Statute</td>
<td>ORS 192.566</td>
<td>State law regarding form for release of information that supersedes former ORS 192.522</td>
<td>Disclosure of protected health information in accordance with ORS 192.558</td>
<td>Authorization form</td>
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<tr>
<td>Oregon Revised Statute</td>
<td>ORS 414.607</td>
<td>State law regarding sharing information within CCO network and disclosure of mental health diagnoses</td>
<td>Governs sharing of patient information between CCOs and network providers</td>
<td>Covers member information, HIV, other health and mental health diagnoses</td>
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<td>Oregon Revised Statute</td>
<td>ORS 192.567</td>
<td>State law regarding sharing protected health information to close family and friends in emergencies</td>
<td>Allows disclosure of otherwise protected health information to close family without consent under special circumstances</td>
<td>Covers general protected health information and mental health information</td>
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| Oregon Revised Statute  | ORS 179.505   | State law regarding disclosure of written accounts by health services providers, including psychotherapy notes | Applies to health care service providers who are employed or under contract with a “public provider,” as defined in the statute; includes community mental health programs, community developmental disabilities programs and other public providers | • Law covers individually identifiable health information (written accounts) created or received by a health care services provider.  
• Statute also covers disclosure of psychotherapy notes, as defined in the statute. |
<p>| Oregon Revised Statute  | ORS 109.675   | State law regarding patients 14 years and older who seek to obtain outpatient treatment for mental or emotional disorder or chemical dependency without parental consent | Applies to minors 14 years of age or older and providers listed in the statute | Covers the right to treatment for patients who are 14 years of age or older                             |
| Oregon Revised Statute  | ORS 109.680   | State law regarding the disclosure of a minor’s diagnosis or treatment information to parents without the minor’s consent | Applies to minors 14 years of age or older and their parents, as well as the providers listed in the statute | Covers information related to diagnosis or treatment of minors 14 years of age or older                  |</p>
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<td>Oregon Revised Statutes</td>
<td>ORS 430.399(6)</td>
<td>Statute concerning records of a person at a treatment or sobering facility and the records’ release with or without patient consent</td>
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<td>Oregon Revised Statutes</td>
<td>ORS 192.398(1)</td>
<td>Provides disclosure exemptions for records of physical or mental health or psychiatric care or treatment of a living individual when records are less than 75 years old</td>
<td>Applies to any holder of public records described in the statute</td>
<td>Covers any public records relating to physical or mental health or psychiatric care or treatment of a living individual when records are less than 75 years old</td>
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<td>Oregon Revised Statutes</td>
<td>ORS 192.553 to ORS 192.581</td>
<td>Set of state laws regarding Oregon’s policy on protected health information</td>
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<td>Covers protected health information held by a covered entity, as defined in ORS 192.556</td>
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<td>Oregon Revised Statutes</td>
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<td>State law regarding facilities notifying the parents or guardian of a person who is under age 18 or is incompetent</td>
<td>Applies to facilities operated under OHA rules</td>
<td>Notification of a person’s voluntary admission or referral</td>
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| **Support for Patients and Communities Act** | H.R. 6                   | • This 2018 federal legislation provides for opioid use disorder prevention, recovery and treatment.  
• Subtitle F (Jessie’s Law sections 7051–53) address inclusion of opioid addiction history in medical records and developing best practices related to patient records of substance use disorder. | Applicable to health care providers and state agencies                         | May cover records related to a patient’s substance use disorder, in particular opioid use disorder |

This tool kit is not legal advice. It is not a substitute for reviewing the law or consulting an attorney.
For more frequently asked questions about applying 42 CFR part 2 to health information exchange (HIE), please see the U.S. Department of Health and Human Services: https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf.

SAMHSA is updating guidance on the new and updated regulations. See https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs.

General privacy law questions

**Q1. What are some of the common acronyms regarding privacy law?**

**A.**  
- PII = Personally identifiable information  
- PHI = Protected health information, which 45 CFR 160.103 defines  
- HIPAA = Health Insurance Portability and Accountability Act of 1996  
- IIHI = Individually identifiable health information, which ORS 179.505 defines  
- CJIS = Criminal Justice Information Services (of the FBI)  
- BAA = Business associate agreement  
- QSO = Qualified service organization  
- QSOA = Qualified service organization agreement

**Q2. Is there any recourse for a health care entity when another entity has a more conservative interpretation of privacy laws that could affect patient care? Does an OHA program offer mediation in this situation?**

**A.** There are often differences in how health entities interpret regulations. No OHA program handles appeals or mediation requests related to such differences. However, where there is a difference in interpretation or application of state and federal laws between different entities, you could follow up with the other covered entity about your interpretation of the regulations. Seek to understand why it differs in its interpretation.
Q3. How do I know when 42 CFR part 2 protects information included in a medical record?

A. Whether information included in a medical record is protected by 42 CFR part 2 generally depends on several factors, such as:

- The type of information
- Who holds the information
- Where the information originated
- Under what terms the information was received, and
- The purpose of the information.

42 CFR part 2 restricts disclosure of any information that would “identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person” (42 CFR 2.12(a)(1)(i)). Further, the information must be “obtained by a federally assisted drug abuse program . . . for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment” (42 CFR 2.12(a)(1)(ii)). Information might also be subject to protections in 42 CFR part 2 by agreement (for example, Qualified Services Organization Agreement under 42 CFR 2.11 or audit/evaluation under 42 CFR 2.53), or if it was received with notice prohibiting its redisclosure (for example, 42 CFR 2.12(d) and 2.32).

For additional information on the applicability of part 2 protections, see the following fact sheets issued by SAMHSA:


and


Q4. Does a provider need to obtain the patient’s consent to disclose their information in order to have a “warm handoff” to another provider?

A. A warm handoff often refers to the process of transferring a patient from one provider to another, prior to discharge, which generally includes face-to-face meeting(s) with the patient and both providers coordinating the transfer of responsibility for
the client’s ongoing care and continuing treatment and services. HIPAA-compliant telehealth, or other technological approaches to this face-to-face meeting, is also allowed and encouraged if this is the only or best way to ensure a warm handoff. Because this type of communication involves disclosing the patient’s name and other protected health information from one provider to the other, it must be authorized under all applicable laws. For example, to the extent that the transferring provider is a HIPAA covered entity, HIPAA permits certain disclosures of protected health information for treatment activities or care coordination purposes without patient consent. See 45 CFR 164.506(c) (regarding disclosure for certain treatment activities or health care operations) and 164.501 (defining health care operations).

To the extent that the sending provider is subject to part 2 or has information protected by part 2, the patient’s consent is generally needed to disclose their information to another provider. See 42 CFR 2.31 and 2.33. Patients are often willing to talk with a community provider or advocate who will be helping them when they leave a treatment setting. OHA encourages and requires offering the patient a warm handoff in certain circumstances. A best practice is for patients to be asked if they want to disclose their name and any other information that the community provider will need for a warm handoff. An individual could then determine what information, even if limited to their name, they want to be disclosed. Please note that in medical emergencies, 42 CFR 2.51 allows disclosure to medical personnel even without patient consent.

**Q5. How do federal privacy laws address the release of a child’s behavioral health record from one provider to another provider without parental signature?**

**A.** HIPAA regulations generally allow sharing patient behavioral health information, excluding psychotherapy notes, between providers when medically appropriate, regardless of the patient’s age. See 45 CFR 164.506, 164.508. For more information regarding exchange of information between providers, see Health and Human Service’s fact sheet, “Permitted Uses and Disclosures: Exchange for Treatment,” at https://www.hhs.gov/sites/default/files/exchange_treatment.pdf.

Part 2, however, sets out more restrictive consent requirements for sharing a minor’s substance use disorder records; applicability will vary depending on the circumstances. For more information regarding part 2 consent requirements for minors, please see 42 CFR 2.14; 2.31.
Q6. Is telehealth (two-way audio and video communications on a secure line) allowable under HIPAA or 42 CFR part 2?

A. Yes. HIPAA and part 2 do not specifically address telehealth. However, they set out data exchange requirements that apply when protected information is transmitted, including via telehealth. For example, the HIPAA regulation at 45 CFR 164.306(a)(1)–(3) states that covered entities and business associates must “ensure the confidentiality, integrity, and availability of all electronic protected health information,” and protect the information from threats, hazards and unauthorized access. The HIPAA regulations require technical security measures to guard against unauthorized access to electronic information being transmitted over an electronic communications network (45 CFR 164.312(e)). HIPAA regulations also require specific administrative safeguards (45 CFR 164.308) and address the issue of encrypting transmitted information (45 CFR 164.312(e)(2)(ii); 45 CFR 164.306(d)(3)(ii)(B)(1)-(2)).

42 CFR part 2 also requires subject programs to “have in place formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information and to protect against reasonably anticipated threats or hazards to the security of patient identifying information” (42 CFR 2.16(a)). These policies and procedures must address electronic records, including creating, receiving, maintaining and transmitting such records (42 CFR 2.16(a)(2)(i)). Thus, both HIPAA and 42 CFR part 2 impose standards that require data transmission, including by telehealth, to be protected from unauthorized access. Behavioral health providers should pursue ways to ensure confidentiality and security so telehealth approaches are available and in use; this especially applies when face-to-face meetings are necessary or required but in-person meetings are not possible due to distance, time, transportation or other barriers.

HIPAA

Q7. What are examples of permitted disclosures of protected health information under HIPAA that do not require individual consent?

A. HIPAA generally permits covered entities to disclose protected health information without patient consent for purposes such as:

- The treatment activities of a health care provider (45 CFR 164.506(c)),
- Payment activities of the covered entity that is receiving the information (45 CFR 164.506(c)(3)), or
• Health care operation activities of the covered entity that is receiving the information, if each covered entity either has or had a relationship with the subject of the protected health information (PHI) being disclosed, the PHI pertains to such relationship, and the disclosure is for one of the allowable purposes (for example, fraud and abuse detection or compliance, quality assessment and improvement activities, patient safety activities, case management or care coordination). See 45 CFR 164.501 (list of health care operation activities) and 164.506.

Please note that, even in situations where HIPAA permits disclosure, 42 CFR part 2 protections may still be more restrictive.

Q8. What public interest and benefit activities are permitted disclosures under HIPAA?

A. HIPAA’s privacy rule permits use or disclosure of protected health information without an individual’s authorization or permission under certain circumstances, including for public interest and benefit activities. See 45 CFR 164.508, 164.512. Public interest and benefit activities include disclosures for the following: (1) as required by law; (2) for public health activities; (3) to assist victims of abuse, neglect and domestic violence; (4) for health oversight activities; (5) for judicial and administrative proceedings; (6) for law enforcement purposes; (7) to make necessary disclosures to coroners, medical examiners and funeral directors regarding decedents; (8) to facilitate cadaveric organ, eye and tissue donation; (9) for research purposes; (10) to avert a serious threat to health or safety; (11) for specialized government functions (military, national security, etc.); and (12) for workers’ compensation or similar programs. See 45 CFR 164.512.

For more information, see HHS’s “Summary of the HIPAA Privacy Rule,” available at https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html (last reviewed on July 26, 2013).

Q9. How do psychotherapy notes differ from service/progress notes (that document the content of the service provided)?

A. The HIPAA Privacy Rule defines psychotherapy notes specifically as “notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual’s medical record.” The definition of psychotherapy notes expressly excludes specific types of information that might otherwise be included in service/progress notes, including “medication prescription
and monitoring, counseling session start and stop times, the modalities and
frequencies of treatment furnished, results of clinical tests, and any summary of
the following items: Diagnosis, functional status, the treatment plan, symptoms,
prognosis, and progress to date.” See 45 CFR 164.501. Note that ORS 179.505 also
defines psychotherapy notes for purposes of ORS 179.505. Psychotherapy notes are
stored separately from service/progress notes to maintain their privacy and specific
protections from disclosure.

Q10. Why are psychotherapy notes treated differently from other mental health
information?

A. According to HHS, “Psychotherapy notes are treated differently from other mental
health information both because they contain particularly sensitive information and
because they are the personal notes of the therapist that typically are not required or
useful for treatment, payment, or health care operations purposes, other than by the
mental health professional who created the notes.”

See “Does HIPAA provide extra protections for mental health information
compared with other health information?” available at https://www.hhs.gov/hipaa/
for-professionals/faq/2088/does-hipaa-provide-extra-protections-mental-health-
information-compared-other-health.html (last reviewed Sept. 12, 2017).

Q11. If the patient’s family is present, does the patient need to provide written
consent, or would verbal consent suffice?

A. 45 CFR 164.510 states, in part:

“A covered entity may use or disclose protected health information, provided that the
individual is informed in advance of the use or disclosure and has the opportunity to
agree to or prohibit or restrict the use or disclosure, in accordance with the applicable
requirements of this section. The covered entity may orally inform the individual of and
obtain the individual’s oral agreement or objection to a use or disclosure permitted by this
section.” (Emphasis added.)

For more information, see “Does the HIPAA Privacy Rule permit a doctor to discuss
a patient’s health status, treatment, or payment arrangements with the patient’s family
and friends?” available at https://www.hhs.gov/hipaa/for-professionals/faq/488/does-
hipaa-permit-a-doctor-to-discuss-a-patients-health-status-with-the-patients-family-
and-friends/index.html (last reviewed on July 26, 2013).

Please note that even when HIPAA permits disclosure, 42 CFR part 2 may still be
more restrictive.
**Q12. What is a federally assisted drug use program?**

**A.** Under part 2, a program is defined as:

- An individual or entity (other than a general medical facility) that holds itself out as providing and does provide drug/alcohol diagnosis, treatment or referral for treatment (for example, freestanding drug and alcohol treatment program, PCPs who provide drug and alcohol services as their principal practice);
- An identified unit within a general medical facility that holds itself out as providing and does provide drug and alcohol diagnosis, treatment or referral for treatment (for example, detox unit, inpatient or outpatient drug and alcohol program within a general medical facility); or
- Medical personnel or other staff in a general medical care facility whose primary function is providing drug and alcohol diagnosis, treatment or referral for treatment, and who are identified as such (for example, addiction specialist working in a primary care practice). See 42 CFR 2.11.

A program is federally assisted if:

- Any U.S. department or agency conducts it in whole or in part, directly or by contract, or
- It is carried out under a license, registration, certification or other authorization that any U.S. department or agency (for example, Medicare) grants, or
- Funds from any U.S. department or agency support it, or
- It receives assistance from the IRS through tax deductions or exemptions. See 42 CFR 2.12(b).

For additional information, see Question/Answer 2 in SAMHSA’s “Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE),” at [https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf](https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf).
Q13. Under part 2, what disclosures are permitted with a patient’s written consent?

A. The current version of 42 CFR 2.33 (Jan. 3, 2018), states:

(a) If a patient consents to a disclosure of their records under 2.31, a part 2 program may disclose those records in accordance with that consent to any person or category of persons identified or generally designated in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of 2.34 and 2.35, respectively.

(b) If a patient consents to a disclosure of their records under 2.31 for payment and/or health care operations activities, a lawful holder who receives such records under the terms of the written consent may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or health care operations on behalf of such lawful holder. Disclosures to contractors, subcontractors, and legal representatives to carry out other purposes such as substance use disorder patient diagnosis, treatment, or referral for treatment are not permitted under this section. In accordance with 2.13(a), disclosures under this section must be limited to that information which is necessary to carry out the stated purpose of the disclosure.

(c) Lawful holders who wish to disclose patient identifying information pursuant to paragraph (b) of this section must have in place a written contract or comparable legal instrument with the contractor or voluntary legal representative, which provides that the contractor, subcontractor, or voluntary legal representative is fully bound by the provisions of part 2 upon receipt of the patient identifying information. In making any such disclosures, the lawful holder must furnish such recipients with the notice required under 2.32; require such recipients to implement appropriate safeguards to prevent unauthorized uses and disclosures; and require such recipients to report any unauthorized uses, disclosures, or breaches of patient identifying information to the lawful holder. The lawful holder may only disclose information to the contractor or subcontractor or voluntary legal representative that is necessary for the contractor or subcontractor or voluntary legal representative to perform its duties under the contract or comparable legal instrument. Contracts may not permit a contractor or subcontractor or voluntary legal representative to re-disclose information to a third party unless that third party is a contract agent of the contractor or subcontractor, helping them provide services described in the contract, and only as long as the agent only further discloses the information back to the contractor or lawful holder from which the information originated.
Q14. Does part 2 require written consent from a patient for a provider to verify insurance benefits for a patient’s treatment (that is, disclosure to a third-party payer)?

A. Yes, part 2 states that any information disclosed that identifies an individual, directly or indirectly, as having a current or past alcohol or drug problem is subject to part 2 protections and requires written consent (on paper or electronic). See 42 CFR 2.12(a); 2.31; 2.33.

Q15. When a disclosure does not seem to violate HIPAA, but does violate the stricter requirement of 42 CFR part 2, what are the disclosure requirements for the covered entity?

A. Federal guidance states that:

A health provider that provides treatment for substance use disorders, including opioid abuse, needs to determine whether it is subject to 42 CFR part 2 (that is, a “part 2 program”) and whether it is a covered entity under HIPAA. Generally, the part 2 rules provide more stringent privacy protections than HIPAA, including in emergency situations. If an entity is subject to both part 2 and HIPAA, it is responsible for complying with the more protective part 2 rules, as well as with HIPAA. HIPAA is intended to be a set of minimum federal privacy standards, so it generally is possible to comply with HIPAA and other laws, such as 42 CFR part 2, that are more protective of individuals’ privacy.


Q16. What part 2 notice requirements prohibit redisclosure of information?

A. 42 CFR 2.32(a) states that any disclosure made with a patient’s consent must be accompanied by one of two regulatory notices:

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

(2) 42 CFR part 2 prohibits unauthorized disclosure of these records.

SAMHSA has indicated that the second (abbreviated) notice was designed to fit in standard health care electronic systems, which often have an 80-character limit. However, SAMHSA states the abbreviated notice can be used in any instance requiring a notice. For more information, see 83 Fed. Reg. 240 (Jan. 3, 2018), at https://www.govinfo.gov/content/pkg/FR-2018-01-03/pdf/2017-28400.pdf.

Q17. Does part 2 allow disclosing substance use disorder patient records received from other agencies or providers?

A. Generally no, unless the disclosure occurs within one of the permitted disclosures under 42 CFR 2, such as a further disclosure with the individual’s consent, a valid court order or a part 2 compliant agreement under 42 CFR 2.11 (qualified service organization).

Q18. Does part 2 allow disclosing substance use disorder patient records received from other agencies or providers?

A. Generally, a part 2 provider is any provider that meets the definition of “program” and is federally assisted (see question 12). As SAMHSA states:

Today, many patients receive treatment for an SUD in a primary care or integrated care setting. These settings may provide both behavioral and physical health services, and individual providers may address all of a patient’s behavioral or physical health needs. Depending on its particular characteristics, an integrated care setting may not have a part 2 program even if it provides some services for the diagnosis, treatment, or referral for treatment of an SUD.

**Q19.** Under part 2, is a minor’s consent needed for a parent to request the minor’s substance use disorder treatment records?

**A.** Generally yes, but the answer to this question can vary depending on several factors. To determine whether consent is needed, see 42 CFR 2.14, which outlines part 2 consent requirements for minor patients.

In Oregon, minors aged 14 and older generally may obtain treatment for a substance use disorder without parental consent. See ORS 109.675 for detail. Substance use disorder treatment records of a minor aged 14 or older generally cannot be disclosed without the minor’s consent for the release of their records (42 CFR 2.14(a)). Regarding the substance use disorder records of minors under age 14, both parental consent and the minor’s consent are generally required to release the minor’s substance use disorder treatment records (42 CFR 2.14(b)). In both cases, there may be exceptions in certain circumstances (see ORS 109.675, ORS 109.680, and 42 CFR 2.14).


**Oregon law**

**Q20.** How are providers applying the “shall disclose” language in the Oregon Revised Statutes (for example, ORS 192.561 and ORS 414.607) when the general rule for dealing with conflict between privacy laws is to accept the more restrictive law?

**A.** In general, the use of the word “shall” implies an obligation or requirement to disclose if certain applicable conditions noted in the rule or statute are met. However, use of the word “shall” does not necessarily determine a provider’s obligations. Ultimately, when determining whether disclosure is permitted or required under the Oregon Revised Statutes, a covered entity must consider all applicable state and federal laws.

**Q21.** Can a substance use treatment facility share identified patients’ admit and discharge date information with the CCO for billing purposes?

**A.** Part 2 rules state that any disclosed information that directly or indirectly identifies an individual as having a current or past substance use disorder is subject to part 2 protections. See question 13, “Under part 2, what disclosures are permitted with a patient’s written consent.”
Health information technology

**Q22. What is Consent2Share?**

**A.** Consent2Share (C2S) is an open source software application sponsored by SAMHSA. C2S is designed to support consent management, data segmentation and health information integration with existing health information exchange (HIE) systems and electronic health records (EHR). The application manages patient consent and segments data that is subject to privacy protections, such as part 2 information. Consent2Share is an option available to entities interested in managing consent and segmenting data within their electronic health records and health information exchange systems. The application is designed to give patients a meaningful choice about what behavioral health information to share with providers.

For more information about C2S, visit [https://bhits.github.io/consent2share/](https://bhits.github.io/consent2share/). You can also listen to an informative webinar sponsored by SAMHSA, available at [https://www.youtube.com/watch?v=WxM3CwAQdXo](https://www.youtube.com/watch?v=WxM3CwAQdXo).

**Q23. Is C2S provided in multiple languages, and are there options for visually impaired patients?**

**A.** As of January 2019, C2S is supported in English and Spanish. There is no information on whether C2S will be available in other languages or if there are options for visually impaired patients.

**Q24. Can C2S be accessed at home from a PC, or would portals be accessible in clinics?**

**A.** To use C2S, patients will need access to any computer or tablet and an email address to create a C2S account. Providers will likely need staff to teach patients how to initially set up and use their C2S account.


**Q25. Is there guidance on how to use C2S?**

**A.** Yes. C2S has four different types of user interfaces: master, provider, staff and patient. SAMHSA has produced user interface guides for the four different types of users. For the most recent versions of those guides, please visit [https://bhits.github.io/consent2share/documentation/userGuides.html](https://bhits.github.io/consent2share/documentation/userGuides.html).

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This tool kit is not legal advice. It is not a substitute for reviewing the law or consulting an attorney.
Q26. How can providers begin to implement Consent2Share?

A. Consent2Share is available for free in its current form online at GitHub (version 3.5.0). For technical guidance on C2S and access to the software application, visit https://bhits.github.io/consent2share/.

SAMHSA has also created an instructional video on how to download, install and run Consent2Share, which is available online at https://www.youtube.com/watch?v=fqLJlx0MS0.

Q27. Where has the SAMHSA Consent2Share application been implemented?

A. Several programs have successfully implemented the Consent2Share platform. SAMHSA funded some of these programs. For example, SAMHSA sponsored pilot projects with the Prince George's County Health Department and Arizona's Health-e Connection. Seattle, Washington has also begun implementing the program.

For more information about programs that have adopted C2S, visit https://www.feisystems.com/solutions/behavioral-health/consent2share/.

Exemptions and exceptions to part 2 regulations

Q28. When can a part 2 provider disclose medical records without patient consent?

A. Part 2 permits the disclosure of patient information without written patient consent under certain circumstances; that is, exempts in certain circumstances from the part 2 written consent requirement. This includes the following circumstances:

• Medical emergencies, see 42 CFR 2.51.
• Research purposes, see 42 CFR 2.52.
• Audits and evaluations, see 42 CFR 2.53.

Please note that under some circumstances, such as court-ordered disclosures, 42 CFR part 2 may not apply at all. See question 30, “What are the requirements for court-ordered disclosures?”.

Q29. Are there circumstances where the restrictions of 42 CFR part 2 do not apply even though a part 2 provider has the information identifying a patient as having or having had a substance use disorder?
A. Yes. 42 CFR 2.12 expressly provides the following exceptions to the applicability of part 2 regulations:

(1) **Department of Veterans Affairs.** These regulations do not apply to information on substance use disorder patients maintained in connection with the Department of Veterans Affairs’ provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38, U.S.C. Those records are governed by 38 U.S.C. 7332 and regulations issued under that authority by the Secretary of Veterans Affairs.

(2) **Armed Forces.** The regulations in this part apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

   (i) Any interchange of that information within the Armed Forces; and
   (ii) Any interchange of that information between the Armed Forces and those components of the Department of Veterans Affairs furnishing health care to veterans.

(3) **Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program.** The restrictions on disclosure in the regulations in this part do not apply to communications of information between or 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 with substance use disorders if the communications are:

   (i) Within a part 2 program; or
   (ii) Between a part 2 program and an entity that has direct administrative control over the program.

(4) **Qualified service organizations.** The restrictions on disclosure in the regulations in this part do not apply to communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program.

(5) **Crimes on part 2 program premises or against part 2 program personnel.** The restrictions on disclosure and use in the regulations in this part do not apply to communications from part 2 program personnel to law enforcement agencies or officials which:

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This tool kit is not legal advice. It is not a substitute for reviewing the law or consulting an attorney.
(i) Are directly related to a patient’s commission of a crime on the premises of the part 2 program or against part 2 program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual’s name and address, and that individual’s last known whereabouts.

(6) **Reports of suspected child abuse and neglect.** The restrictions on disclosure and use in the regulations in this part do not apply to the reporting under state law of incidents of suspected child abuse and neglect to the appropriate state or local authorities. However, the restrictions continue to apply to the original substance use disorder patient records maintained by the part 2 program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect.

**Q30. What are the requirements for court-ordered disclosures?**

**A.** The requirements for court-ordered disclosures differ depending on the purpose and use of the records. Those requirements are outlined in 42 CFR subparts E: 2.64 (noncriminal purposes), 2.65 (criminal investigation or prosecution), 2.66 (investigation or prosecution of a part 2 program or record holder), and 2.67 (investigation of part 2 program employees or agents in connection with criminal matter).

Part 2 summarizes the legal effect of a court order entered under subpart E as follows:

**42 CFR 2.61**

(a) Effect. An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information that would otherwise be prohibited by 42 U.S.C. 290dd–2 and the regulations in this part. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under the regulations in this part.

(b) Examples.

(1) A person holding records subject to the regulations in this part receives a subpoena for those records. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under the regulations in this part.
(2) An authorizing court order is entered under the regulations in this part, but the person holding the records does not want to make the disclosure. If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person holding the records must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of the regulations in this part.

Consents and qualified service organization agreements (QSOAs)

Q31. To provide a valid written consent under part 2, does the individual need to designate a specific named person to receive the information, or is it enough to designate an entity such as a hospital or insurance company?

A. It depends on who is receiving the information and whether they have a treating provider relationship with the individual. See 42 CFR 2.31. On Jan. 18, 2017, the Federal Register published the following table summarizing who must be designated in a valid consent.

Table 1: Designating Individuals and Organizations in the “To Whom” Section of the Consent Form

<table>
<thead>
<tr>
<th>42 CFR 2.31</th>
<th>Individual or entity to whom disclosure is to be made</th>
<th>Treating provider relationship with patient whose information is being disclosed</th>
<th>Primary designation</th>
<th>Required additional designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)(4)(i)</td>
<td>Individual</td>
<td>Yes</td>
<td>Name of individual(s) (e.g., Jane Doe, MD)</td>
<td>None</td>
</tr>
<tr>
<td>(a)(4)(i)</td>
<td>Individual</td>
<td>No</td>
<td>Name of individual(s) (e.g., John Doe)</td>
<td>None</td>
</tr>
<tr>
<td>(a)(4)(ii)</td>
<td>Entity</td>
<td>Yes</td>
<td>Name of entity (e.g., Lakeview County Hospital)</td>
<td>None</td>
</tr>
<tr>
<td>(a)(4)(iii)(A)</td>
<td>Entity</td>
<td>No</td>
<td>Name of entity that is a third-party payer as specified under 2.31(a)(4)(iii)(A) (e.g., Medicare)</td>
<td>None</td>
</tr>
</tbody>
</table>
Q32. What is a qualified service organization (QSO)?

A. Under 42 CFR 2.11, a qualified service organization means an individual or entity that:

(1) Provides services to a part 2 program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

(2) Has entered into a written agreement with a part 2 program under which that individual or entity:

   (i) Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is fully bound by the regulations in this part; and

   (ii) If necessary, will 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 the regulations in this part.

Note that, “The restrictions on disclosure in the [part 2 regulations] do not apply to communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program” (see 42 CFR 2.12).

Q33. Can a behavioral health provider (specifically a substance use treatment provider) communicate patient information with CCOs?

A. The answer to this question would depend on the circumstances presented. Possible factors might include the purpose of the communication, whether the CCO qualifies as a QSO, whether the patient has or is willing to provide written consent, or whether the circumstances presented fall under one of the recognized exemptions or exceptions under part 2. Please note the answer to question 13 regarding consent for payment and health care operations activities.
Q34. Why is a qualified service organization agreement (QSOA) needed between providers if HIPAA allows the sharing of treatment information?

A. Although HIPAA regulations might allow the sharing of some patient behavioral health information among providers for care coordination, treatment, payment or health care operations, 42 CFR part 2 is more restrictive and prohibits provider-to-provider sharing of any substance use disorder records without specific authorization, such as written consent or a QSOA. Please note that part 2 does not allow a QSOA to be used to authorize disclosures among providers for the purposes of treatment without the individual’s written consent.

Q35. When a consent references a specific recipient’s name (for example, their primary care provider), does this cover release to that person’s office?

A. It depends. In general, “[i]f a patient consents to a disclosure of their records under 42 CFR 2.31, a part 2 program may disclose those records in accordance with that consent to any person or category of persons identified or generally designated in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of 2.34 and 2.35, respectively” (42 CFR 2.33(a)). Therefore, whether a consent form covers the specific recipient’s office may depend on how the consent form designates the recipient(s). Please see the table within question 31 regarding the designation of entities versus individuals.

Note, however, that 42 CFR 2.12(3) provides the following exception:

Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program.

The restrictions on disclosure in the regulations in this part do not apply to communications of information between or 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 with substance use disorders if the communications are:

(i) Within a part 2 program; or

(ii) Between a part 2 program and an entity that has direct administrative control over the program.
Q36. When completing a consent form, is it enough for a patient to check the box for disclosure of substance abuse records and have the client sign the form?

A. No. 42 CFR 2.31(a) details information that a valid written consent form must include. For instance, “[h]ow much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed” (42 CFR 2.31(a)(3)).

Q37. Can a blank consent form be emailed to a client and then faxed back to the provider once completed?

A. The part 2 regulations do not specifically address faxed consent forms. However, 42 CFR 2.31(a) states that “written consent to a disclosure under the regulations in this part may be paper or electronic.” Part 2 also allows for electronic signatures “to the extent that they are not prohibited by any applicable law” (42 CFR 2.31(a)(8)).

Q38. Do the sample forms contained in this tool kit apply to releasing information on children under age 14?

A. The sample forms are not specifically designated for any age group, but the required signatories to the sample forms might be different depending on the age of the patient whose information is to be disclosed. Because Oregon law generally allows minors who are age 14 years or older to obtain chemical dependency diagnoses and treatment without parental knowledge or consent (ORS 109.675), 42 CFR 2.14(a) generally requires only the patient’s consent to disclose their information when they are age 14 or older.

That means if the patient is age 14 or older, the parents’ consent to disclosure is not necessary or sufficient to authorize disclosure of the minor’s information under part 2. However, for minors under the age of 14, 42 CFR 2.14(b) generally requires both the patient and parent’s consent to authorize the disclosure of the minor’s information.
Q39. If an individual has signed a consent form to authorize their provider to disclose their SUD treatment records “for payment and health care operations activities,” what activities do “payment and health care operations activities” include?

A. SAMHSA addressed this in the Federal Register on Jan. 3, 2018: “Examples of permissible activities under 42 CFR 2.33(b) that SAMHSA considers to be payment and health care operations activities include:

- Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- Clinical professional support services (for example, quality assessment and improvement initiatives; utilization review and management services);
- Patient safety activities;
- Activities pertaining to:
  » The training of student trainees and health care professionals;
  » The assessment of practitioner competencies;
  » The assessment of provider and/or health plan performance; and
  » Training of non-health care professionals;
- Accreditation, certification, licensing, or credentialing activities;
- Underwriting, enrollment, premium rating, and other activities related 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 claims for health care;
- Third-party liability coverage;
- Activities related to addressing fraud, waste and abuse;
- Conducting or arranging for medical review, legal services, and auditing functions;
- 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;
- 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;
• Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
• Resolution of internal grievances;
• The sale, transfer, merger, consolidation, or dissolution of an organization;
• Determinations of eligibility or coverage (for example, coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
• Risk adjusting amounts due based on enrollee health status and demographic characteristics; and
• Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.”

“Payment and health care operations activities” do not include substance use disorder patient diagnosis, treatment, referral for treatment, care coordination, or case management. See 42 CFR 2.33(b) and 83 Fed Reg 239 (Jan. 3, 2018).

Q40. Are the sample consent forms in this tool kit mandatory?

A. No, it is not mandatory for providers to use these sample forms. These are examples only. If you are using a consent form to obtain information from OHA, using OHA’s own forms may help the process; however, it is not required.

Q41. Can we modify the language, wording and/or phrasing from those used in the sample forms to better serve the needs of a low literacy population?

A. These sample consent forms are provided as a courtesy and are not mandatory. Nothing prevents you from preparing your own consent forms and consulting your own legal counsel regarding your obligations as appropriate.

Q42. Why did a CCO tell me that it could share mental health information without a valid consent form under some circumstances, but not share substance use disorder information unless an explicit consent form authorizes the disclosure?

A. Different legal restrictions apply to different types of information. In this example, the CCO may be referring to 42 CFR part 2, which sets stringent protective requirements for substance use disorder treatment records but not for mental health records.
Q43. Can the consent forms be signed electronically?

A. Yes, they can, unless prohibited by another law. Electronic signatures are authorized by 42 CFR 2.31(a)(8). HIPAA regulations do not specifically address electronic signatures for release forms, but the federal HHS website addresses that: “In the absence of specific standards [for electronic signatures], covered entities must ensure any electronic signature used will result in a legally binding contract under applicable State or other law.” Source: https://www.hhs.gov/hipaa/for-professionals/faq/247/are-business-associate-contracts-in-electronic-form-acceptable/index.html.

Q44. Who is responsible for setting up qualified service organization agreements (QSOAs)?

A. A part 2 program, or lawful holder of information that is subject to part 2, is responsible for ensuring its compliance with law and using qualified service organization agreements when needed. A part 2 program and an individual or entity that qualifies as a QSO under 42 CFR 2.11 can directly set up a qualified service organization agreement with each other. The state is generally not responsible for setting up such agreements when it is not a party to the agreement.

A sample QSOA that can be used by part 2 programs is in the “Sample common consent form and instructions” section.

Q45. What is the difference between a business associate agreement (BAA) and a QSOA?

A. QSOAs under part 2 and business associate agreements under 164.314(a) and 164.504(e) of the HIPAA Security and Privacy Rules have some similarities in that they can facilitate information disclosure between a part 2 program and an organization that provides services to the program, including health information exchanges (HIEs). However, there are important differences. BAAs apply to third-party organizations serving covered entities under HIPAA; QSOAs apply to third-party organizations that serve substance use programs covered under 42 CFR part 2. If a program is both a HIPAA-covered entity and a 42 CFR part 2 program, agreements with the third-party organization may need to meet the requirements of both a BAA and a QSOA. The BAA and QSOA vary in their required provisions. Nothing prohibits entities from combining a BAA and QSOA into a single agreement.
A “business associate” under HIPAA “is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity’s workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity.” See “Business Associates,” available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html. For a complete definition, see 45 CFR 160.103.

HIPAA set outs a comprehensive list of requirements for BA agreements under 45 CFR 164.504(e). Those requirements include, for example, that the business associate (BA) report to the covered entity whenever it is aware of any unauthorized use or disclosure of protected information. The BA must return or destroy all protected health information when the agreement terminates.


The terms of a QSOA are set out in part 2. For instance, under part 2, the QSOA must require that the entity acknowledge it is bound by part 2 regulations when receiving patient records from a part 2 program. The receiving entity must resist judicial proceedings to obtain access to patient records except as permitted by part 2. See 42 CFR 2.11.

Q46. Who retains information in QSOAs?

A. Under a QSOA, the part 2 provider/entity would share the necessary information as defined in the QSOA with the qualified service organization (QSO). The terms of the agreement may describe more specifically which entity could receive, store, process or deal with patient records. Both parties to the QSOA are bound by all part 2 regulations. See 42 CFR 2.11.
Q47. Are QSOA agreements needed to share patient information between different parts of the same organization?

A. Communication within two parts of the same program or between two entities with common administrative control is permissible under 42 CFR 2.12(c)(3) without a QSOA, provided the communication occurs only between or among personnel having a need for the information in connection with duties arising out of the provision of diagnosis, treatment or referral for treatment. For disclosures beyond what is permissible under 42 CFR 2.12(c)(3), one needs some other authority to disclose substance use disorder treatment information, such as the patient’s consent or other provision of part 2.

Q48. Under part 2, can a client really revoke authorization to communicate with a primary care provider if that communication is part of treatment?

A. As indicated under the written consent requirements, “the consent is subject to revocation at any time except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer.” See 42 CFR 2.31(a)(6).

Section 2.31(b) expressly states that a “disclosure may not be made on the basis of a consent” that is “known to have been revoked.”

Q49. Why isn’t the QSOA exception, with its reference to medical services, used to address most information-sharing obstacles?

A. The QSOA exemption would not resolve most challenges related to information sharing because it is contingent on a particular relationship between the part 2 program and the QSO. The exemption can only be used if a person or organization is providing a service to a part 2 program (for example, data processing; bill collecting; dosage preparation; lab analyses; or legal, medical, accounting or other professional services). In many instances, the recipient entity and the part 2 program will not have that specific relationship.
Q50. Can a part 2 program contract with a QSO for a service whereby the QSO discloses specific information to other providers (PCP, hospital) or CCOs for care coordination purposes (that is, the service provided is not only sharing information to/from the substance use disorder [SUD] program itself, but to share information on behalf of the SUD to other providers/CCOs)?

A. As SAMHSA explains:

A QSOA is a two-way agreement between a part 2 program and the entity providing the service . . . The QSOA authorizes communication between those two parties; however, the 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 redisclose 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 more information, see “Applying the Substance Abuse Confidentiality Regulations,” at https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs (last updated May 1, 2018).
Examples of allowable sharing

Reliance eHealth Collaborative developed a legal use case matrix based on information available in 2017. It is available at [http://reliancehie.org/wp-content/uploads/2017/08/Reliance-Legal-Use-Case-Matrix-1-6-15-FINAL.xlsx](http://reliancehie.org/wp-content/uploads/2017/08/Reliance-Legal-Use-Case-Matrix-1-6-15-FINAL.xlsx). It is not intended to serve as legal advice to other organizations or agencies. A grant from the Office of the National Coordinator for Health IT (ONC) (#90IX0007/01-00) funded this work.

The matrix includes examples of allowable sharing of protected information. The examples consider elements of the analysis such as the information type to be disclosed; disclosing party; recipient of information; purpose for information sharing; and if disclosure and re-disclosure are permitted.

When reviewing these use cases, bear in mind the exceptions to 42 CFR part 2. Exceptions can include, for instance:

- Veterans’ Affairs/armed forces
- Program or administrative entity personnel
- Qualified service organizations
- Child abuse
- Medical emergencies
- Personal representatives
- Audit and evaluation
- Direct administrative control

Please note that these examples may encompass some of the common uses and types of disclosures, but they are not comprehensive and are not a substitute for a case-by-case application of law to each disclosure.

Links to Oregon Revised Statutes and Code of Federal Regulation (CFR) 42 part 2, referenced in the charts:

- 42 CFR part 2 [http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2](http://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2)

This tool kit is not legal advice. It is not a substitute for reviewing the law or consulting an attorney.
Sample common consent form and instructions

You may access the “Authorization for Disclosure, Sharing and Use of Individual Information” through DHS/OHA Publications and Forms:

1. Go to https://sharedsystems.dhsoha.state.or.us/forms/.
2. In the form number field, type 3010.
3. Click the “Search” button.
4. Select the language you want, then click on the text link “Click to view the highlighted document.”
5. If the PDF does not show correctly in your browser, download it from the browser window and save it to your computer. Open it from the folder where you saved it.

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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 treatment information between a part 2 provider and a qualified service organization. Sample QSOA language is on page 36.

HIPAA generally permits protected health information disclosure without patient consent for treatment, payment or health care operations. However, 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:

(a) Provides services to a part 2 program (an individual or entity that is federally assisted and holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment), such as 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, and

(b) Has entered into a written agreement with a part 2 program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

QSOAs under part 2 are similar to a business associate agreement under 164.314(a) and 164.504(e) of the HIPAA Security and Privacy Rules. 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 health information exchanges (HIEs). (1)
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 at: https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf. (2)

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.
Sample qualified service organization agreement language

42 CFR 2.11 requires specific acknowledgements to be contained in a qualified service organization agreement. Following is sample language for a qualified service organization agreement.

This is an agreement between ________ (“the service entity”) and ________ (“the program”). The service entity will be providing the following qualified services to the program: ___________________________. To provide these services, the service entity acknowledges it will receive, store, process or otherwise deal with patient records from the program.

• Service entity acknowledges that — in receiving, storing, processing or otherwise dealing with any patient records from the program — it is fully bound by 42 CFR part 2 and, if necessary, shall 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 the regulations in 42 CFR part 2.

• In compliance with 42 CFR part 2, the program allows the service entity to access, receive, store, process or otherwise deal with patient records from the program while providing services to the Program under this agreement.

________________________________________ Date: _________________
Signature of service entity

________________________________________ Date: _________________
Signature of the program

This tool kit is not legal advice. It is not a substitute for reviewing the law or consulting an attorney.
Endnotes


Other resources

Electronic Code of Federal Regulations:  
https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=42%3A1.0.1.1.2

Federal Register:  
• (Jan. 18, 2017)  

• (Jan. 3, 2018)  

SAMHSA fact sheets regarding substance abuse confidentiality regulations:  
https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs

Oregon Department of Justice Confidentiality Guidance:  
https://justice.oregon.gov/ConfidentialityGuide/

Office of Health Information Technology:  
https://www.oregon.gov/oha/HPA/OHIT/Pages/index.aspx

OHA’s Minor Rights: Access and Consent to Health Care:  

Information on H.R. 6 (2018):  

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