Frequently Asked Questions

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Applying the Substance Abuse Confidentiality Regulations (42 CFR Part 2) to OCHIN Members
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PURPOSE
The federal alcohol and substance abuse confidentiality regulations (42 CFR Part 2) apply only to certain programs and related health information. Questions about the scope of these regulations, and the manner in which they intersect with HIPAA, have arisen with increasing frequency among OCHIN members. The purpose of this document is to provide an overview of these frequently asked questions generated by OCHIN members in relation to the 42 CFR Part 2 regulations. This document is intended to supplement, but not replace, the review and analysis that each OCHIN member must engage in to ensure compliance with applicable law.

FREQUENTLY ASKED QUESTIONS

Q. Do the 42 CFR Part 2 regulations apply to all medical records containing a reference to substance abuse treatment activity?

No. The 42 CFR Part 2 regulations apply only to federally assisted alcohol and substance abuse treatment “programs” defined in the regulations as follows:

A. An individual or entity (other than a general medical care facility) which holds itself out as providing, and provides alcohol or substance abuse diagnosis, treatment or referral for treatment; or

B. An identified unit within a general medical facility which holds itself out as providing, and provides alcohol or substance abuse diagnosis, treatment or referral for treatment; or

C. Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or substance abuse diagnosis, treatment or referral for treatment and who are identified as such providers.

Although the test for “federal assistance” is fairly broad, the regulations establish narrow criteria that apply to meeting the definition of a program. Taking these criteria together, the determination of whether 42 CFR Part 2 applies requires an examination of at least the following three questions: (1) Is the provider a “general medical care facility”? (2) Even if it is a “general medical care facility” is the provider an identified unit within the facility that “holds itself out” to the public as providing substance abuse treatment services? (3) Does the provider consist of medical personnel whose “primary function” is the provision of alcohol or drug abuse treatment and who are identified as such providers.

Q. Are all records related to screening, brief intervention and referral to treatment (SBIRT) services governed by the 42 CFR Part 2 regulations?

No. Records related to SBIRT services would not fall under the 42 CFR Part 2 regulations unless the individual or entity providing the services holds itself out as an alcohol or substance abuse treatment provider. Although the regulations do not contain a specific definition of what it means for a provider to “hold itself out” as providing substance abuse treatment services, SAMHSA noted the following as factors to consider: licensure under state law to provide drug and alcohol counseling or treatment services; advertising or posting of notices in the offices; certifications in addition medicine; listing in registries; Internet statements; consultation activities for non-“program” practitioners; evidence of substance abuse treatment program information being provided to patients and/or their families. Even if the 42 CFR Part 2 regulations do not apply, it is important to note that HIPAA and/or state laws will apply to all treatment records.

Q. Do all primary care providers who prescribe controlled substances to treat substance abuse meet the definition of a “program” under the regulations?
No. Primary care providers who prescribe controlled substances to treat patients with substance use disorders do not necessarily meet the definition of a “program” under 42 CFR Part 2 even though they have a DEA license and are therefore federally assisted. To be considered a program, the provider must hold themselves out as primarily providing, and actually provide alcohol or substance abuse diagnosis, treatment or referral for treatment. If the provider works in a general health care facility, which includes a group practice, the provider would also need to work in a unit that is primarily identified as providing alcohol or substance abuse treatment.

**Q. Would records related to the referral of a patient for treatment in an overdose situation fall within the scope of 42 CFR Part 2?**

No. Simply making a referral for some type of substance abuse treatment does not rise to the level of meeting the required element of an entity “holding itself out” as providing substance abuse treatment. The Substance Abuse and Mental Health Services Administration (“SAMHSA”) reinforced this conclusion by clarifying that the 42 CFR Part 2 regulations would not apply to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or substance abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

**Q. What does it mean for a program to be “federally assisted”?**

To be a Program that falls under 42 CFR Part 2, an individual or entity must be federally assisted and hold itself out as providing, and actually provide alcohol or substance abuse diagnosis, treatment or referral for treatment. Federally assisted programs:

1. Are authorized, licensed, certified, or registered by the Federal government; or
2. Receive Federal funds in any form, even if the funds do not directly pay for the alcohol or substance abuse services; or
3. Are assisted by the Internal Revenue Service through a grant of tax exempt status, or allowance of tax deductions for contributions; or
4. Are authorized to conduct business by the Federal government (e.g. Medicare provider, that is authorized to conduct methadone maintenance treatment, or registered with the Drug Enforcement Agency (DEA) to dispense a controlled substance used in the treatment of alcohol or substance abuse; or
5. Are conducted directly by the Federal government.

Alcohol and substance abuse treatment Programs that are for-profit, with private practitioners that do not receive Federal assistance and that only see patients with private health insurance or self-pay patients are not required to follow the 42 CFR Part 2 requirements, unless required to do so by State laws. Also, a provider who does not use controlled substances for treatment and who does not otherwise meet the definition of a Program is not subject to 42 CFR Part 2 requirements.

**Q. How does 42 CFR Part 2 interact with HIPAA?**

Even if the 42 CFR Part 2 regulations do not apply, HIPAA will continue to apply and govern permissible uses and disclosures of protected health information. When both rules apply, the preemption provisions within HIPAA provide that the rules that are more protective of individual privacy will control. When 42 CFR Part 2 applies, one of the biggest differences is that the substance abuse confidentiality rules impose stricter consent/authorization requirements, limiting the disclosure of covered records even between health care providers with a common treatment relationship with the patient. Additional information about the 42 CFR Part 2 consent requirements is provided below.

**Q. What are permissible methods for sharing information protected by 42 CFR Part 2 with other health care providers including members of the OCHIN collaborative?**
Program information that is protected under 42 CFR Part 2 may be disclosed via the OCHIN electronic medical record to those providers that are part of the OCHIN collaborative, provided that the program has obtained the patient’s consent to do so. The 42 CFR Part 2 rules contain detailed requirements related to the content of any such consent that are beyond the scope of these FAQs. For OCHIN Members who desire to rely on the consent exception for purposes of allowing 42 CFR Part 2 data to be stored within the OCHIN collaborative, careful attention must be paid to these consent requirements in order to ensure compliance.

A program may also share information with a qualified service organization or “QSO” through the use of a Qualified Service Organization Agreement (QSOA). These QSOA’s, analogous to Business Associate Agreements under HIPAA, require that the QSO acknowledge receipt of the patient information and that it is fully bound by the 42 CFR Part 2 regulations. In addition, the QSOA must contain a statement that the QSO will resist in judicial proceedings any efforts to obtain access to patient records, except as permitted by the regulations. Patient consent is not required when information is provided under a QSOA, but the scope of permissible uses of the information is more limited than those that may apply under a patient consent. (42 CFR § 2.12(c)(4)).

Q. May a patient revoke a previously executed consent under 42 CFR Part 2?

Yes. When patients have signed an authorization/consent allowing disclosure of their information to multiple individuals or organizations, they can revoke the authorization to one or more of those individuals or organizations. Revocation can be done verbally, or in writing. When a patient revokes their consent, that verbal or written revocation must be documented/scanned and flagged in the patient’s medical record.

Q. May information governed by 42 CFR Part 2 be disclosed without patient consent in medical emergencies?

Yes. If a healthcare provider that is treating an alcohol or drug treatment Program patient determines that a medical emergency exists and that the patient’s condition poses an immediate threat to the health of any individual (including the patient) and that the situation requires immediate medical intervention, information may be released from the patient’s medical record to the necessary medical personnel who are treating a medical emergency, as needed. Patient authorization/consent is not required during a medical emergency. A healthcare provider who is treating the patient for a medical emergency can make the determination that 42 CFR Part 2 Program treatment information is needed in order to provide medical care. The entire record can be released to a treating provider during the emergency, if it is determined that the entire record is needed. Disclosure of 42 CFR Part 2 Program information that occurred to respond to a medical emergency must be documented by the Program, including the nature of the emergency, the date and time that the information was disclosed, who disclosed the information, and the name of the person to whom the information was disclosed and their affiliation with a health care facility. Medical emergencies may include mental health emergencies. (42 CFR § 2.51).

Re-disclosure of 42 CFR Part 2 Program records that were disclosed during a medical emergency is permitted without obtaining the patient’s authorization/consent, if re-disclosure is necessary for continuing patient care.

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1 42 CFR Part 2 also allows for limited disclosures without patient consent under some circumstances, such as child abuse reporting (42 CFR § 2.12(c)(6)), crimes on program premises or against program personnel (42 CFR § 2.12(c)(5)), and court ordered disclosures when certain procedures and criteria are met (42 CFR §§ 2.61-2.67).
SUMMARY AND CONCLUSIONS

Only certain organizations and individuals are considered a 42 CFR Part 2 program. Only 42 CFR Part 2 program records require the additional protections described under 42 CFR Part 2. Information that is protected under 42 CFR Part 2 may be disclosed via the OCHIN electronic medical record to those providers that are part of the OCHIN collaborative, provided that the Program has obtained the patient’s authorization/consent to do so. In order to disclose information from these Programs, the patient must sign a 42 CFR Part 2 compliant authorization/consent form. 42 CFR Part 2 Programs are encouraged to seek independent legal advice on the contents of the consent form as well as the frequency of such consents.

42 CFR Part 2 Programs may allow their patients’ records to be disclosed to other outside individuals or organizations in order for that outside individual or organization to provide services to the 42 CFR Part 2 Program, without patient consent, if a written QSOA is in place between the two organizations or in the case of a medical emergency.

HIPAA Privacy and Security Standards apply to all protected health information within the OCHIN collaborative, even if 42 CFR Part 2 program protections do not apply.

REFERENCES


Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2 (Revised), Substance Abuse and Mental Health Services Administration U.S. Department of Health and Human Services December 14, 2011.

Frequently Asked Questions, Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE), Legal Action Center for the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services, 2010.

HIPAA Regulations 45 CFR § 160, 162, and 164