

42 CFR PART 2 v HIPAA: COMPARE AND CONTRAST

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HIPAA & 42 CFR Part 2

- Health Insurance Portability and Accountability Act of 1996
 - Guidelines for health plans, health care clearinghouses and health care providers who transmit information electronically for billing and other specified transactions
- 42 CFR Part 2
 - Specifically addresses confidentiality of substance use disorder patient records.

The Framework of Principles

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- Privacy is the state of being alone, or the right to keep one's personal matters and relationships secret
- Confidentiality has been defined by the International Organization for Standardization as "ensuring that information is accessible only to those authorized to have access"
- Security is measures taken to guarantee freedom of secrecy of action communication or the like.

Applicability

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42 CFR Part 2

- Federally-assisted substance use disorder treatment programs

HIPAA

- Health Plans
- Health Care Clearinghouses
- Health Care Providers that transmit electronic information

Program

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Per 42 CFR Part 2

- 1. An individual or entity who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or,
- 2. An identified unit within a general medical facility that holds itself as providing, and provides, substance use disorder diagnosis, treatment or referral treatment; or,
- 3. Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

Who is considered a client?

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42 CFR Part 2

- Client means any individual who has applied for or been given diagnosis or treatment for substance use disorder at a federally assisted program
- Includes any individual who, after arrest on a criminal charge, is identified as an individual with a substance use disorder in order to determine that individual's eligibility to participate in a part 2 program.

HIPAA

- The person who is the subject of the protected health information—past current or future—clinical or financial—any medium
- The individuals and organizations who are subject to HIPAA regulations as a Continuing Education or Business Associate.

Protected Health Information

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Individually Identifiable Health Information which is:

- Created or received by a health care provider, health plan, employer or health care clearinghouse
- Related to the past, present or future physical or mental health or condition of an individual
- Related to the provision of health care to an individual
- Related to the past, present or future payment for the provision of health care to an individual
- Identifies the individual or there is reasonable basis to believe that the information can be used to identify the individual
- Is transmitted by electronic media or maintained in any medium

Client Identifying Information

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42 CFR Part 2 And HIPAA

- Name
- Address
- Social Security Number
- Fingerprints
- Photograph
- Names of relatives/household
- Name of employer
- Variety of dates
- Telephone/fax number

42 CFR Part 2 And HIPAA

- Email address/URL/IP
- Medical record number
- Account/health plan number
- Vehicle or other device serial number
- Does not include a number assigned by a program for internal use only if that number does not consist of or contain numbers that could be used to identify a patient

Individuals Allowed Access (HIPAA)

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- ❑ **Workforce:** Employees, volunteers, trainees, and other persons with access to PHI and under the control of the Covered Entity
- ❑ **Business Associates:** Separate entity working on behalf of the CE providing TPO and/or associated activities which require access and/or use of PHI from the CE

Allowable Disclosures

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42 CFR Part 2

- ❑ Medical Emergency*
- ❑ Internal Communications
- ❑ Business Associates
- ❑ Child Abuse Reports
- ❑ Crime against program property or staff
- ❑ Auditors
- ❑ Research*
- ❑ Court Order
- ❑ Payment
- ❑ Operations

HIPAA

- ❑ Treatment
- ❑ Payment
- ❑ Operations
- ❑ Abuse Reports
- ❑ Crime against program property or staff
- ❑ Governmental Agency
- ❑ MINIMUM NECESSARY

Otherwise...

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- Under 42 CFR Part 2 a consent is required

Non-Client/Patient

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The Final Rule removes the permission granted under the existing regulations to disclose that an identified individual is not and never has been a patient.

Final rule guidance states that confirming the identity of an individual who is not and has never been a patient while remaining silent on the identity of an actual patient could, by inference, compromise patient privacy if the individual are of a small group of individuals.

Consents

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42 CFR Part 2

- Name of patient
- From Whom
- To Whom
- What to disclose
- Purpose of disclosure
- Redisclosure Statement
- Revocation Statement
- Expiration Information
- Signature of Patient
- Date of Signature

HIPAA

- Name of Patient
- From Whom
- To Whom
- What to disclose
- Purpose of disclosure
- Revocation Information
- Statement re: Conditional Treatment
- Statement re: Ability to be re-disclosed & not protected
- Expiration information
- Signature of patient and date

Definition

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Lawful Holders of PHI

- A lawful holder of patient identifying information is an individual or entity who has received patient identifying information as the result of a part of a part 2-compliant patient consent (with a prohibition on re-disclosure note) as permitted under the Part 2 statute, regulations, or guidance. Thus, a patient who has obtained a copy of their records, or a family member who has received such information from a patient, would not be considered lawful holders.

Definition

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- Treating Provider Relationship
 - A treating provider relationship exists with another individual or entity when, “regardless of whether there has been a actual in-person encounter: 1) a patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treatment, or agrees to accept consultation, for any condition by an individual or entity; and 2) the individual or entity agrees to undertake diagnosis, evaluation, or treatment of the patient, or consultation with the patient, for any condition.”

Treating Provider Relationship

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- SAMHSA considers an entity to have a treatment provider relationship with a patient “if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.”
- **Absent such a relationship, consents to disclose would have to specifically name the individuals or entities to which disclosure may be made.** (see table below) SAMHSA did not include “care management relationship” to be a “treating provider relationship.”

42 CFR 2.31	Individual or entity to whom disclosure is to be made	Treating provider relationship with patient whose information is being disclosed	Primary designation	Required additional designation
(a)(4)(i)	Individual	Yes	Name of individual (eg Jane Doe MD)	None
(a)(4)(i)	Individual	No	Name of individual (eg Jane Doe MD)	None
(4)(4)(ii)	Entity	Yes	Name of entity (eg Providence Hospital)	None
(a)(4)(iii)(B)	Entity	No	Name of entity that is not covered by 2.31 (eg HIE, research institution, etc.)	At least one of the following: <ul style="list-style-type: none"> • Name of Individual participant • Name of an entity with treating provider relationship with patient whose information is being disclosed • "General designation" of individual or entity participant or class of those participants limited to those participants who have a treatment provider relationship with a patient whose information is being disclosed (eg my current and future treating providers)

Child Abuse/Neglect

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<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;">42 CFR Part 2</div> <ul style="list-style-type: none"> <input type="checkbox"/> Specific exception allows reporting of only child abuse/neglect <input type="checkbox"/> Restrictions on disclosure and use continue to apply to the original alcohol and drug abuse client records maintained by the program including their disclosure or use for criminal or civil proceedings which may arise out of the report 	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;">HIPAA</div> <ul style="list-style-type: none"> <input type="checkbox"/> Allows a report to appropriate authorities of abuse, including child abuse
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Public Health Authorities/Disease Reporting

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42 CFR Part 2

- No specific exemption for reporting - need consent, court order, or can report if done anonymously
- Can disclose to FDA if error in manufacturing e.g., labeling or sale of drug used in treatment - exclusive purpose notifying clients and their physicians of potential dangers

HIPAA

- Authority to disclose to public health authorities for a variety of circumstances without client authorization

Subpoenas/Court Orders

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42 CFR Part 2

- A subpoena alone is not sufficient to release information - a court order is also required - must be issued by judge in accordance with specific procedures and criteria

HIPAA

- Can disclose in response to a court (or administrative tribunal) order only, or a subpoena and court order, or by discovery request or lawful process alone

Law Enforcement

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42 CFR Part 2

- Generally cannot disclose information without subpoena and court order - arrest/search warrant not sufficient
- Can disclose for crime committed by clients on program premises or against program personnel or a threat to commit such a crime

HIPAA

- Can disclose to law enforcement and jails without consent/authorization:
 - As required by law
 - With a subpoena
 - With a warrant
 - To locate missing persons
 - Victim of crime
 - Crime on program premises

Research

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42 CFR Part 2

- Allowable if:
 - Director/Manager determines appropriate and,
 - Disclosure allowed by patient; or
 - Subject to 45 CFR part 46
 - CE or BA
 - List of conditions re: redisclosure, record retention, report format
 - IRBs

Others

- Protection of Human Subjects (45 CFR 46, Subpart A)*
- FDA regulations (21 CFR 50 & 56)*
- HIPAA Privacy Rule (45 CFR 160 & 164)*
- Public Health Service Act Certificates of Confidentiality (301(d), 42 USC 241(d))*

Prohibition on Re-Disclosure

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42 CFR Part 2

- Can only disclose pursuant to a consent or other permitted purpose
- Prohibition against re-disclosure of information to another - can only disclose to those named in consent
- Must include a written prohibition statement to accompany the consent
- Any recipient of information is subject to the rule and may not disclose the information except as permitted by the rule

HIPAA

- No specific prohibition against re-disclosure
- However, if the entity is a covered entity or a business associate, privacy protections continue to apply

Redisclosure

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- The Final Rule clarifies that the prohibition against re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language or both.

New Redisclosure Statement

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- Required language on any release of Part 2 information:
 - “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. 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.”

Optional Redisclosure Statement

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- To accommodate EHRs or other text limited situations, an abbreviated statement may be used:
 - “42 CFR part 2 prohibits unauthorized disclosure of these records.”

Client Access to Records

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42 CFR Part 2

- Has right to clinical record
- Also subject to restriction on use 2.23(b)

HIPAA

- Client has right to access own records
- Exceptions:
 - Psychotherapy notes
 - Information compiled in anticipation of civil, criminal or administrative proceeding

Client Rights

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42 CFR Part 2

- Clients must be given written summary of confidentiality provisions and notice that Federal law and regulations protect the confidentiality of alcohol and drug abuse client records.

HIPAA

- Receive notice of covered entity's privacy practices
- Access own information
- Request corrections of erroneous/incomplete information
- Request restriction of uses and disclosures
- Request transmittal of communications in an alternative manner
- Obtain an accounting of disclosures

Other HIPAA Privacy Mandates

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- Designate a Privacy Officer
- Adopt written comprehensive policies
- Train staff routinely
- Personnel sanctions for breaches
- Establish a grievance process
- Physical safeguards
- Mitigate results of violations
- Minimum Necessary Requirement
- Privacy Notice
- Accounting of Disclosures
- Correction of erroneous/incomplete information

Enforcement, Compliance and Penalties

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42 CFR Part 2

- Enforcement – US Attorney for the judicial district in which the violation occurs
- Fined in accordance with Title 18 of the US Code

HIPAA

- Enforcement – HHS' Office of Civil Rights
- Penalties - Civil - \$100/person per violation up to \$1,500,000/same violation in one year
- Criminal - \$150,000 up to \$1,500,000 with additional time in prison

Contact Information

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References

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- Title 42, Chapter 1, Subchapter A, Part 2—Confidentiality of Alcohol and Drug Abuse Patient Records
- Confidentiality of Alcohol and Drug Abuse Patient Records, Proposed Final Rule §2.11, Published January 18, 2017
- Confidentiality of Alcohol and Drug Abuse Patient Records, Proposed Final Rule §2.11, Published January 3, 2018
- Substance Abuse and Mental Health Services Administration: <http://bit.ly/2nsONeN>