NAVIGATING HIPAA AND 42 CFR PART 2 IN THE SB 123 PROGRAM

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OVERVIEW

HIPAA
(45 CFR Part 164)

42 CFR Part 2
(Sections 2.1 – 2.67)

- Both sets of regulations address the confidentiality and security of a person's individual health information.
- Both address the uses and disclosures of protected information, and allow access by individual patients.
- Both are federally enforced and have penalties for violations.

HIPAA OVERVIEW

Who must comply with HIPAA?

1) "**Covered Entities**" who are health care service providers who electronically furnish, bill or receive payment for health care in the course of normal business.
2) "**Business Associates**" who are persons or entities that perform certain function or activities that involve the use or disclosure of PHI on behalf of, or provide services to, a Covered Entity.

HIPAA OVERVIEW

The Health Insurance Portability and Accountability Act (HIPAA) has 3 components:

1) **Privacy Rule**- standards for when protected health information ("PHI") may be used/disclosed.
2) **Security Rule**- safeguards that must be implemented to protect ePHI.
3) **Breach Notification Rule**- requirements to notify affected individuals, DHHS; and sometimes the media of a breach of PHI.

42 CFR PART 2 OVERVIEW

Who must comply with 42 CFR Part 2?

- **Federally assisted program** that holds itself out as providing and provides alcohol or drug abuse diagnosis, treatment or referral ("Part 2 program").

- Third party payers who receive information from Part 2 programs.

- Entities having direct administrative control of a Part 2 program.

- Persons/entities who are "lawful holders" of information received from Part 2 programs- received by patient consent or by other legal permission with notice of prohibition on re-disclosure.

PART 2 OVERVIEW

"**Program**" means:

- Individual/entity holding itself out as providing SUD diagnosis, treatment or referral.
- An identified unit in a general medical facility that holds itself out as providing SUD diagnosis, treatment or referral.
- Medical personnel in a general medical facility whose primary function is providing SUD diagnosis, treatment or referral and are identified as such.

PART 2 OVERVIEW

"**Federally assisted**" means:

- Program is conducted directly, by contract or otherwise by any department or agency of the U.S. (separates VA and Military).
- Program is carried out under a license, certification, registration or other authorization of a department or agency of the U.S.
  - Participates in Medicare.
  - Authorized to conduct maintenance treatment or withdrawal management.
  - Holds a DEA registration (if controlled substances used in treatment of SUD).
- Program is supported by funds provided by any department or agency of the U.S. (receives federal assistance, conducted by state or local government, non-profit tax status, etc.)

PART 2 OVERVIEW

- Part 2 severely restricts Part 2 programs' communications about identifiable individuals outside of the program's personnel that have a "need for the information" in connection with their duties.

- The purposes for the restrictions are to decrease the risk that:
  - Information about individuals in recovery will be shared for the purpose of criminal prosecution;
  - such individuals will be discriminated against; or
  - individuals will avoid seeking treatment for substance use disorders.

PART 2 OVERVIEW

- Regulations do not require disclosure, but may permit disclosure if conditions and requirements are met.

- Restricts the use of information to investigate, initiate or substantiate criminal charges against a patient obtained by a Part 2 program for treating, diagnosing or making a referral with respect to a patient's substance use disorder.

PART 2 OVERVIEW

In addition to Part 2's general rules, the following are covered:

- Disclosures permitted with patient consent.
- Disclosures permitted without patient consent.
- Court orders authorizing disclosures.

PART 2 OVERVIEW

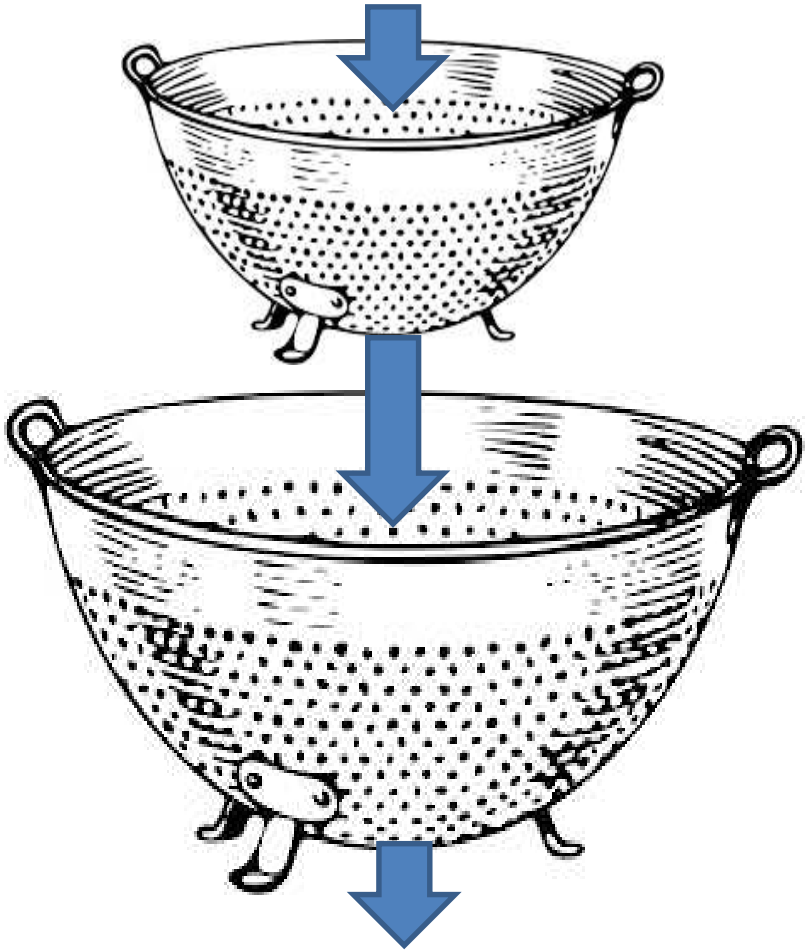
- The Part 2 regulation were originally issued in 1975, almost 30 years before HIPAA's privacy rules went into effect.

- Over time, SAMHSA has amended the Part 2 regulations to alleviate some of the confidentiality burdens and align the regulations with HIPAA. The most recent amendments were on July 13, 2020.

- Part 2 programs must comply with both the Part 2 regulations and HIPAA. However, the Part 2 regulations contain **stricter** requirements and limitations on use and disclosure due to the sensitivity of the information involved.

HIPAA AND 42 CFR PART 2

SUD Information



42 CFR Part 2 requirements and limitations

HIPPA requirements and limitations

Access, Uses, and Disclosures

PART 2 CHANGES ON THE HORIZON

- As part of the CARES Act signed into law on March 27, 2020, Congress included significant amendments to the federal law governing confidentiality of SUD records.

- The provision requires HHS to issue conforming amendments to the Part 2 regulations effective for uses and disclosures of records on or after March 27, 2021.

Part 2 Changes On the Horizon

- The forthcoming changes will continue to harmonize the Part 2 regulations with HIPAA and allow greater flexibility to share SUD information while maintaining protections for patients.

https://www.healthcarebusinesstoday.com/cares-act-changes-to-federal-substance-use-privacy-law/

Enforcement and Penalties

HIPAA

- Office of Civil Rights enforces ("OCR")
- Civil penalties of $119.00 up to $59,522.00 per violation, with an annual cap of $1,785.651 for all violations of an identical requirement.
- Criminal penalties of up to $250,000.00 and 10 years imprisonment.

42 CFR Part 2

- Department of Justice enforces ("DOJ")
- Criminal fines of $500.00 for 1st offense and $5,000.00 for subsequent offenses.

*Civil penalties coming in 2021 and HHS will enforce.

COVERED INFORMATION

HIPAA

- Protected Health Information ("PHI")
  - Individually-identifying information (18 common identifiers)
  - Maintained in any format
  - Created, transmitted, received or maintained by entity in its capacity as a health care provider.
  - Past, present or future condition, care, or payment.

*includes medical record number.

42 CFR Part 2

- Patient-identifying information regarding SUD
  - Any information directly or indirectly identifying patient as being diagnosed with, having, or being referred for SUD treatment.
  - Identifiers similar to HIPAA.

* Exception for internal number used by a Part 2 program that cannot be used to identify patients by external parties.

REQUIRED NOTICES TO PATIENTS

HIPAA

- Must distribute (post on website and make available to anyone who asks for it) a Notice of Privacy Practices to patients that includes:
  - How PHI may be used and disclosed.
  - An individual's rights with respect to the information, and how the individual may exercise these rights.
  - The Covered Entities legal duties with respect to the information, including the requirement to protect the privacy of PHI.
  - An effective date of the Notice.

42 CFR Part 2

- Notice to patients of the federal confidentiality requirements. This includes a summary of the federal law and regulations.
  - The limited circumstances in which a Part 2 program may acknowledge or disclose patient information identifying the patient as having or having had a SUD.
  - Information that violation of Part 2 laws and regulations is a crime, and that suspected violations may be reported to authorities (include contact info.).
  - Statements that a patient's commission of a crime on Part 2 program premises or against personnel is not protected.
  - Statement that reports of suspected child abuse and neglect under state law are not protected.
  - Citation to the federal law and regulations.

*See 42 CFR § 2.22(b) for specifics.

Part 2 programs must have both!

Acknowledging Presence of Patient

HIPAA

- Inclusion in patient directory is permissible if patient has the opportunity to opt out.
- May discuss care or condition of patient in presence of family/friends if patient has opportunity to object and does not.

42 CFR Part 2

- Only with patient's written consent.
- Otherwise, cannot in any way identify that patient is or has been diagnosed or treated for SUD.
- Verbal consent of patient to discuss care or condition is <u>not</u> permitted.

PROHIBITED ACCESS, USE & DISCLOSURES

HIPAA

No access, use or disclosure of a patient's PHI without the patient's authorization or consent unless a HIPAA exception applies.

42 CFR Part 2

No disclosure (directly, indirectly, by reference to public information, or through verification by another person) of any information that identifies a person as having/had a SUD or been referred for a SUD without patient consent unless a Part 2 exception applies.

- May not even acknowledge person is a patient in a program.
- Can't require ID card/bracelet be worn outside the program.

PATIENT ACCESS

HIPAA

- Generally may access and copy designated record set upon request. This does not include:
  - QA, peer review, risk management records, etc.
  - Psychotherapy (personal) notes of provider that are separately maintained.
  - Information compiled in reasonable anticipation of civil, criminal or administrative action.

42 CFR Part 2

- Patient access and copying is not prohibited.
- No written consent required.
- Still cannot be used for criminal investigation, charges, or substantiation.

*Part 2 programs should follow HIPAA for patient requests for their own access and copies.

DISCLOSURES WITHOUT PATIENT CONSENT/AUTHORIZATION

HIPAA

- Treatment, payment, most healthcare operations.
- Limited information to family/friends involved in care or payment.
- Limited information in facility directory
- Public health
- Substantial risk of harm
- Health oversight activities

42 CFR Part 2

- Within Part 2 program to those have a need to know.
- Medical emergencies where patient cannot consent (must document disclosure).
- Reporting crimes or threats on Part 2 premises or against personnel to law enforcement (must limit information disclosed).
- Reporting child abuse or neglect.
- Audit of Part 2 program by government, payer, or other lawful holder (subject to conditions)
- Research (subject to conditions)

CONSENT FOR DISCLOSURE

HIPAA

- By patient request:
  - Informal writing is acceptable
  - Name and address of recipient
  - Signed by patient
- 3rd party request:
  - Must obtain formal written authorization from patient or personal representative.
  - Re-disclosure not protected.
  - May be revoked/expire.

42 CFR Part 2

- Must have formal authorization/consent for any disclosure other than specified exceptions.
- Redisclosure prohibited without a Part 2 written consent by the patient.
- Recipient must receive a notice that accompanies the disclosure of the prohibition on redisclosure (See 42 CFR § 2.32)

Invalid 42 CFR Part 2 Consents for Disclosure

A Part 2 program cannot make a disclosure if the patient's written consent:

- Has expired;
- Does not substantially conform to the requirements for a written consent in 42 CFR § 2.31(a);
- Is known to have been revoked by the patient; or
- Is known, or could reasonably be known, by the individual or entity holding the records to be materially false.

Required Part 2 Consent Components

42 CFR § 2.31(a)

1) Patient's full name.
2) Specific name(s) or general designations of the Part 2 program, entity or individual permitted to make the disclosure (Who will be the permitted disclosers?)
3) How much and what kind of information is to be disclosed (explicit description of the SUD information that may be disclosed).
4) Designation of recipients- the names of the individuals or names of the entities to which a disclosure is to be made.
5) The purpose of the disclosure (disclosure must be limited to this purpose).
6) May be revoked at any time (except to extent already relied upon)
7) Expiration date, event or condition.
8) Signature of the patient.
9) Date on which the patient signed the Consent.

Recipients of SUD Disclosures

Another provider

Community Corrections

Beacon or other payers

CAN YOU DO A MULTI-RECIPIENT CONSENT?

- The description of how much and what kind of SUD information is to be disclosed must limited to what the recipient(s) need to know. Therefore, the description must correlate and be limited to the specific purpose for making the disclosure:
  - Treatment
  - Payment
  - Correctional monitoring
- The designation of the recipients must also align with the purpose for disclosure and scope of what will be disclosed.
- Ability to revoke or condition of expiration must align as well.

DISCLOSURES TO CRIMINAL JUSTICE SYSTEM

- If the patient's participation in the Part 2 program is a condition of the disposition of the patient's criminal proceeding, parole, or release from custody.
- Only to CJS individuals with a "need for the information" to monitor patient's progress.
- CJS staff may only re-disclose it to carry out their official duties connected to the purpose for the consent.
- Still requires written patient consent:
  - Must state the period of validity (reasonable)
  - Must state consent is revocable upon a specified amount of time or a specified event.

*** See 42 CFR § 2.35**

Disclosures to Prescription Drug Monitoring Programs

- A Part 2 program or other lawful holder is permitted to report any SUD medication prescribed or dispensed by the Part 2 program to the applicable state prescription drug monitoring program <u>if required by state law.</u>

- Written patient consent must still be obtained for this purpose prior to reporting.

DISCLOSURE PURSUANT TO SUBPOENAS AND COURT ORDERS

HIPAA

May disclose when:

- Ordered or subpoenaed by a judge or magistrate.
- Issued a grand jury subpoena.
- A subpoena is signed by an attorney or clerk of the court, but only if:
  - You notify patient and patient has an opportunity to object to the disclosure, or
  - There is a qualified protective order in place.

42 CFR Part 2

May disclose when:

- The records have been subpoenaed and a court has issued an order authorizing disclosure.
  - Protect life or serious bodily injury.
  - Extremely serious crime by patient (e.g. homicide, rape, child abuse, etc.).
  - Investigation of the Part 2 program.

***See 42 CFR §§ 2.61 through 2.66**

Access, Use and Disclosure with Business Associates and QSOs

HIPAA

- Covered entities must have business associate agreements ("BAA") with business associates and subcontractors.
  - Examples: attorney services, billing company, EHR software vendor, 340B program administrator, etc.

42 CFR Part 2

- Part 2 programs must also have a qualified service organization agreement ("QSOA") with entities that provide services to Part 2 programs and meet the definition of a QSO.
  - Examples: attorney services, accounting, billing company, 340B program administrator, etc.

HIPAA Business Associate Agreements

Business associate agrees:

- Not to disclose PHI in a manner that would violate HIPAA if same disclosure made by the Covered Entity would be a HIPAA violation.
- Comply with HIPAA's security rule requirements.
- Assist the Covered Entity in complying with certain rights such as patient-requested restrictions on disclosures, making amendments, and providing an accounting of disclosures.
- Other terms that may be specific to the relationship or advisable to include.

42 CFR Part 2
Qualified Service Organization Agreements

QSO agrees:

- It is bound by Part 2 in receiving, storing, processing or dealing with Part 2 patient records.
- In any judicial proceedings to obtain the SUD information, the QSO will resist efforts to obtain access, unless an exception applies.
- It cannot re-disclose the SUD information except as necessary to carry out its duties.

BUSINESS ASSOCIATES AND QSOs

Part 2 Program

BAA
and
QSOA

42 CFR Part 2
Qualified Service Organization Agreements

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SECURITY OF PATIENT INFORMATION

HIPAA Security Rule

- Covered Entities must meet specific administrative, physical and technical safeguard standards to protect security and integrity of electronic PHI (See 45 CFR § 164.304).
- Covered Entities must periodically assess and update its security measures; and document the rationale for many of its security decisions.

*** HIPAA Privacy Rule requires substantially the same safeguards for paper records.**

42 CFR Part 2

- Part 2 programs AND lawful holders must have formal policies and procedures to reasonably protect against unauthorized uses and discloses and reasonably anticipated threats or hazards to the security of patient-identifying information.
- Applies to paper and electronic records.

***See 42 CFR § 2.16**

Part 2 Programs must meet both!

HIPAA Breach Notification Rule

- Part 2 programs must also comply with the Breach Notification Rule that requires notification to patients when their unsecured PHI is impermissibly used or disclosed ("breached") in a way that compromises the privacy and security of the PHI.

- Also requires notification of HHS and the media (if more than 500 persons affected)

Disposing records after Discontinuation of Part 2 Program

Look first at state, federal law or other legal requirements for retention. If records must still be maintained, Part 2 program must:

- Seal all paper patient records in envelopes or containers with a specific label (See 42 CFR § 2.19(b)(1)(i)).
- Sanitize all copy media, printers, etc. used to produce the paper records in order to render the data non-retrievable.
- Maintain the paper records under the restrictions of the regulations until required retention period ends, and then destroy the records in a non-retrievable manner.

Disposing records after Discontinuation of Part 2 Program

For electronic records which must be maintained, Part 2 programs must:

- Transfer records to a portable electronic device with encryption or transfer the records (and a backup copy) to separate electronic media with encryption.
- Seal and specifically label the container holding the electronic device or media, and hold the records under the restrictions of the Part 2 regulations.
- Maintain a method and ability to decrypt the records.
- Destroy the records in a non-retrievable manner upon the expiration of the retention period.

QUESTIONS?

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