

Protecting Confidentiality of Substance Use Disorder Patient Records: The Updated "Part 2" Regulations

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Introduction

- Updated rules governing the confidentiality of substance abuse treatment records.
- “Part 2” drug and alcohol confidentiality regulations.
- SAMHSA published revised regulations to amend Part 2 – became effective on March 21, 2017.



What changed
and what has
essentially
stayed the same

Best practices in
tribal programs

Challenges and
questions

Revised Part 2 Regulations

- Regulations were last updated in 1987.
- Were in need of change to account for advances in technology and modern delivery of health care.



Health care industry asked for Part 2 to be aligned with HIPAA privacy and security requirements.

SAMHSA mainly choose not to do that. Mostly maintains stringent & unique requirements of Part 2.

Who Must Comply With Part 2

- All “federally assisted” individuals and organizations.
- Tribal substance use treatment programs are subject to the Part 2 requirements by virtue of federal funding under the ISDEAA.
- Providers who only provide screening, brief intervention, or referral to treatment (SBIRT) within the context of general health care are not Part 2 programs.

Definitions-Terminology (§ 2.4)

- “Alcohol and drug abuse patient records” → “Substance use disorder patient records.”
- “Detoxification” → “Withdrawal management.”
- “Methadone” treatment → “Opioid treatment programs.”
- “Patients” = current and former patients.
- “Records” = paper and electronic.

Definitions-Terminology (§ 2.4)

- “Disclose” is revised to mean “to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, 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.”
- New term: “treating provider relationship.” Includes relationship even when no in-person encounter, so long as the patient and provider agree to a treatment or evaluation relationship.

Disclosures Without Patient Consent

- Still have exceptions allowing disclosure without patient consent for:
 - Internal program communications (just within the Part 2 program);
 - Crimes on program premises or against program personnel;
 - Mandated reports of child abuse or neglect;
and
 - Pursuant to court orders.

Disclosures Without Patient Consent (Con't)

- Medical Emergencies (§ 2.51).
 - As necessary to meet a bona fide medical emergency.
 - Increased discretion.
- Research (§ 2.52).
 - Revised for consistency with HIPAA privacy regulations governing research activities.
 - Allows researchers to use data links to other data sets that are from a data repository that are subject to an Institutional Review Board's approval and other regulatory requirements.

Disclosures Without Patient Consent (Con't)

- Qualified Service Organizations (§§ 2.11, 2.12).
 - Population health management
 - “Medical services” means “medical staffing.”
- Audit and Evaluation (§ 2.53).
 - Revised to address electronic records.

Disclosures *With* Patient Consent (§ 2.31)

- All disclosures not otherwise allowed without patient consent require the patient to sign a consent form.
- SAME:
 - Patient's name
 - Name of the Part 2 program
 - A date, event or condition on which the consent will expire, if not revoked before.
 - Signature and date.
 - Electronic signature is okay, so long as not prohibited by other applicable law.

Disclosures *With* Patient Consent (§ 2.31)

- REVISED:
 - Paper or electronic consent form.
 - Covers paper and electronic records.
 - Need an “explicit description of the substance use disorder information that may be disclosed,” though—
 - “All my substance use disorder information.”
 - Or limit to a subset of information, such as “substance use history summaries, medications and dosages.”



Consent Form – To Whom (§ 2.31)

Consent forms must identify the recipients of confidential information in the “to whom” portion of the consent form.

- Previously, Part 2 required a separate consent form for each party to whom patient-identifying information could be disclosed.
- Continues to permit consent forms to meet this requirement by authorizing disclosures to specific individuals.
- Third-party payers: designate the name of the third-party payer.

Consent Form – To Whom (§ 2.31)

- Expanded pool of potential recipients among the patient’s treating providers.
 - If an entity itself has a treating provider relationship with the patient, then specifying the name of the entity is ok.
 - If an entity, such as a health information exchange (HIE), is facilitating data sharing among providers, name of each such entity and—
 - The name of each individual participant; or
 - The name of any entity participant that has a treating provider relationship with the patient; or
 - A general designation like “my current and future treating providers”.
- For all other individuals or entities that are *not* treating providers, the consent must specify the names of each particular authorized recipient.

Prohibition on Redisclosure (§2.32)

- The required statement has been updated. See § 2.32.
- Applies to information that would identify, directly or indirectly, an individual that has been diagnosed, treated or referred for treatment for a substance use disorder
 - Does not apply to other information in the record that does not identify the patient.

Accounting for Disclosures (§ 2.13)

- New list required when patients made a general designation in the “to whom” portion of the consent form.
 - If consent form did not use a general designation (e.g., named a specific individual), accounting not required.
- Unlike the 6-year accounting requirement in HIPAA, the Part 2 list of disclosures need only cover disclosures made in the previous 2-year period.
- Patients can make a written request for a copy of the list. Response must be given within 30 days + include a brief description of each disclosure.

Security of Records (§§ 2.16, 2.19)

- Covers paper and electronic records.
- Accessing, transferring, maintaining and destroying both paper and electronic records.
- To align with the HIPAA security rule: Security policies for electronic records include “creating, receiving, maintaining and transmitting such records.”
- Applies to Part 2 program + “other lawful holders of patient identifying information.”
- New requirements to be followed by discontinued Part 2 programs.

Sample Forms

- Old Regs:
 - Sample notice of confidentiality requirements
 - Sample consent form.
- No forms in the new regulations.
- SAMHSA has promised more guidance on forms in the “near future.”



What Does This Mean For Your Program

- Update confidentiality and security policies and procedures, including procedures for physical and electronic security of records
- Update notice to patients and possibly HIPAA Notice of Privacy Practices
- Update patient consent/authorization forms
- Staff training

Questions?

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