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Substance Use Treatment:
Revised Part 2 Regulations Compliance

Impact for Treatment Programs, Integration of Physical and Behavioral Health Records, Health Systems

TUESDAY, OCTOBER 24, 2017

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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AGENDA (1/2)

- **Overview of 42 C.F.R. Part 2**
- **Applicability of 42 C.F.R. Part 2**
  - What information?
  - Who is subject?
- **Revised 42 C.F.R. Part 2: The Highlights**
  - Consent requirements
  - Disclosures without patient consent
  - Impact on Part 2 programs and other lawful holders of Part 2 information

AGENDA (2/2)

- **Physical and Behavioral Health Integration and Data Exchange**
  - Continued barriers to integration
  - Limitations of Consent2Share
- **Best Practices for Compliance**
  - Segmentation, segregation and access controls
  - Data submission policies and procedures
  - Consent management and forms
  - Qualified Service Organization Agreements and "contract agent" arrangements

42 C.F.R. Part 2 Overview

The 42 C.F.R. Part 2 regulations implement the Confidentiality of Substance Use Disorder Treatment Records Statute (42 U.S.C. § 290dd-2), which provides heightened privacy protection to protected health information that identifies a patient as a substance - abuser and is obtained by a federally-assisted substance use disorder program.

The Part 2 regulations supplement other privacy laws, including HIPAA and other state confidentiality laws.

History of 42 C.F.R. Part 2 (1/2)

1970 & 1972

Congress enacted two statutes—the "Alcohol and Drug Abuse Acts"—that restricted the use and disclosure of information identifying individuals as alcohol and drug abusers.

P.L. 91-616; P.L. 92-255

37 Fed. Reg. 24636

1975

Part 2 regulations established.

40 Fed. Reg. 27802

1987

Modest substantive changes.

52 Fed. Reg. 21798

History of 42 C.F.R. Part 2 (2/2)

2004, 2010-11 & 2014

SAMHSA guidance issued.

See SAMHSA.gov

2016 & 2017

Proposed revision in 2016 and revised regulations went in effect on March 20, 2017.

Supplemental Notice of Proposed Rule Making (SNPRM) (comment period closed on Feb. 17, 2017).

81 FR 6987; 82 FR 6052; 82 FR 8346; 82 FR 5485

What's Next?

Proposed legislative changes on the horizon.

SB 1850/HB3545 (2017)

Applicability of 42 C.F.R. Part 2 (1/3)

- **Framework for Determining Applicability:**
  - **What information?** Is it Part 2 information?
  - **From whom?** Is the original source of the Part 2 information a Part 2 program?
  - **How was it received?** Am I Part 2 program or lawful holder of Part 2 information?

Applicability of 42 C.F.R. Part 2 (2/3)

- **What is Part 2 Information?**
  - Protected health information that identifies a person as a substance abuser; AND
  - Is obtained by a Part 2 program. 42 C.F.R. § 2.12(a).
- **What is a Part 2 Program? *FACT SPECIFIC DETERMINATION***
  - An individual or entity (including a unit or personnel within a general medical facility) who holds itself out as providing and provides substance use disorder (SUD) diagnosis, treatment, or referral for treatment; and
  - Is federally assisted (*e.g.*, is contracted with the federal government, licensed by the federal government to provide SUD treatment, receives any federal funds, or is a 501(c)(3) non-profit). 42 C.F.R. §§ 2.11 (definitions of "Part 2 program" and "program), 2.12(b)(b) ("federal assistance").
  - Examples: Treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, school-based programs, and private practitioners who hold themselves out as providing, and provide substance use disorder treatment. 42 C.F.R. § 2.12(e).
- **What is not?**
  - Examples: Providing SBIRT—screening, brief intervention, and referrals for substance use disorder treatment—within a general health care setting (*e.g.*, emergency room), so long as it is not the **primary** function of the medical staff providing it. 82 FR 6052.

Applicability of 42 C.F.R. Part 2 (3/3)

- **Who are other lawful holders?**
  - Third Party Payors
  - Entities that have direct administrative control over the Part 2 program (*e.g.*, a general medical facility in which a substance use disorder treatment unit is located)
  - Consent recipients who receive the Part 2 information with the prohibition on re-disclosure notice
  - Qualified Service Organizations (QSOs) and their contract agents pursuant to contract
  - Researchers and auditors who receive Part 2 information without patient consent

42 C.F.R. §§ 2.12(d), 2.11 (QSOs), 2.52 (researchers), 2.53 (auditors); 82 F.R. 6052, 6068.

Don't forget HIPAA and State Laws….

- **Dual compliance with HIPAA and state law is required.**
- **HIPAA**
  - Additional Authorization Requirements
  - Notice of Privacy Practices
  - Patient Rights
  - Security
- **State Laws**
  - 42 C.F.R. § 2.20: ". . . . If a disclosure permitted under the regulations in this part is prohibited under state law, neither the regulations in this part nor the authorizing statute may be construed to authorize any violation of that state law. However, no state law may either authorize or compel any disclosure prohibited by the regulations in this part."

Overview of Changes in 2017 Final Rule

- **2017 Final Rule**: 82 FR 6052
- **What hasn't changed**
  - Applicability
  - Patient consent still required for TPO
  - No new exceptions to consent requirement
  - Prohibition on re-disclosure still required (but updated language)
- **Summary of Changes**
  - Definitions: modernized to be consistent with current terminology in the field.
  - Some alignment with HIPAA: security & record destruction
  - Notice to Patient: contact info for reporting violations
  - Consent Requirements
  - Exceptions to Consent
  - Updated Prohibition on Re-Disclosure Notice
  - SNPRM: disclosures to subcontractors; abbreviated re-disclosure notice
- **Today's Focus**
  - **Changes to Consent Requirements**
  - **Changes to Consent Exceptions**

Overview of Consent Structure & Exceptions

- **Rule of Thumb**: Patient consent is required, unless an exception applies.
- **Exceptions**:
  - Medical emergency, 42 C.F.R. § 2.51.
  - Research, 42 C.F.R. § 2.52.
  - Audit and evaluations, 42 C.F.R. § 2.53.
  - Court orders, 42 C.F.R. Subpart E.
  - Direct administrative controls, 42 C.F.R. § 2.12(c)(3).
  - Qualified Service Organizations (QSOs) and their contract agents, 42 C.F.R. § 2.12(c)(4). & SAMHSA's 2010 & 2011 guidance.
  - Child abuse/neglect, 42 C.F.R. § 2.12(c)(6).
  - Cause of death, 42 C.F.R. § 2.15(b).

Overview of Consent Requirements, 42 C.F.R. § 2.31

- **Patient name, signature and date.** Special rules apply if the patient is a minor, incompetent or deceased and when a personal representative may sign. 42 C.F.R. §§ 2.14, 2.15.
- **From whom.** The specific name or general designation. SAMHSA abandoned proposal to eliminate the general designation option. 82 FR 6052, at 6077 & 6087.
- **To whom (BIG CHANGES!)**. It's complicated under the 2017 Final Rule. . . .
- **Amount and Kind (SEE WHAT'S NEW!)**.
- **Purpose.** SAMHSA added clarifying language that disclosure must be limited to that which is necessary to carry out the stated purpose in accordance with 42 C.F.R. § 2.13(a).
- **Revocation**. Consent is subject to revocation at any time, except if consent already relied upon.
- **Expiration date or event**.
- **List of Disclosures (NEW!)**. Ability to generate is required if a general designation consent is used.
- **Additional Requirements**: Disclosures to central registries and elements of the criminal justice systems (*e.g.*, probation/parole) must meets additional requirements in 42 C.F.R. §§ 2.34 and 2.35.

Revised Consent Requirements: To Whom, 42 C.F.R. § 2.31(a)(4)

- **1987 Standard**: The name or title of the individual or the name of the organization to which disclosure is to be made. SAMHSA prohibited use of a general designation, such as "all my healthcare providers."
- **2017 Final Rule**: 2017 Final Rule offers essentially 3 options, including a general designation
  - Name of entity (or individuals) with a treating provider relationship (*e.g.*, XYZ Clinic) or health plan.
  - Name of individual that does not have a treating provider relationship (*e.g.*, Jane Doe)
  - **General Designation***: name of entity without a treatment provider relationship (*e.g.*, HIO, ACO, CIN, research institution) and name of entities with a treating provider relationship, individuals, or general designation of individuals/entities/class limited to those with a treating provider relationship (past, current or future).
- **Treating Provider Relationship**, 42 C.F.R. § 2.11.

TABLE 1—DESIGNATING INDIVIDUALS AND ORGANIZATIONS IN THE "TO WHOM" SECTION OF THE CONSENT FORM

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(s) (*e.g.*, Jane Doe, MD).	None.
(a)(4)(i)	Individual	No	Name of individual(s) (*e.g.*, John Doe)	None.
(a)(4)(ii)	Entity	Yes	Name of entity (*e.g.*, Lakeview County Hospital).	None.
(a)(4)(iii)(A)	Entity	No	Name of entity that is a third-party payer as specified under §2.31(a)(4)(iii)(A) (*e.g.*, Medicare).	None.
(a)(4)(iii)(B)	Entity	No	Name of entity that is not covered by §2.31(a)(4)(iii)(A) (*e.g.*, HIE, or research institution).	At least one of the following: 1. The name(s) of an individual participant(s) (*e.g.*, Jane Doe, MD, or John Doe). 2. The name(s) of an entity participant(s) with a treating provider relationship with the patient whose information is being disclosed (*e.g.*, Lakeview County Hospital). 3. A general designation of an individual or entity participant(s) or a class of participants limited to those participants who have a treating provider relationship with the patient whose information is being disclosed (*e.g.*, my current and future treating providers).

82 FR 6052, 6080

List of Disclosures, 42 C.F.R. § 2.13(d)

- Required if a General Designation Consent form is used.
- Consent form must include a statement notifying patients that they have a right to make a written request for a list of disclosures (up to 2 years). 42 C.F.R. § 2.31(a)(4)(i)(B)(3)(i).
- List of Disclosures requirements (42 C.F.R. § 2.13(d)):
  - Must respond within 30 days.
  - For each disclosure list the name of the entities, date and brief description.
- Compliance burden is on the intermediary entity (*e.g.*, HIO, ACO, research institution).
- Ability to generate a "list of disclosures" must exist before a general designation consent is used. 82 FR 6052, 6056-57, 6072.

Revised Consent Requirements: Amount and Kind, 42 C.F.R. § 2.31(a)(3)

- **1987 Standard**: How much and what kind of information is to be disclosed.
- **2017 Final Rule**: How much and what kind of information is to be disclosed, including an explicit description of the substance use disorder information that may be disclosed.
- **SAMHSA's "Granular Consent" Interpretation**: Interpreted by SAMHSA to allow for the disclosure of "all substance use disorder information," but only if more detailed options are included other than "all or nothing." 82 FR 6052, at 6086.
  - Does this conflict with the plain language of the regulations?
  - Does this conflict with SAMHSA's acknowledgment (82 FR 6091) that it lacks statutory authority to require data segmentation?

Revised Medical Emergency Exception, 42 C.F.R. § 2.51

- **1987 Standard**: . . . patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.
- **2017 Final Rule**: . . . patient identifying information may be disclosed to medical personnel to the extent necessary to meet a **bona fide medical emergency** in which the patient's prior informed consent cannot be obtained.
- **Impact**: greater discretion in determining whether a medical emergency exists. 82 FR 6052, 6094.
- **What Didn't Change?**
  - Individual determination of a medical emergency is required. Automation is not permitted. 82 FR 6052, 6095.
  - Emergency exception cannot be used to circumvent the consent requirement. 82 FR 6052, 6094-95.
  - Intermediary entities must give notice to the Part 2 program that is the source of the Part 2 data upon disclosure. 82 FR 6052, 6096.
- **Public Health Emergencies?**: It's unclear whether this exception applies to federal or state declarations of a public health emergency related to the opioid epidemic. SAMHSA has stated it will issue subregulatory guidance. 82 FR 6052, 6079.

Revised QSO Exception, 42 C.F.R. §§ 2.11 & 2.12(c)(4)

- **2017 Final Rule Changes to the QSO Definition** (42 C.F.R. § 2.11):
  - Replaced "medical . . . services" with "medical staffing."
  - Added "population health management." Preamble describes as "increasing desired health outcomes through monitoring and identifying individual patients within a group." 82 FR 6052, 6066 & 6068.
  - Declined to include "care coordination" or clarify how "care coordination" differs from "population health management." 82 FR 6052, 6067.
- **What does it mean?**
  - QSO exception cannot be used to circumvent the consent requirement where the disclosure is used for treatment purposes. 82 FR 6052, 6067.
  - Disclosures for "population health services" must be limited to the office or unit responsible for population health management in the organization; it does not permit disclosure to the entire organization. 82 FR 6052, 6066-67.

Revised Research Exception, 42 C.F.R. § 2.52

- Significant changes to the research exception.
- Part 2 programs and other lawful holders of Part 2 information may now disclose to researchers for scientific research if the disclosing entity is subject to, and in compliance with, HIPAA and/or the Common Rule.
- Recipient researchers are subject to the Part 2 regulations.
- Data linkages to public and private repositories are permitted. But requires
  - Review by IRB;
  - Researchers must not disclose Part 2 information to law enforcement; and
  - Data repositories must comply with 42 C.F.R. Part 2; destroy linked data after providing information to researchers; and ensure Part 2 information is not provided to law enforcement.

Impact on Part 2 Programs and Other Lawful Holders

- **Part 2 programs**: unlikely to cause significant changes in day-to-day operations.
- **Other Lawful Holders**: some increased flexibility, such as disclosures for research.
- **Data integration and health information exchange**: Challenges in aligning patient rights, improved access, and existing technology

Data Integration

- **Data Integration**

Data integration is the combination of multiple types of data from various different sources into a single infrastructure, such as clinical data repository. The impetus over the last decade has been to integrate **behavioral** and **physical** health information.

Challenges:

- Differences in coding methodologies for physical and behavioral health entities
- Resource strain for adapting to new technology
- Shifting regulatory landscape

Health Information Exchange

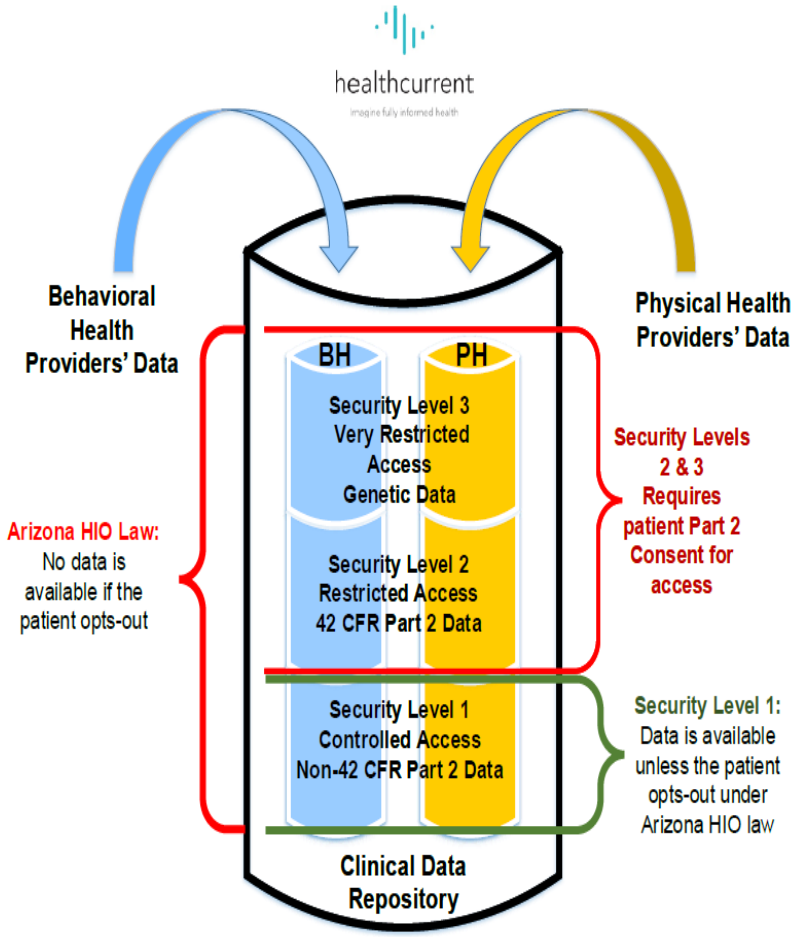
- **Health Information Exchange**

Health information exchanges are the key to data integration, as it permits providers, plans and other components of the healthcare system to timely share patient information. It is an integral component of the health information technology (HIT) infrastructure.

Development:

- Statewide HIE Coordinators/Grant Funding
- Sequoia Project – e-Health exchange
- Strategic Health Information Exchange Collaborative, Patient Centered Data Home
- Improved Interoperability

Adapting to Regulatory Requirements



Applicable Regulations:

- Federal: HIPAA, 42 C.F.R. Part 2, GINA
- State (Arizona):
  - Health Information Organization (A.R.S. § 36-3801 *et seq.*)
  - Genetic Testing (A.R.S. § 12-2801 *et seq.*)
  - Mental Health (A.R.S. § 36-509(A))
  - Communicable Disease (A.R.S. § 36-664(A))

Part 2 Implementation Barriers

- **Continued Challenges with Hosting Part 2 Information**
  - Data segregation is still required because no exception for TPO.
  - May result in over-restricting access to co-mingled Part 2 and behavioral/physical health information.

- **Implementing Consent Requirements**
  - Amount & Kind: lack of data segmentation and standardization makes granular consent difficult to implement.
  - To Whom: the "treating provider relationship" limitations on when an entity's name can be used has the unintended consequence of prohibiting access by public health authorities charged with combating the opioid epidemic and probation departments who monitor the patient's compliance with drug treatment probation requirements. The need for multiple consent forms (e.g. general designation produces substantial administrative burden.

Part 2 Implementation Barriers

- **Prohibition on Re-Disclosure Notice**
  - Display difficulties due to length

> ***Notice to Recipient of Substance Use Disorder Treatment 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 (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.*

  - SNPRM would permit a truncated display (82 FR 5485, 5487)
- **General Designation Consents / List of Disclosures**
  - Implementation difficulties
  - How will patients make their requests to intermediaries? 82 FR 6052, 6072.
- **Medical Emergencies**
  - Establishing appropriate safeguards to ensure and document a "bona fide medical emergency"

Limitations of Consent2Share

- **SAMHSA's Consent2Share**: is an open source tool for consent management and data segmentation designed to integrate with existing EHR and HIE systems. It's access control services are designed to be compliant with 42 C.F.R. Part 2. The goal of C2S is to enable more patient control over what information is shared among providers, health plans, etc. (e.g. allowing patient to exclude medications, lab results)

  Limitations:

  - Inconsistencies in coding methodologies and means of data transfer (e.g. CCD, HL7, PDF)
  - Inability to guarantee every document in a patient's record will be completely scrubbed of information the patient wishes to restrict disclosure
  - Administrative burden

Best Practices

- Data segmentation
- Segregation of Part 2 information
- Technological and administrative access controls
- Data submission policies and procedures (for intermediary entities)
- Consent management and forms
- Qualified Service Organization Agreements and "contract agent" arrangements

Additional Resources

- **SAMHSA Guidance**
  - 2010 HIE FAQs, https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf
  - 2011 Confidentiality FAQs, https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs
  - 2014 Listening Session & Comments, https://www.samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations
  - 42 CFR Part 2: Final Rule Overview Webinar, https://www.youtube.com/watch?v=DUPTlYwz6fU

- **Legal Action Center, Sample Consent Forms**, https://lac.org/resources/substance-use-resources/confidentiality-resources/sample-forms-confidentiality/

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