The Office of the National Coordinator for Health Information Technology

42 CFR: Health IT Considerations

ONC SIM Resource Center Learning Event
April 25, 2017

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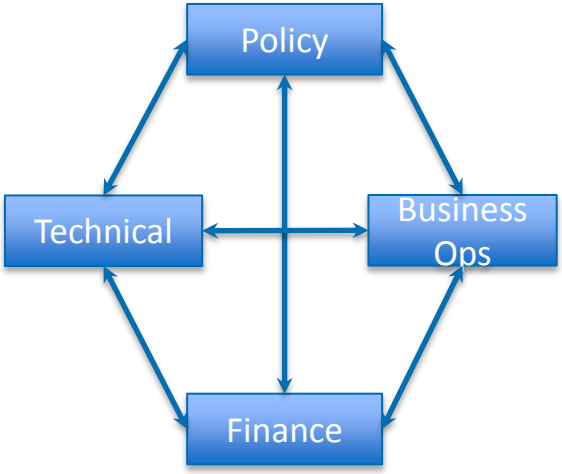
Agenda

- Introduction and Framing the Discussion
- 42 CFR Update: Danielle Tarino
- Health IT Application to States, HIEs and Providers
- Listening Session April 26, 2017: State Discussion of What Would be Helpful to Know to Operationalize Changes
- Q&A
- Adjourn

Implementation Considerations

- Policy
- Technical
- Business Operations: Workflow
- Finance



Substance Abuse and Mental Health Services Administration

SAMHSA

www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

Behavioral Health is Essential To Health

Prevention Works

Treatment is Effective

People Recover

Modernizing 42 CFR Part 2 - Overview

Confidentiality of Substance Use Disorder Patient Records Final Rule (42 CFR Part 2)

- Background
- Notice of Proposed Rulemaking (NPRM)
- Final Rule
- Supplemental Notice of Proposed Rulemaking (SNPRM)

Modernizing 42 CFR Part 2: Rights and Responsibilities

- Modern version of the Hippocratic Oath:

"I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know."

http://guides.library.jhu.edu/c.php?g=202502&p=1335759

Access and Quality Hinge on Trust…

- Cyberattacks on personal health records growing “exponentially”
- GAO Report: Electronic Health Information – HHS Needs to Strengthen Security and Privacy Guidance and Oversight

Health Privacy Legislation

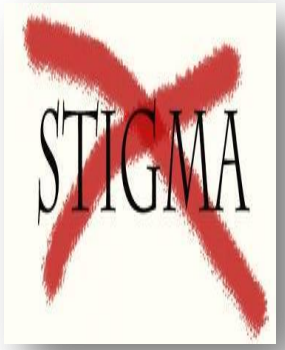
- Congress recognized that the stigma associated with substance use disorders and fear of prosecution deterred people from entering treatment, and enacted the statute authorizing **42 CFR Part 2** to ensure an individual's right to privacy and confidentiality.
- For decades 42 CFR Part 2 has been in the vanguard of personal privacy protections and the cornerstone of treatment programs across the country.

Basics: 42 CFR Part 2

- Implements federal drug and alcohol confidentiality law (42 U.S.C. §290dd-2).
  - » Protects confidentiality of the identity, diagnosis, prognosis, or treatment of any patient records maintained in connection with the performance of any federally assisted program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation or research.

Context: 42 CFR Part 2

- The law and regulations were written during a time of great concern about the potential use of substance use disorder information against an individual.
- The purpose of 42 CFR Part 2 is to ensure that a patient receiving treatment for a substance use disorder in a Part 2 program is not made more vulnerable than an individual with a substance use disorder who does not seek treatment.



Why Revise 42 CFR Part 2?

- Regulations were first promulgated in 1975 and last substantively updated in 1987.
- Significant changes have impacted health care delivery since then:
  - New models of integrated care that rely on information sharing to support coordination of patient care.
  - Electronic infrastructure for information exchange.
  - New focus on performance measurement.

Considerations in Revising 42 CFR Part 2

- Breach of privacy of information protected by Part 2 can still lead to civil and criminal consequences for patients, including:
  - Loss of employment, housing, and/or child custody.
  - Discrimination by medical professionals and insurers.
  - Arrest, prosecution and incarceration.

Preventing Unintended Consequences

- Importantly, the consequences of fewer and laxer privacy controls and regulations can disproportionally penalize minority, underserved, and otherwise marginalized populations.
  - » In this context, loosening privacy controls could *increase* rather than reduce health disparities, and *impede* rather than promote access.

Listening to the Public

- SAMHSA held a Public Listening Session in 2014 to solicit feedback on 42 CFR Part 2.
  - Approximately 1,800 individuals participated in the session (in person or by phone).
  - SAMHSA received 112 oral comments and 635 written comments.
  - http://www.youtube.com/playlist?list=PLBXgZMI_zqfTRftyiS4ckNi9bYW4Vmj82

The Process: 42 CFR Part 2 Notice of Proposed Rulemaking (NPRM)

- In addition to considering the wealth of public input received from the Listening Session, SAMHSA collaborated with its federal partner experts in developing the NPRM.
- The NPRM was published in the Federal Register on February 9, 2016 (81 FR 6988).
- The Comment Period was 60 days and closed on April 11, 2016.
- 376 comments were received.

42 CFR Part 2 New Final Rule

- The final rule was published in the Federal Register on January 18, 2017 (82 FR 6052).
- The effective date was initially scheduled for February 17, 2017.
- Review by the administration resulted in a revised effective date of March 21, 2017.
- https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

42 CFR Part 2

[SAMHSA–4162–20]

RIN 0930–AA21

Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this final rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations and facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking treatment for a substance use disorder. These modifications also help clarify the regulations and reduce unnecessary burden.

Acronyms

ACO Accountable Care Organization
ABAM American Board of Addiction

Protection and Facilitation

- The final rule is intended to modernize the Part 2 rules by facilitating the electronic exchange of substance use disorder information for treatment and other legitimate health care purposes while ensuring appropriate confidentiality protections for records that might identify an individual, directly or indirectly, as having a substance use disorder.

Language Matters

- In the final rule, SAMHSA made terminology changes throughout for clarity, consistency, and to modernize the regulations (e.g., from “alcohol and drug abuse” to “substance use disorder”).
  - SAMHSA changed the name of the regulations to**: Confidentiality of Substance Use Disorder Patient Records**.

Consent Requirements (§2.31)

- The final rule:
  - Allows, in certain circumstances, a patient to include a *general designation* in the "To Whom" section of the consent form.
    - There is a distinction between those with and without a treating provider relationship with the patient.
  - Requires an explicit description of the "Amount and Kind" of substance use disorder treatment information.

Consent Requirements (§2.31) (cont.)

- The final rule retains the "From Whom" provision of the 1987 regulations (as amended) with minor updates to terminology.
  - The final "From Whom" provision of the consent requirements *specifies that a written consent to a disclosure of patient identifying information must* include the specific name(s) or general designation(s) of the Part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure.
- The final rule requires the consent form to include a statement that the patient understands:
  - When using a general designation in the "To Whom" section, the patient's right to obtain, upon request, a list of entities to whom his/her information has been disclosed, pursuant to the general designation (see §2.13).
- The final rule permits electronic signatures (to the extent that they are not prohibited by any applicable law).

Confidentiality Restrictions and Safeguards (§2.13)

- The final rule requires that, upon request, patients who have included a general designation in the "To Whom" section of the consent form must be provided a list of entities to whom their information has been disclosed pursuant to a general designation (List of Disclosures).
  - » However, in the final rule, SAMHSA clarified that the entity that serves as an intermediary, ***NOT the Part 2 program***, is responsible for complying with the List of Disclosures requirement.
- The final rule clarifies that the general designation on the consent form may not be used until entities required to comply with the List of Disclosures provision have the ability to do so.
- SAMHSA may issue subregulatory guidance on this provision.

Prohibition on Re-Disclosure (§2.32)

- The final rule clarifies that the prohibition on 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, and allows other health-related information shared by the Part 2 program to be re-disclosed, if permissible under other applicable laws.
- SAMHSA made some additional minor clarifying revisions to §2.32 relative to:
  - The use of general authorizations.
  - The restrictions on using information to criminally investigate or prosecute a patient with a substance use disorder.

Applicability (§2.12)

- Applicability is based on the definition of *Program,* which did not change except for updating terminology.
- Consistent with SAMHSA's previous FAQ guidance, a practice comprised of primary care providers could be considered a "general medical facility" and be subject to 42 CFR Part 2 if the practice is both "federally assisted" and meets the definition of a program under §2.11.

Security for Records (§2.16)

- The final rule:
  - Addresses both paper and electronic records.
  - Clarifies that both Part 2 programs and other lawful holders of patient identifying information must have in place formal policies and procedures for the security of records, including sanitizing media associated with both paper and electronic records.
    - Must reasonably protect against unauthorized uses and disclosures of patient identifying information and protect against reasonably anticipated threats or hazards to the security of patient identifying information.
  - Replaces relevant language in other sections with reference to the policies and procedures requirement in §2.16.
- SAMHSA may provide subregulatory guidance on this provision.

Medical Emergencies (§2.51)

- The final rule revises the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a "bona fide medical emergency" exists.
- SAMHSA is considering issuing subregulatory guidance addressing this provision.

Research (§2.52)

- The final rule allows a Part 2 program or other lawful holder of patient identifying information to disclose Part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule).

Research (§2.52): Disclosure Modifications

- In the final rule:
  - §2.52(a) clarifies that lawful holders may re-disclose Part 2 data for research purposes, subject to the other conditions imposed in §2.52.
  - §2.52(a)(2) clarifies that disclosure of Part 2 data also is permitted for research that qualifies for exemption under the Common Rule due to the lower risk to subjects in circumstances where exemptions apply.

Research (§2.52): Data Linkages

- The final rule enables researchers holding Part 2 data to link to data sets from federal and non-federal data repositories provided certain conditions are met.
  - » Supports more advanced research, including studies of longitudinal effects of patient treatments.

Research (§2.52): Records Management

- The final rule addresses the retention and disposal of Part 2 data used in research by referencing §2.16, Security for Records.
- SAMSHA may issue additional subregulatory guidance on the Research provision.

Audit and Evaluation (§2.53)

- The final rule:
  - Includes provisions for both paper and electronic patient records.
  - Permits the Part 2 program, not just the Part 2 program director, to determine who is qualified to conduct an audit or evaluation.
  - Updates the Medicare and Medicaid audit or evaluation section to include the Children's Health Insurance Program (CHIP).
  - Permits an audit or evaluation necessary to meet the requirements (under certain conditions) of Centers for Medicare & Medicaid (CMS)-regulated accountable care organizations or similar CMS-regulated organizations (including CMS-regulated Qualified Entities).
  - Revises the requirements for destroying records by referencing §2.16, Security for Records.

Reports of Violations (§2.4)

- The final rule revises the requirement for reporting violations of Part 2 by opioid treatment programs to the Food and Drug Administration (FDA) because authority over these programs was transferred from the FDA to SAMHSA in 2001.

Notice to Patients of Federal Confidentiality Requirements (§2.22)

- The final rule:
  - Clarifies that the written summary of federal law and regulations may be provided to patients in either paper or electronic format.
  - Requires the statement regarding the reporting of violations to include contact information for the appropriate authorities.

Disposition of Records by Discontinued Programs (§2.19)

- The final rule:
  - Includes provisions for both paper and electronic patient records.
  - Adds requirements for sanitizing paper records and electronic media, which is distinctly different from deleting electronic media.
  - Requires the process of sanitizing paper media (including printer and FAX ribbons, drums, etc.) or electronic media to be permanent and irreversible, so that there is no risk that the information may be recovered.

Disposition of Records by Discontinued Programs (§2.19) (cont.)

- Makes a distinction between electronic devices (something that has computing capability, such as a laptop, tablet, etc.) and electronic media (something that can be read on an electronic device, such as a CD/DVD, flash drive, etc.).
- Allows one year to complete the process of sanitizing electronic media that are subject to longer retention periods required by law.
  - This change should allow for select patient records to be removed from both the specific site and any operational sources without disrupting other patient records.

Definitions (§2.11)

- The final rule revises the previous regulations by:
  - Consolidating all but one definition in a single section (§2.11).
    - "Federally assisted" remains in the Applicability provision at §2.12 for the purpose of clarity.
  - Modernizing terminology and ensuring consistency of use across regulations.

Existing Definitions (§2.11)

- Updated terminology: *Central registry.*
  - *Diagnosis.*
  - *Disclose (formerly Disclose or disclosure).*
  - *Maintenance treatment*.
  - *Program*.
- *Member program:* updated terminology and replaced a reference to a specific geographic distance.
- *Patient identifying information:* ". . . or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy ~~and speed~~ either directly or by reference to other ~~publicly~~ available information."
  - Clarified the meaning of the term *similar information* in the preamble discussion.

Existing Definitions (§2.11) (cont.)

- *Patient:* updated terminology and added that the definition includes both current and former patients.
- *Person:* added "Also referred to as 'individual or entity'".
- *Qualified Service Organization:* updated terminology; also revised the list of examples to add *population health management* and to clarify that the term *medical services* is limited to *medical staffing services.*
- *Records:* updated terminology, added examples of a record, and "any information, whether recorded or not, created by, ~~relating to a patient~~ received or acquired by a part 2 program relating to a patient…"
- *Treatment:* updated terminology and deleted the term *management* because it has a broader meaning than when the regulations were last revised.

New Definitions (§2.11)

- *Part 2 program:* which is separate and distinct from the definition of *Program.*
- *Part 2 program director:* which replaced *Program director*.
- *Withdrawal management: which replaced Detoxification treatment.*
- *Substance Use Disorder:* which replaced *Alcohol abuse* and *Drug abuse*.
- *Treating provider relationship:* added because the final rule revises the consent requirements to permit, in certain circumstances, a general designation of individuals or entities to which a disclosure can be made, but only if they have a *treating provider relationship* with the patient whose information is being disclosed.

2017 Supplemental Notice of Proposed Rulemaking (SNPRM)

- In addition to the final rule, SAMHSA issued a SNPRM on January 18, 2017 (82 FR 5485).
  - SAMHSA sought to obtain additional comments and information on some additional proposed clarifications to 42 CFR Part 2.
  - https://www.regulations.gov/document?D=HHS-OS-2016-0005-0378.
  - The Comment Period was 30 days and closed on February 17, 2017.

SNPRM Overview: Permissible Disclosures

- SAMHSA issued this SNPRM in response to public comments received on the NPRM that addressed specific changes not proposed in the NPRM.
- These comments led SAMHSA to propose additional clarifications and modifications to the Part 2 rules to clarify the scope of permissible disclosures.

Stakeholder Concerns: Use and Disclosure

- The NPRM comments highlighted varying interpretations of the rule's restrictions on lawful holders and their contractors' and subcontractors' use and disclosure of patient identifying information for purposes of carrying out payment, health care operations, and other health care-related activities.
  - » Third-party payers, other lawful holders, and their contractors and subcontractors and legal representatives play a critical role in the provision of health care services.

SNPRM Proposed Provisions §2.32 and §2.33

- Specifically, SAMHSA sought comments on the following proposed provisions:
  - §2.32 (Prohibition on Re-disclosure) – to consider whether an abbreviated notice would be appropriate and in which circumstances.
  - § 2.33 (Disclosures Permitted with Written Consent) – to define and limit the circumstances in which certain disclosures for the purposes of payment and health care operations can be made.

SNPRM Proposed Provision: §2.53

- §2.53 (Audit and Evaluation) - to expressly address **further disclosures** to contractors, subcontractors, and legal representatives for purposes of carrying out a Medicaid, Medicare, or CHIP audit or evaluation.

Prohibition on Re-Disclosure (§2.32): Added Notification?

- SAMHSA did not propose to substantively modify the existing notice at §2.32, *but sought comment on whether it should add an abbreviated notice to accompany re-disclosure for use in certain circumstances where a shorter notice may be warranted.*
  - For example, "Data is subject to 42 CFR Part 2. Use/disclose in conformance with Part 2."

Disclosures Permitted With Written Consent (§2.33): Patient Identifying Information (PII)

- SAMHSA proposed to explicitly list and limit under §2.33(b) specific types of activities for which any lawful holder of patient identifying information would be allowed to further disclose the minimal information necessary for specific payment and health care operations activities.
  - » *Lawful holders may disclose patient identifying information to contractors, subcontractors, and legal representatives for the purposes described in the list of activities.*
- The list of activities is similar to HIPAA Privacy Rule's definitions of "payment" and "health care operations," but excludes those related to diagnosis, treatment, or referral for treatment (e.g., care coordination or case management).
  - » *Consent is required*, and *contractors, subcontractors, and legal representatives must perform a function that is consistent with the stated purpose of the consent and only use the information to perform that function*.

Disclosures Permitted With Written Consent (§2.33): PII and Contractors and Subcontractors

- SAMHSA proposed new regulatory text under §2.33(c) *requiring that lawful holders that engage contractors and subcontractors* to carry out payment and health care operations that will entail using or disclosing patient identifying information include specific contract and subcontract provisions *requiring contractors and subcontractors to comply with the provisions of Part 2*.
  - » An appropriate comparable instrument will suffice in cases involving a legal representative.

Disclosures Permitted With Written Consent (§2.33): Adequate Privacy Protections?

- SAMHSA solicited comment on whether the proposed listing of explicitly permitted activities is adequate and appropriate to ensure the health care industry's ability to conduct necessary payment and the described health care operational functions, while still affording adequate privacy protections.

Disclosures Permitted With Written Consent (§2.33): Clarity On Scope of Consent

- SAMHSA sought comments on the proper mechanisms to convey the scope of the consent to lawful holders, contractors, subcontractors, and legal representatives, including those who are downstream recipients of patient identifying information given current electronic data exchange technical designs.

Audit and Evaluation (§2.53)

- SAMHSA proposed to revise the Audit and Evaluation provision to address the following issues raised by commenters:
  - Contractors, subcontractors, and legal representatives may be tasked with conducting audit and evaluation activities.
  - Such entities may not be CMS-regulated, and audits may be conducted for private payers as well as Medicare and Medicaid programs.
  - Audits and evaluations may include quality improvement activities, as well as efforts related to reimbursement and financing.

Responsiveness to Public Comments?

- The new proposals and clarifications discussed in this SNPRM are intended to provide the desired solutions and understanding sought by commenters to the NPRM, while also offering patient protections appropriate to the current health care environment.
- The payment, health care operations, and audit and evaluation functions discussed in the SNPRM may be subject to other applicable laws and regulations in addition to 42 CFR Part 2 (e.g., the HIPAA Privacy and Security Rules).

Patient Privacy and Due Diligence

- The fact that lawful holders and Part 2 programs are permitted to disclose data in no way obviates:
  - The purpose of Part 2: to protect patient identifying information for patients seeking diagnosis, treatment, or referral for treatment for substance use disorders.
  - The responsibility lawful holders and Part 2 programs have: to exercise due diligence with respect to their contractors, subcontractors, or legal representatives to whom they disclose or with whom they exchange patient identifying information.

Final Rule and SNPRM Next Steps

- SAMHSA will:
  - Review SNPRM comments received by the deadline and determine how to move forward.
  - Consider developing subregulatory guidance.
  - Consider the need for additional webinars, other presentations, and outreach materials.
  - Consistent with the 21st Century Cures Act, "convene relevant stakeholders" to discuss its effect on "patient care, health outcomes, and patient privacy."

Closing Thoughts: Privacy and Best Care

- 42 CFR Part 2 and other regulations provide ground rules, but how these rules are applied to ensure privacy *and* the best care requires careful analysis and monitoring.
  - Who needs what information when?
  - Who determines who needs what information when?
  - What are the consequences and outcomes?
  - And more…

Questions and Discussion

Next Steps and Adjourn

- Listening Session
- Date: April 26, 2017
- Time: 4:00pm ET
- Registration Link: https://attendee.gotowebinar.com/register/6242341309165111809

The Office of the National Coordinator for Health Information Technology

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