

Update on 42 CFR part 2: Confidentiality of Substance Use Disorder Patient Records

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SAMHSA
Substance Abuse and Mental Health
Services Administration

DISCLAIMER

This presentation is not intended to constitute legal advice. Any examples discussed are for illustrative purposes only. All questions about compliance with 42 CFR part 2, HIPAA and other applicable state and federal laws and requirements should be directed to an individual's, agency's or organization's legal counsel.

Why 42 CFR part 2 Exists?

- Congress noted in 1970s that discrimination associated with substance use disorders (SUDs) and fear of prosecution deterred people from entering treatment.
- Authorizing statute for confidentiality of SUD patient records regulations was intended to help ensure an individual's right to privacy and confidentiality when in or seeking diagnosis/treatment.
- Persons with substance use disorders continue to be subject to discrimination in such areas as employment, education, housing, child care and in the health care system.

Statute and Regulation

- ✓ 42 USC § 290dd-2 on the Confidentiality of records **is the basis for 42 CFR part 2 regulations and can only be changed by Congress.**
- ✓ 42 USC § 290dd-2 required the HHS Secretary promulgate regulations codified as “42 CFR part 2” or “part 2.”
- ✓ Part 2 regulations were first promulgated on July 1, 1975.
- ✓ Substantive revisions were made in 1987, 2017, 2018.

Key Provisions of 42 U.S.C. § 290dd-2

- ✓ “Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States” **shall be confidential.**
- ✓ However, SUD records may be disclosed, as permitted, with the prior written consent of the patient.

Exceptions in 42 U.S.C. § 290dd-2

- ✓ A consumer/patient's SUD information may be disclosed without consent:
 - To medical personnel to the extent necessary to meet a bona fide medical emergency.
 - To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluations (but individual patients cannot be identified by those personnel in any report or otherwise disclosed).
 - If authorized by a court order showing good cause (e.g., need to avert a substantial risk of death or serious bodily harm).
 - Except as authorized by court order, no record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

Exclusions in 42 U.S.C. § 290dd-2

- ✓ Statute does NOT apply to:
 - Exchange of records within the Uniformed Services, Department of Veterans Affairs (VA) components providing health care to Veterans or between the VA and the Uniformed Services.
 - Reports to state and local authorities under state law of suspected child abuse or neglect.

Statute and regulations-Penalty

- Penalty: Violations to be fined under Title 18 of US Code (Federal Crimes and Criminal Procedure)(§2.3)
- Purpose and Effect (§2.2): Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute.
- Penalty is enforced by Department of Justice (DOJ), not SAMHSA.
- Reports of (alleged) violations may be made to US Attorney in district where violation occurs (§2.4).
- For opioid treatment program (OTP), may report to SAMHSA and US Attorney (SAMSHA oversees OTP accreditation/certification).

Part 2, HIPAA and State Law

- Part 2 aligns with the Health Insurance Portability and Accountability Act (HIPAA) to extent feasible under its governing statute.
- SUD records and information may be subject to both HIPAA and part 2 and state laws.
- If both HIPAA and part 2 apply, follow the law that is more stringent.
- Part 2 (§ 2.20) does not preempt more stringent state laws.
- Working Paper: 2016 Compilation of State Behavioral Health Patient Treatment Privacy and Disclosure Laws and Regulations, National Association of State Mental Health Program Directors: <https://www.nasmhpd.org/content/tac-assessment-working-paper-2016-compilation-state-behavioral-health-patient-treatment>.

A Framework for Understanding part 2

Applicability: Is information covered/protected by part 2 (§§2.11-2.23)?

Exceptions: If so covered, does it fall under one of the exceptions to consent/exclusions (§2.12, §2.23, §§2.51-2.53)?

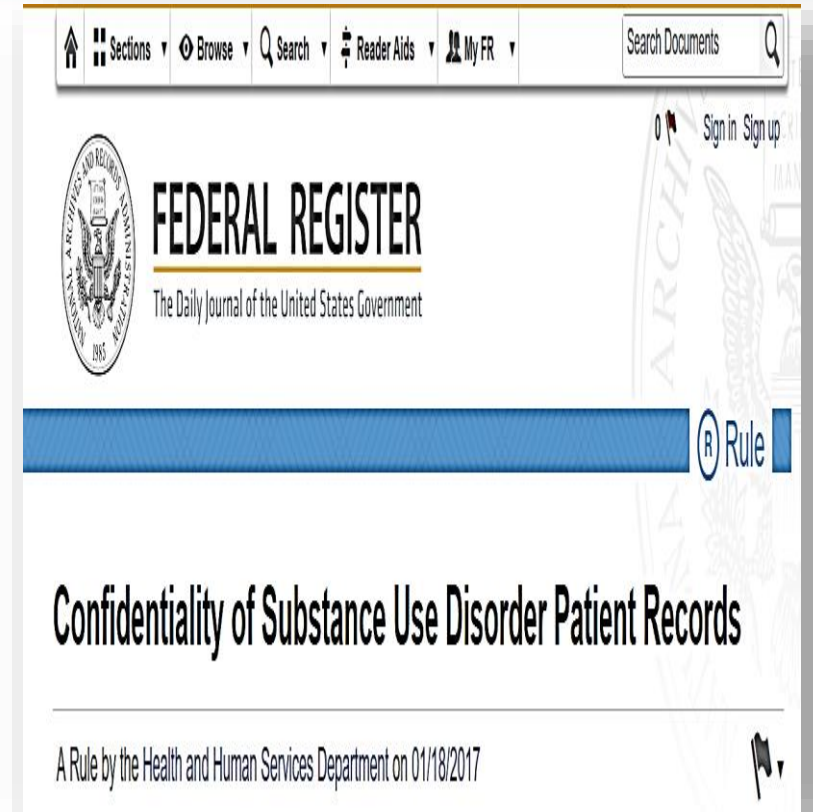
Consent: Will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?

Court orders: If no exception/exclusion to part 2 applies and patient does not consent to disclosure, can a court order be obtained (§§2.61-2.67)?

Approach adapted from: Dennis Helms, A Guide to the New Federal Rules Governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 4 Contemp. Drug Probs. 259 (1975)

Regulation: 42 CFR part 2 Revisions

- Updated final part 2 rule: Jan. 18, 2017 (82 FR 6052).
 - Effective March 21, 2017
- Supplemental Notice of Proposed Rulemaking (SNPRM) concurrently published proposing additional changes (82 FR 5485)
- Final rule based on SNPRM completed January 3, 2018 (83 FR 239)



2017 Final Rule,
<https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00719.pdf>

Why Did SAMSHA Revise 42 CFR part 2?

- Last substantive updates prior to 2017/2018 were 30 years ago.
- Significant changes in health care delivery:
 - New models of integrated care that rely on information sharing to improve safety & outcomes
 - New focus on performance measurement & value based reimbursement
 - Evolving electronic infrastructure for managing and exchanging information and use of electronic health records
 - Final 2017 rule: “SAMHSA has endeavored to strike an appropriate balance between the important privacy protections afforded patients with substance use disorders and the necessary exchange of information to improve treatment outcomes for these individuals.”

42 CFR part 2 Recent Highlights

2017 publication of 42 CFR part 2 updates

- Webinars and other public assistance
- Supplemental Notice of Proposed Rulemaking (SNPRM) and final 2017 rule published
- Further input sought

42 CFR part 2 Recent Highlights

2018 publication of further 42 CFR part 2 updates/Final Rule based on SNPRM

- Hosted listening session to receive input on part 2 (Jan. 2018)
- Tribal Consultation (July 2018)
- Fact Sheets with ONC (May 2018)
- Center of Excellence Grant/Funding Opportunity Announcement (FOA) Awarded (Dec. 2018)
- Potential additional regulatory changes/HHS Regulatory Sprint to Coordinated Care (ongoing)

Resources- Guidance

- SAMHSA recently developed two fact sheets in collaboration with the Office of the National Coordinator for Health Information Technology (ONC). These materials are intended to provide additional information to providers impacted by 42 CFR part 2 regarding topics such as applicability, the role of health information exchanges, and how 42 CFR part 2 applies to patient consent.
- These materials are posted on SAMHSA's website at <https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines>.

Resources- Guidance

- One fact sheet is entitled *Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?*. This fact sheet includes examples and background focused on the definition of part 2 program and consent requirements.
- A second fact sheet, *Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?*, focuses on how part 2 applies in the context of health information exchanges.

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QUICKLINKS

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PROJECT OVERVIEW

WHEN WILL SERVICES BE AVAILABLE?

WHO IS INVOLVED IN THE INITIATIVE? 

- Core Project Staff
- National Advisory Group Members

HOW WILL WE KNOW WE ARE SUCCESSFUL?

THE CHALLENGE

Patient privacy and confidentiality form a crucial component of the patient-doctor treatment relationship, particularly when seeking treatment for mental health or substance use disorders. Multiple federal privacy laws, in addition to state laws, provide privacy protections for mental health and substance use disorder treatment records, while permitting communication of these records to other healthcare providers, patients' families, and others.

In the face of these overlapping laws, it can be difficult for patients, their families, and health professionals to understand: What exact information can be shared, with whom, and at what times?

Federal privacy laws and regulations, like the Health Insurance Portability and Accountability Act (HIPAA), the federal substance use disorder privacy law and regulations (including 42 CFR Part 2), and the Family Educational Rights and Privacy Act (FERPA), were put in place to protect the information of patients getting or seeking treatment. These privacy laws govern the sharing of patient information with healthcare providers, family members, schools, and other community organizations.



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https://caiglobal.org/index.php?option=com_content&view=article&id=61&Itemid=174

Resources-SAMHSA part 2 Information Website

The screenshot shows a web browser window displaying the SAMHSA website. The address bar shows the URL: <https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines>. The page title is "Laws, Regulations, and Guidelines". The SAMHSA logo is prominently displayed at the top left, with the text "Substance Abuse and Mental Health Services Administration" below it. A search bar is located at the top right. The main navigation menu includes links for "Find Help & Treatment", "Grants", "Data", "Programs & Campaigns", "Newsroom", "About Us", and "Publications". The page content is organized into a sidebar and a main body. The sidebar on the left lists categories: "Health Information Technology", "Health IT for Behavioral Health Professionals", "Health IT for Patients and Families", "SAMHSA's Efforts", "Laws, Regulations, and Guidelines", and "Publications and Resources". The main body features a section titled "42 CFR Part 2 Confidentiality of Substance Use Disorder Patient Records". This section includes a brief overview of the law, a link to learn more, and a section titled "Proposed Revisions and the Notice of Proposed Rulemaking (NPRM)". The "Proposed Revisions" section states that the U.S. healthcare system has changed significantly since 42 CFR Part 2 was last substantially updated in 1987. It lists several key changes: new models of integrated care, electronic infrastructure for data exchange, expansion of prescription drug monitoring programs, and a new focus on measuring performance in health care. To the right of the main text, there are several promotional banners for "Health IT.gov", "BHbusiness PLUS", "KnowBullying", and "DISASTER Mobile App". At the bottom right, there is a link to "Data and Statistics" and "Interactive Data Systems".

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Health Information Technology

Health IT for Behavioral Health Professionals

Health IT for Patients and Families

SAMHSA's Efforts

Laws, Regulations, and Guidelines

Publications and Resources

42 CFR Part 2 Confidentiality of Substance Use Disorder Patient Records

Learn about 42 CFR Part 2, a federal law governing confidentiality for people seeking treatment for substance use disorders from federally assisted programs.

Federal privacy laws and regulations exist to protect patients' personal health information. These policies guide healthcare professionals, health IT vendors, and insurance companies to maintain information security and patient confidentiality.

If you or a family member seeks treatment for a substance use disorder, or you are a professional who works with this population, it is important to understand a federal statute called *Confidentiality of Alcohol and Drug Abuse Patient Records, 42 Code of Federal Regulations (CFR) 2*, also known as 42 CFR Part 2.

The federal statute governs confidentiality for people seeking treatment for substance use disorders from federally assisted programs.

This law generally requires a federally assisted substance use program to have a patient's consent before releasing information to others. It encourages people to seek treatment and reassures patient privacy.

Proposed Revisions and the Notice of Proposed Rulemaking (NPRM)

The U.S. healthcare system has changed significantly since 42 CFR Part 2 was last substantially updated in 1987. Over the last 25 years, changes to health care include:

- New models of integrated care for supporting patient care
- An electronic infrastructure for managing and exchanging patient data
- The expansion of prescription drug monitoring programs
- A new focus on measuring performance in health care

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Data and Statistics

[Interactive Data Systems](#)

See <https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines> for further information.

SAMHSA Priorities

Patient privacy remains a critical concern. However, equally important is the need for:

- Providers to be able to share information to improve SUD patient treatment
- SUD patients to benefit from integrated care
- Patients, providers, and the overall health system to benefit from use of new technologies and approaches (e.g., Health Information Exchanges, Electronic Health Records, and Multi-payer Claims Databases)
- Further/ongoing consideration of how to align Part 2 with HIPAA. See 2018 Final Rule: “SAMHSA plans to explore additional alignment with HIPAA and is considering additional rulemaking.”

QUESTIONS OR COMMENTS?

THANK YOU!!!

Please contact us for assistance:
PrivacyRegulations@samhsa.hhs.gov

For Further Information: <https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines>