

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

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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.

Confidentiality of SUD Records: Statute and Regulation

- Congress noted in 1970s discrimination associated with substance use disorders (SUDs) and fear of prosecution deterring people from entering treatment
- At that time most SUD treatment provided by specialty providers
- Authorizing statute for confidentiality of SUD patient records regulations intended to ensure an individual's right to privacy and confidentiality.
- Persons with SUDs continue to need appropriate protections to prevent misuse of medical information related to substance use

Confidentiality of SUD Records: Statute and Regulation

Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. §1175) and Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. §4582) authorized confidentiality for patient records

- Authorizing statute now codified at 42 U.S.C. § 290dd-2.
- Initial Part 2 regulations promulgated July 1, 1975.
- Substantive revisions: 1987, 2017, 2018.

Statute: 42 U.S.C. § 290dd-2

42 U.S.C. § 290dd-2 is the basis for 42 CFR Part 2 regulations, and can only be changed by Congress:

- *“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**
- May be disclosed as permitted by prior written consent of the patient
- Subject to certain exceptions/exclusions

Statute: 42 U.S.C. § 290dd-2

Exceptions to consent requirement:

- 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 evaluation 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

Statute: 42 U.S.C. § 290dd-2

- Statute does not apply to:
 - Exchange of records within the Department of Veterans Affairs or between the VA and the Uniformed Services. VA to issue regulations and coordinate with HHS
 - Reports under state law of suspected child abuse or neglect
- Penalty: Violations fined under Title 18 of US Code
- Instructs HHS Secretary to promulgate regulations
- These regulations known as “42 CFR part 2” or “part 2”
- CFR=Code of Federal Regulations

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)

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.”

Regulation: 42 CFR Part 2 Revisions

Process of revising regulations started in 2014 with SAMHSA Part 2 Listening Session –

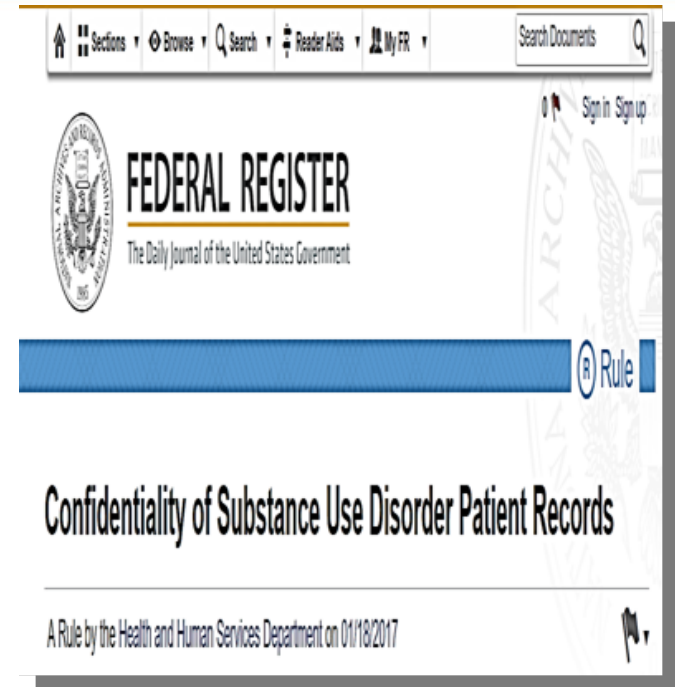
<https://www.samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations>

Notice of Proposed Rulemaking (81 Federal Register (FR) 6987) - February 9, 2016 –

<https://www.regulations.gov/document?D=HHS-OS-2016-0005-0001>

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 Jan. 3, 2018 (83 FR 239)



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

Jan. 18, 2017, Final Rule (82 FR 6052)

Among the numerous changes made to Part 2 in the rule:

- Entire rule updated to apply to electronic as well as paper exchange of patient identifying information
- Definitions (§ 2.11) – revised/added several definitions, e.g., added “Treating provider relationship,” reference to ‘substance use disorder’ instead of alcohol abuse or drug abuse
- Applicability (§ 2.12) – Restrictions apply to information received from “Other lawful holders”
- Confidentiality restrictions and safeguards (§ 2.13) – added List of Disclosures requirement

Jan. 18, 2017, Final Rule (82 FR 6052)

- Consent requirements (§ 2.31) – e.g., permits a general designation in the “To Whom” section of the consent
- Medical emergencies (§ 2.51) – Revised consistent with statutory language
- Research (§ 2.52) – E.g., more closely aligned with HIPAA and the Common Rule
- Audit and evaluation (§ 2.53) – Permits audits and evaluations to meet certain CMS requirements

Jan. 3, 2018: Final Rule (Based on 2017 SNPRM)

EFFECTIVE FEBRUARY 2, 2018

The screenshot shows the top navigation bar of the Federal Register website with links for Home, Sections, Browse, Search, Reader Aids, and My FR. A search box labeled 'Search Documents' is on the right. Below the navigation bar is the Federal Register logo and the text 'FEDERAL REGISTER The Daily Journal of the United States Government'. A blue horizontal bar contains a 'Rule' icon. The main title of the document is 'Confidentiality of Substance Use Disorder Patient Records', followed by the text 'A Rule by the Health and Human Services Department on 01/03/2018'.

<https://www.gpo.gov/fdsys/pkg/FR-2018-01-03/pdf/2017-28400.pdf>

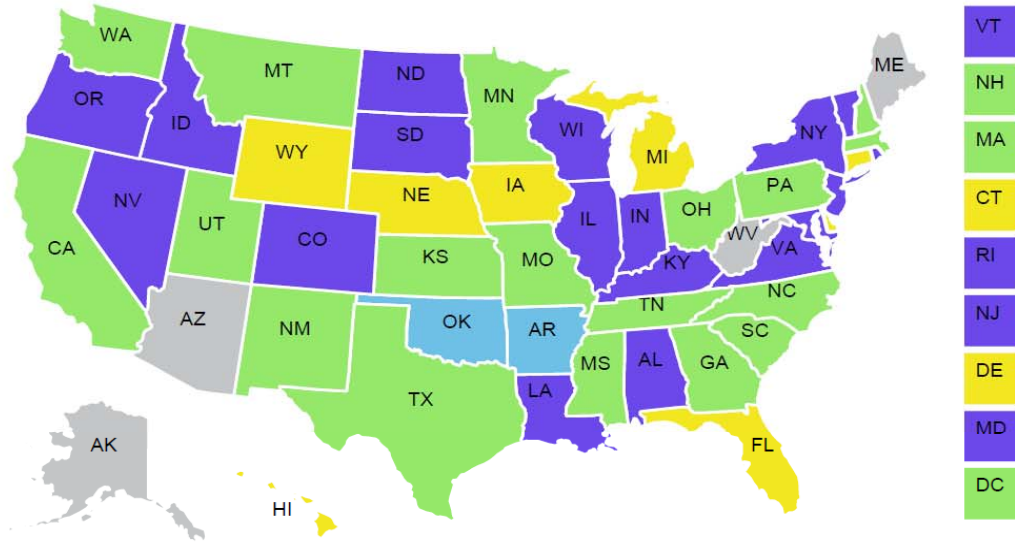
Jan. 3, 2018: Final Rule (Based on 2017 SNPRM)

- Permit additional disclosures of patient identifying information by lawful holders to contractors, subcontractors and legal representatives with initial patient consent, to facilitate payment and healthcare operations such as claims management, quality assessment, and patient safety activities. (Must include contract/subcontract provisions about Part 2).
- Permit additional disclosures of Part 2 patient identifying information by lawful holders to certain contractors, subcontractors, and legal representatives for the purpose of conducting an audit or evaluation
- Assist users of electronic health records (EHRs) by permitting use of an abbreviated notice of prohibition on re-disclosure more easily accommodated in EHR text fields.

Medical Privacy

- Substance use disorder patient records and information may be subject to HIPAA, Part 2, *and* state laws (and other requirements)
- Part 2 (§ 2.20) does not preempt more stringent state laws
- If both HIPAA and Part 2 apply, follow the law that is more stringent
- NASMHPD 2016 Report: “...[S]tates almost universally either defer within their own laws to 42 CFR Part 2 and HIPAA regulations by incorporation [or] by reference, or have laws less comprehensive than the restrictions on disclosure imposed by 42 CFR Part 2 and HIPAA” (<https://www.nasmhpd.org/content/tac-assessment-working-paper-2016-compilation-state-behavioral-health-patient-treatment>).

State laws and Substance Use Disorder Records- Disclosure **with** Patient Consent



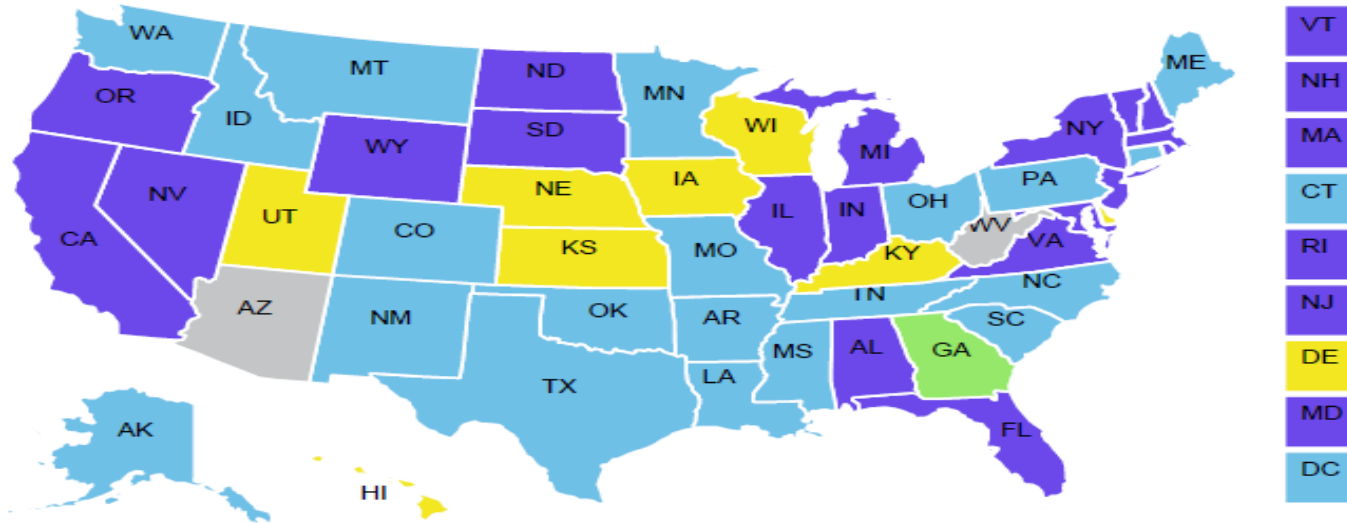
Source:
Healthinfollow.org

State Consent Requirements for Disclosure of Records as Compared with Part 2

- Stricter than Part 2
- Same as Part 2
- Less strict than Part 2/Part 2 Controls
- No law specifying consent requirements; Part 2 controls
- State has separate requirements for entities not governed by Part 2

State laws and Substance Use Disorder Records- Disclosure **without** Patient Consent

[Last Updated 10/24/2013]



Source:
Healthinfollow.org

State Disclosure Without Consent Requirements Compared with Part 2

- Light Blue: Stricter than Part 2
- Dark Blue/Purple: Same as Part 2
- Light Green: Less strict than Part 2/Part 2 Controls
- Grey: No law specifying disclosure requirements; Part 2 applies
- Yellow: State has separate requirements for entities not governed by Part 2

21st Century Cures Act

- SEC. 11002. CONFIDENTIALITY OF RECORDS.
- **Not later than 1 year after the date on which the Secretary of Health and Human Services (in this title referred to as the ``Secretary'') first finalizes regulations updating part 2 of title 42, Code of Federal Regulations, relating to confidentiality of alcohol and drug abuse patient records, after the date of enactment of this Act, the Secretary shall convene relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy**

42 CFR Part 2 Listening Session, Jan. 31, 2018

The screenshot shows a web browser displaying the Federal Register website. The URL in the address bar is <https://www.federalregister.gov/documents/2018/01/09/2018-00150/confidentiality-of-substance-use-disorder-p>. The page features the Federal Register logo and the text "The Daily Journal of the United States Government". A blue banner at the top right says "Notice". Below the banner, the title of the document is "Confidentiality of Substance Use Disorder Patient Records" with a subtitle "A Notice by the Substance Abuse and Mental Health Services Administration on 01/09/2018". The document content is divided into two columns. The left column contains the following sections: "AGENCY: Substance Abuse and Mental Health Services Administration, HHS.", "ACTION: Notice of public meeting.", "SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) announces that it will hold a public listening session on Wednesday, January 31, 2018, to solicit information concerning the Confidentiality of Substance Use Disorder Patient Records regulations as required by Section 11002 of the 21st Century Cures Act. The listening session will provide an opportunity for the public to provide input to SAMHSA concerning the effect of part 2 on 'patient care, health outcomes, and patient privacy' as well as potential regulatory changes and future subregulatory guidance.", "DATES: The listening session will be held on Wednesday, January 31, 2018, from 8:30 a.m. (Eastern) to 1:00 p.m. (Eastern).", and "FOR FURTHER INFORMATION CONTACT:". The right column contains "DOCUMENT DETAILS" with the following information: "Printed version: PDF", "Publication Date: 01/09/2018", "Agencies: Substance Abuse and Mental Health Services Administration", "Dates: The listening session will be held on Wednesday, January 31, 2018, from 8:30 a.m. (Eastern) to 1:00 p.m. (Eastern).", "Document Type: Notice", "Document Citation: 83 FR 1041", "Page: 1041-1042 (2 pages)", and "Document Number: 2018-00150".

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

Part 2 Listening Session, 2018

- 86 in-person participants at SAMHSA building in Rockville, MD, and roughly 1200 online (phone/Web conference). Comments accepted in-person, via phone and in writing to PrivacyRegulations@samhsa.hhs.gov through Feb. 28, 2018.
- Comments emphasized aligning Part 2 and HIPAA, further steps to foster care coordination and integrated care, need to respect stigma of SUD and impact on patients of privacy and confidentiality violations, need for more subregulatory guidance/technical assistance, electronic health records and consent implementation challenges.
- Sample comment: “Anything that you can do to better align Part 2 specifically with HIPAA is very much appreciated, and we urge administration to implement regulations that can bring us to that and really allow us to integrate care in the way that we would love to for the benefit of our patients.”-American Psychiatric Association
- Sample comment: “[U]nfortunately the current status of the CFR 42 [regulations] leave us in the position of not being able to communicate with providers after somebody has left or completed a treatment program, which leaves them at high risk, and one of the issues that I think this highlights in the behavioral health system is, again, the issue of discrimination against people who are seeking treatment and who need continuing care.”- Hartford, CT, health system representative

Part 2 Listening Session, 2018

- Sample comment: “Part 2 and the final regulations published in the past year all rely on the receipt of patient consent, which can often be impossible or difficult to obtain, and in those instances, the care cannot be coordinated, even though that would be in the consumer’s best interest.”-Association for Behavioral Health and Wellness (ABHW)
- Sample comment: “Remember that fear of exposure that is the centerpiece of the treatment context and why [...] privacy is so critical. Every time we weaken confidentiality, we weaken that hope of recovery. The opioid epidemic has revived some historical attitudes criminalizing substance use disorder with talk of involuntary commitment. You know, we are now trying so hard to get a hold of folks and support them, but now more than ever, these protections are needed for the treatment environment so there’s a safe place for someone to begin their recovery...”- Licensed Psychologist
- SAMHSA will review all listening session comments, including written comments.
- Transcript, SAMHSA introductory PowerPoint and audio recording to be posted online at <https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines>

42 CFR PART 2 CURRENT STATUS

- 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
- 2018 publication of further 42 CFR Part 2 updates/Final Rule based on SNPRM.
 - Hosted listening session on January 31st 2018 to receive input on implementation of the 2017 Final Rule and reaction to final rule on SNPRM.
 - Tribal Consultation (postponed due to government shutdown, to be rescheduled)
 - Subregulatory guidance

SAMHSA Priorities

- In 2018, 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 consideration of the benefits of aligning Part 2 with HIPAA. See 2018 Final Rule: “SAMHSA plans to explore additional alignment with HIPAA and is considering additional rulemaking”

SAMHSA Priorities

Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, M.D., Ph.D.

“It is critical that we keep in mind that we aim to protect the rights of individuals with substance use disorders, their rights to privacy, but also the rights to high-quality care in a way no different than for others without substance use disorders seeking treatment. To do less under the assumption of a special need for privacy is itself discriminatory and assures those living with substance use disorders a lower standard of care. My personal view is that we reinforce stigma by making such delineations.”

-Comments at SAMHSA Jan. 31, 2018, Part 2 Listening Session

QUESTIONS OR COMMENTS?

THANK YOU!!!

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

The screenshot displays the SAMHSA website interface. At the top, the SAMHSA logo is on the left, and navigation links for Home, Newsroom, Site Map, and Contact Us are on the right. A search bar is located below the logo. Social media icons for Facebook, Twitter, YouTube, and LinkedIn are also present. A red navigation bar contains links for Find Help & Treatment, Topics, Programs & Campaigns, Grants, Data, About Us, and Publications. The breadcrumb trail reads: About Us > Who We Are > Laws and Regulations > Confidentiality Regulations FAQs. The main heading is 'Substance Abuse Confidentiality Regulations'. Below it, a sub-heading reads 'Frequently Asked Questions (FAQs) regarding the Substance Abuse Confidentiality Regulations.' The main content area is titled 'Applying the Substance Abuse Confidentiality Regulations' and includes the text: 'Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, 42 CFR Part 2 (REVISED)'. A disclaimer follows: 'These Frequently Asked Questions (FAQs) are for information purposes only and are not intended as legal advice. Specific questions regarding compliance with federal law should be referred to your legal counsel. State laws may also apply.'