

LEGAL ACTION CENTER
Confidentiality & Communication
An Abridged and Updated Guide to 42 CFR Part 2 and HIPAA Fundamentals
(8th Edition, 2nd Revision May 2021)

PREFACE TO THE 8th EDITION (2nd Revision)

This newly revised edition of *Confidentiality and Communication* offers an updated overview of the federal privacy protections for substance use disorder (SUD) treatment records, including the Health Insurance Portability and Accountability Act (HIPAA) and the confidentiality law for SUD treatment records, 42 USC § 290dd-2, and its implementing regulations, 42 CFR Part 2 (Part 2).

Federal health privacy law is in a period of ongoing and unprecedented change. In July and December 2020, the Substance Abuse and Mental Health Services Administration (SAMHSA) released two sets of changes to Part 2. SAMHSA characterized these changes as *transitional*, because Part 2 will need additional amendments to implement the Coronavirus Aid, Relief, and Economic Security (CARES) Act, enacted on March 27, 2020.¹ The CARES Act amended Part 2's underlying statute, and will go into effect once SAMHSA and the Office for Civil Rights (OCR) update the regulations.² **This revised edition of the book covers all the 2020 changes and flags the areas subject to change in a future rulemaking implementing the CARES Act changes.**

SAMHSA has also issued guidance in response to the COVID-19 pandemic and the increased need for telehealth delivery of SUD services.³ **This revised edition also covers the recent COVID-19 guidance from SAMHSA.**

All these recent changes follow on the heels of multiple revisions to the Part 2 regulations. In 2017, SAMHSA amended Part 2 for the first time in 30 years, significantly modernizing the confidentiality regulations.⁴ SAMHSA further amended Part 2 in 2018.⁵ **All the 2017 and 2018 changes to Part 2 are flagged and discussed throughout this revised edition.**

In addition to the ongoing changes to Part 2, OCR proposed amendments to the HIPAA Privacy Rule in January 2021⁶ and the Office of the National Coordinator (ONC) finalized the Cures Act Information Blocking Rule, effective April 2021.⁷ Although the proposed changes to HIPAA do not directly impact the confidentiality of Part 2 records, they will still impact the confidentiality of substance use information in patients' general medical files if the information is not protected by Part 2; the proposed changes would loosen a number of HIPAA's restrictions against sharing protected health information.⁸ Similarly, the Information Blocking Rule does not change the confidentiality protections for Part 2 records, but will still impact the confidentiality of non-Part 2 records with substance use information, and will likely impact some aspects of Part 2 programs' operations; the Information Blocking Rule prohibits, with some exceptions, healthcare providers from "blocking" access, exchange, or use of electronic health information (EHI).⁹

The revised edition is intended to help SUD treatment programs, patients, and the larger system of healthcare providers, insurance plans, and social service programs understand the current landscape of patients' privacy rights and anticipate proposed changes. The book presents the current legal standard at the time of publication (May 2021), highlights areas that changed in 2017, 2018, and 2020, and flags issues that are subject to change once HHS implements the CARES Act changes (2021 or later).

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Given the constant evolution of the federal privacy landscape, this edition of *Confidentiality and Communication* is an abridged version of previous editions: it covers the information SUD treatment providers and others need to know to comply with the new changes to Part 2, including all the major elements of the federal health privacy laws and their application to SUD treatment programs. Once HHS finalizes new regulations implementing the CARES Act changes, we will publish a new, expanded edition featuring the new law and an in-depth analysis regarding collaboration between systems and health information technology.

As always, *Confidentiality and Communication* emphasizes both the legal and practical considerations for providers and their duty to maintain patient confidentiality. It builds on Legal Action Center's 40-year experience interpreting the privacy laws for SUD treatment records. We hope this edition serves as a useful resource during a time of extraordinary change, so that providers can continue to offer their important services while secure in their understanding of current law.

May 15, 2021

¹ Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3221, Pub. L. No. 116-136 (2020), *available at* <https://www.congress.gov/bill/116th-congress/house-bill/748/text>.

² SAMHSA, Statement on 42 CFR Part 2 Amendments Process (April 9, 2021), <https://www.samhsa.gov/newsroom/statements/2021/42-cfr-part-2-amendments-process>.

³ SAMHSA, COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance (2020), <https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf>.

⁴ Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052 (Jan. 8, 2017) (to be codified at 42 CFR Part 2), *available at* <https://www.govinfo.gov/content/pkg/FR-2017-01-18/pdf/2017-00719.pdf>.

⁵ Confidentiality of Substance Use Disorder Patient Records, 83 Fed. Reg. 239 (Jan. 3, 2018) (to be codified at 42 CFR Part 2), *available at* <https://www.govinfo.gov/content/pkg/FR-2018-01-03/pdf/2017-28400.pdf>.

⁶ Proposed Modification to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6446 (proposed Jan. 21, 2021), *available at* <https://www.federalregister.gov/documents/2021/01/21/2020-27157/proposed-modifications-to-the-hipaa-privacy-rule-to-support-and-remove-barriers-to-coordinated-care>.

⁷ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642 (June 30, 2020) (to be codified at 45 CFR Parts 170, 171), *available at* <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>. For effective dates, see ONC, New Applicability Dates Included in ONC Interim Final Rule (Oct. 2020), https://www.healthit.gov/cures/sites/default/files/cures/2020-10/Highlighted_Regulatory_Dates_All.pdf.

⁸ Legal Action Center, Comments on Notice of Proposed Rulemaking (May 6, 2021), <https://www.lac.org/assets/files/LAC-HIPAA-NPRM-Comments-5-6-21-submitted.pdf>.

⁹ For more information about the ONC Cures Act Final Rule on Information Blocking and its implications for Part 2 programs, see the Center of Excellence for Protected Health Information for forthcoming resources, www.coephi.org.