



**AHI Leadership Summit and
North Country Telehealth Conference**

Compliance with Part 2 Regulations in Telemedicine

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Rivkin Radler LLP
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Overview

Part 2 Regulations

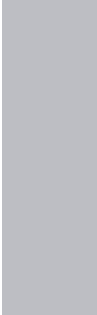
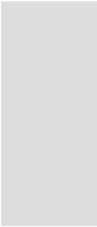
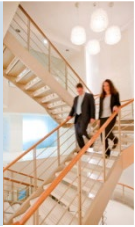
- General Requirements, Applicable Entities, and Covered Information
- Consent Forms
- Differences with HIPAA
- Exceptions and Disclosures that do not need consent

Telemedicine

- Confidentiality
- COVID Pandemic
- Prescription Requirements

Recent Changes

- HHS Fact Sheet
- CARES Act
- SAMHSA Guidance
- Lessons



Part 2 Regulations



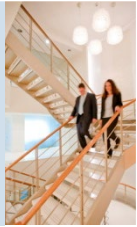
General Requirements

- Goal to protect patients from discrimination
- Prohibited from disclosing information that would identify patient as having a substance abuse disorder unless consent or court order
- Very specific consent contents
- Required to resist compelled disclosure, absent a consent or order
- Specific contents of court order, after having a hearing to allow patient opportunity to object
- Prohibition on re-disclosure



Applicable Entities

- “Program” means “which in whole or in part holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment.” 42 C.F.R. § 2.11.
- Excludes hospital emergency departments and general medical or surgical wards. 85 Fed. Reg. 42986-01, 42995 (2020).





Covered Information

Records means any information, whether recorded or not, created by, received, or acquired by a Part 2 program relating to a patient (e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts). 42 CFR § 2.11

- Covers verbal information

Substance use disorder means a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use. 42 CFR § 2.11

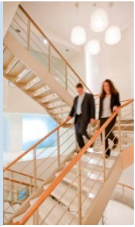


Differences With HIPAA

- More restrictive than HIPAA
 - HIPAA has more exceptions
- Specific to substance abuse disorder records, as opposed to PHI
- Under HIPAA, patient information is permitted to be used and disclosed for treatment, payment, and health care operations unless the patient opts-out
 - Part 2 regulations requires express written authorization
- Part 2 regulations provide additional protection of patient SUD records in civil legal proceedings
 - Requires a special court order and a hearing

Penalty for Violation

- Criminal fine is the exclusive remedy for a violation
- Reports of violations to go the United States Attorney and Substance Abuse and Mental Health Services Administration
- The United States Attorney General prosecutes violations
 - No private right of action





Consent Forms

Under the Part 2 regulations, consent forms must have:

- the name of the patient,
- the names of individuals/entities permitted to disclose or receive patient identifying information,
- the amount and kind of the information being disclosed, and the purpose of the disclosure
- duration of consent

OASAS templates





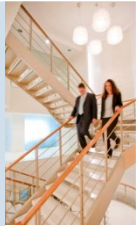
Exceptions (42 CFR § 2.12(c))

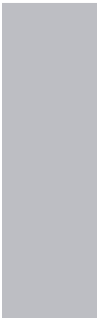
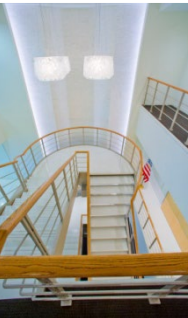
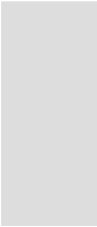
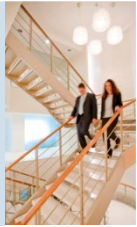
- 1) Department of Veterans Affairs
- 2) Armed Forces
- 3) Communication between Part 2 Program and an entity with direct administrative control over Part 2 Program
- 4) Qualified Service Organizations
- 5) Crimes on Part 2 Program premises or against Part 2 Program personnel
- 6) Reports of suspected child abuse and neglect



Disclosures That Do Not Need Consent

- Medical emergencies (42 CFR § 2.51)
- Research (42 CFR § 2.52)
- Audit and Evaluation (42 CFR § 2.53)
 - Medicare, Medicaid and CHIP





Telemedicine



Confidentiality

- Communication with patients regarding office practices
- Metadata
- Hackability of devices
 - Patient verification
 - Reliability of vendor
 - Public internet
- Location of confidential conversations for both
- Ability to obtain consent
 - Lack of access to technology (providers and patients)
- Documentation and record keeping
 - Secure system and not personal devices
- Special sensitivity of patient information
 - Stigma and prejudice



Substance Abuse Providers and COVID Pandemic

COVID Pandemic

- Offices closing
- Difficulties in obtaining consent
- Inability to access or transfer records
- Staffing
- Limiting exposure



Providers were using telemedicine to provide care to patients but added challenges of being remote from facility during state of emergency



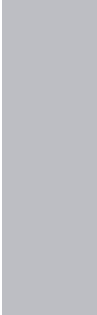
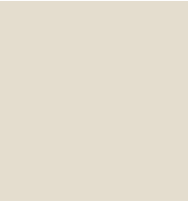
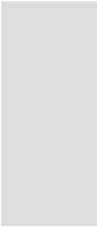
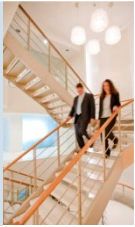
Prescription Requirements

1) Take Home Medications

- SAMHSA exemption to face-to-face encounter for opioid treatment programs treated with buprenorphine during pandemic

2) Controlled Substances

- DEA requirements during pandemic
 - Real-time, audio-visual, two-way interactive communication system
 - Must be authorized to dispense in state the practitioner is registered with DEA and dispensing state



Recent Changes



HHS Fact Sheet in July 2020

- Records by non-Part 2 providers are not covered under Part 2 unless received from a Part 2 Program
- When a patient sends a message to personal device of Part 2 program employee, the employee can sanitize a personal device by deleting message
- Patient can consent to disclosure to an entity without naming a specific individual
- Opioid treatment programs can enroll in state prescription drug monitoring programs and report information and non-opioid treatment programs and non-central registry can submit query to central registry to determine if patients are already receiving treatment



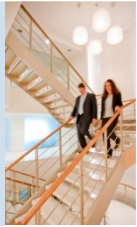
CARES Act

- For disclosure of Part 2 Records occurring on or after March 27, 2021:
 - Allows for the use or disclosure of records for purposes of treatment, payment, and health care operations with written consent
 - Same exception in HIPAA
 - Allows for disclosure of deidentified records to public health authorities without consent



SAMHSA Guidance

- **“We emphasize that, under the medical emergency exception, providers make their own determinations whether a bona fide medical emergency exists for purposes of providing needed treatment to patients.”**
- Allows re-disclosure to medical personnel for treatment of emergency





Bona Fide Medical Emergency

- “the situation in which an individual requires **urgent** clinical care to treat an **immediately** life-threatening condition (including, but not limited to, heart attack, stroke, overdose), and in which it is infeasible to seek the individual's consent to release of relevant, sensitive SUD records prior to administering potentially life-saving care.” 85 Fed. Reg. 42986-10, 4318 (2020).





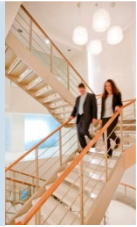
Bona Fide Medical Emergency Explained

- Any health care provider treating patient can make the medical emergency determination
- Includes national or major disasters when a state of emergency is declared
 - SAMHSA explicitly stated this exception would **not** apply prior to declaration
- Exception no longer applies when operations resume
 - SAMHSA explicitly stated this exception would **not** apply prior to closing



Gray Areas

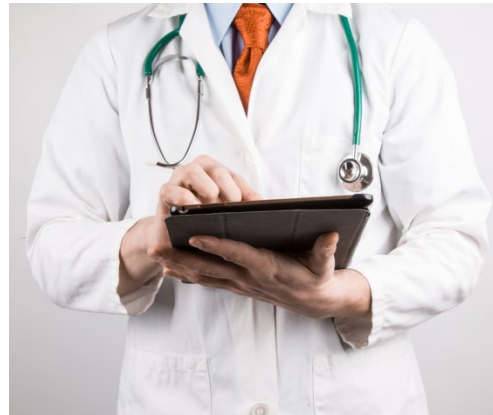
- Prior to becoming an urgent care situation
- Immediate life-threatening condition
 - Likely going to a hospital, not a Part 2 facility
- Prior to closing and after reopening during state of emergency
- Facility specific emergency
 - Example: weather

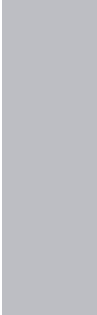
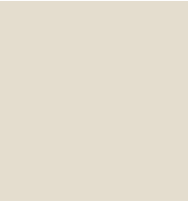
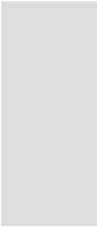
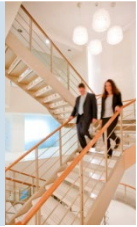




Lessons

- Create a backup plan
- Discuss telemedicine with patients ahead of time
- Discuss telemedicine practices with staff ahead of time
- Think ahead when obtaining consent!
 - Consider emergency situations and telemedicine





Questions?



For More Information



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Resources

- 42 CFR Part 2
- *Giroux v. Bear*, 2017 WL 1082396 (D. S.D. 2017).
- *State v. Dalton*, 147 N.E.3d 1205 (Ohio 2019).
- 85 Fed. Reg. 42986-01
- Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule, HHS.gov (July, 13, 2020)
<https://www.hhs.gov/about/news/2020/07/13/fact-sheet-samhsa-42-cfr-part-2-revised-rule.html>
- <https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf>
- Use of Telemedicine While Providing Medication Assisted Treatment (MAT), DEA (May, 15, 2018),
https://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/telemedicine-dea-guidance.pdf
- Caring for Patients During COVID-19 Pandemic, American Society of Addiction Medicine,
https://www.asam.org/docs/default-source/covid-19/telehealth-guidance.pdf?sfvrsn=9c6e53c2_4
- CONGRESSIONAL RESEARCH SERVICE, *Selected Health Provisions in Title III of the CARES Act* (P.L.116-136) 65-66.
- Telehealth Best Practices for Behavioral Health Providers During the COVID-19 Pandemic, NYC Department of Health (June 16, 2020)
<https://www1.nyc.gov/assets/doh/downloads/pdf/imm/covid-19-provider-behavioral-telehealth.pdf>