SAMHSA 42 CFR Part 2 Revised Rule

January 19, 2021
About The HITEQ Center

The HITEQ Center is a HRSA-funded National Training and Technical Assistance Partner (NTTAPs) that collaborates with HRSA partners including Health Center Controlled Networks, Primary Care Associations and other NTTAPs to engage health centers in the optimization of health IT to address key health center needs through:

- A **national website** ([www.hiteqcenter.org](http://www.hiteqcenter.org)) with health center-focused resources, toolkits, training, and a calendar of related events.
- Learning **collaboratives**, remote **trainings**, and on-demand **technical assistance** on key topic areas.

**HITEQ Topic Areas**

- Access to comprehensive care using health IT and telehealth
- Privacy and security
- Advancing interoperability
- Electronic patient engagement
- Readiness for value based care
- Using health IT and telehealth to improve Clinical quality and Health equity
- Using health IT or telehealth to address emerging issues: behavioral health, HIV prevention, and emergency preparedness

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SAMHSA 42 CFR Part 2 Revised

Key Points for Health Centers on Rule Changes, What they Mean and Health IT Considerations

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She has practiced law for over 30 years, most recently serving as Legal Counsel to New Hampshire Governor Maggie Hassan and her senior health care policy advisor, working with the Governor on initiatives to expand access to health, mental health and substance use disorder services for New Hampshire citizens. Lucy is an experienced New Hampshire health care and regulatory attorney. Previously a shareholder in the firm of Rath, Young and Pignatelli, P.C., and Chair of the firm’s Healthcare Practice Group, Lucy assisted providers and businesses navigate the changing health care environment. Prior to private practice, Lucy served as an Assistant Attorney General in the New Hampshire Department of Justice and began her practice in the San Francisco offices of Brobeck, Phleger and Harrison.
Lauren LaRochelle joined the Institute for Health Policy and Practice as a Health Law and Policy Senior Associate in January 2019. Lauren provides support across various projects in the Health Law and Policy focal group. Prior to joining IHPP, she served as an Assistant Attorney General in the Office of the Maine Attorney General advising various professional licensing boards. She also clerked for the Maine Supreme Judicial Court.

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Agenda: Substance Use Disorder (SUD) Confidentiality Primer

42 CFR PART 2 BASICS AND UPDATES

TELEHEALTH AND SUD PRIVACY
Goals for Today

Reminder about basic 42 CFR Part 2 issues for health centers.

Update on important changes in final 42 CFR Part 2 regulation:
• The Substance Abuse and Mental Health Services Administration (SAMHSA) released a final rule on July 13, effective August 14, 2020

Highlight future changes coming through CARES Act 2020 amendments to 42 CFR Part 2’s enabling legislation.
• CARES Act amendments require implementing regulations that will not be published prior to March 27, 2021.

Highlight rule, discuss practice implication, respond to questions.
The Confidentiality of Substance Use Patient Records – 42 CFR Part 2

Who Governs?
The Substance Abuse and Mental Health Services Administration, Department of HHS.

What?
The protection of patient records created by federally funded programs for the treatment of substance use disorder (SUD).

Why?
Because persons with SUD may encounter significant discrimination or experience other negative consequences if their information is improperly disclosed.

How?
Help facilitate the provision of well-coordinated care while ensuring appropriate and heightened confidentiality protections for persons in treatment through Part 2 programs.
Part 2 is Just Part of the Many Privacy and Confidentiality Laws

<table>
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<tr>
<th>Jurisdiction</th>
<th>Statute or Regulation</th>
<th>Scope</th>
</tr>
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<tbody>
<tr>
<td>Federal</td>
<td>HIPAA Privacy Rules</td>
<td>Protects individually identifiable health information maintained by providers, payers and their contractors from disclosure. Heightened protections for psychotherapy notes.</td>
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<tr>
<td></td>
<td>42 CFR Part 2</td>
<td>Protects the confidentiality of substance abuse patient records from disclosure without express patient consent.</td>
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<td>FERPA</td>
<td>Protects education records</td>
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<tr>
<td>State Laws</td>
<td>Privacy of medical records</td>
<td>E.g., Medical information in the medical records in the possession of any health care provider shall be deemed to be the property of the patient</td>
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<td></td>
<td>Special rules for minors</td>
<td>E.g., Protects reports and records of treatment of minors for drug dependency as confidential</td>
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<td></td>
<td>Privacy of mental health records</td>
<td>E.g., Protects communications between mental health practitioners and patients as privileged</td>
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<td></td>
<td>Privacy of substance use treatment records</td>
<td>E.g., Protects information held by a licensed alcohol or other drug use professional performing substance use counseling services.</td>
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<tr>
<td></td>
<td>Special rules for patients in acute distress</td>
<td>E.g., Regulates disclosure of information amongst providers in the event of a mental health emergency or involuntary admission.</td>
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</table>
Is the Health Center a Part 2 Program?

A Part 2 program is:

• An individual or entity (or a unit in a general medical care facility) that holds itself out as providing and does provide SUD treatment, diagnosis or referral for treatment; or

• Medical personnel or staff in a general medical facility whose primary function is the provision of SUD services and who are identified as SUD providers; and

• Is federally “assisted” (with the exception of some Veterans’ Administration services).
Polling Questions

Do all primary care providers who prescribe controlled substances to treat substance use disorders meet the definition of a “program” under Part 2?

- Yes
- No

Is information generated by the provision of SBIRT (Screening, Brief Intervention and Referral to Treatment) services covered by Part 2?

- Yes
- No
- It depends
SAMHSA Guidance on Health Centers

• The term “general medical care facility” is not defined in 42 CFR 2.11.

• Federally qualified health centers would generally be considered “general medical care” facilities.

• Not every primary care provider who prescribes controlled substances meets the definition of a Part 2 “program.”

• Primary care providers who work in a health center would only meet Part 2’s definition of a program if:
  1) they work in an identified unit within the health center that holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment, or
  2) the primary function of the providers is alcohol or drug abuse diagnosis, treatment or referral for treatment and they are identified as providers of such services.

• In order for a Part 2 program in a health center to share information with other parts or units within the general medical care facility, administrative controls must be in place to protect Part 2 information if it is shared.
Key Questions for Health Centers

1. Which providers or programs hold themselves out as providing and do provide SUD diagnosis, treatment or referral to treatment?

2. Are any providers subject to 42 CFR Part 2 due to state regulation?
A **Part 2 patient** is any individual who has applied for or been given a diagnosis, treatment, or referral for treatment for a SUD at a Part 2 program.

“**Treatment**” means the care of a patient suffering from a SUD, a condition which is identified as having been caused by the SUD, or both, in order to reduce or eliminate the adverse effects on the patient.

**Part 2 Protected Records** include:
1) Any information that would identify a patient as a SUD patient either directly or by verification;
2) Any information about a patient created, received or acquired by a Part 2 program for the purpose of treating alcohol or drug abuse, making a diagnosis for treatment, or making a referral for that treatment;

*Unless* that person provides a written consent, or the disclosure meets another exception.
Are treatment records created by a family practice physician at a health center who does not hold herself out as a SUD provider protected by Part 2?

Treatment records created by a non-Part 2 provider in the health center based on her own patient encounters are explicitly not covered by Part 2 under the new rules – even if she occasionally prescribes medically assisted treatment for a primary care patient with a SUD.
Remind Me – Is there still a difference between HIPAA and Part 2?
YES!

HIPAA
• After a patient receives notice of the provider’s privacy policy, a covered provider may disclose health information to another covered provider without written authorization for the purposes of:
  • Treatment;
  • Payment;
  • Health care operations;
• And other purposes with a patient’s valid verbal or written authorization.

Part 2
• Unless an exception applies, a Part 2 program may only disclose health information with express written consent
  • For a specific purpose
  • To a specific entity or individual
  • (Through an information exchange with a general designation)
• With express written consent for payment and health care operations.
• Other specific purposes authorized by regulation.
Part 2 Requirements – Check List

I. Patient Records Security policies that meet the new Part 2 standards

II. Notice of privacy rights that meet Part 2 requirements

III. Compliant consent forms

IV. Non re-disclosure notices when Part 2 information disclosed with consent

IV. Qualified Service Organization Agreements when necessary
Security Polices (2.16)

Part 2 program or lawful holder of Part 2 information must have formal policies and procedures to reasonably protect against unauthorized uses and disclosures of patient identifying information.

Policies must ensure protection of paper and electronic records.

Topics of policies should include transferring records, storing records, de-identification, etc.

Should be included in health center’s general privacy policies and procedures.
**Notice to Patients** at time of admission to the Part 2 Program (2.22)

Federal law protect the confidentiality of SUD patient records!

- A general description of the limited circumstances under which a Part 2 program may acknowledge that an individual is present or disclose outside the program information identifying a patient as having or having had a SUD.
- Violation of Part 2 is a crime and suspected violations may be reported.
- Information related to patient’s commission of a crime on the premises or against personnel is not protected.
- Reports of suspected child abuse and neglect are not protected.
- A citation to the federal law and regulations and where a .
- May include summary of state law and additional consistent policies.
Patient Consent: Elements (2.31)

1) Name of the Patient
2) Names of Part 2 entities or providers making the disclosure
3) How much and what kind of information is to be disclosed including specific reference to SUD
4) “To Whom” is the disclosure being made?
5) The purpose of the disclosure
6) Right to revocation at any time going forward
7) The date, event or condition upon which the consent will expire.
Part 2 Consent - the details matter...

To Whom

• The name of the individual(s) or
• The name of the entity(ies)

...to whom disclosure will be made.
Prohibition on Re-Disclosure (2.32)

**Must Use**
Each disclosure made with the patient’s written consent must be accompanied by either the long-form or short-form notice of prohibition on re-disclosure.

**Magic Words**
“42 CFR part 2 prohibits unauthorized disclosure of these records.”
Non-Disclosure Notice –
Each disclosure with consent must be accompanied by a non-disclosure notice

Is there a disclosure of part 2 information with a consent? If YES -

OPTION 1 – long version

“This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR Part 2). The federal rules prohibit you from making any further disclosures of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with substance use disorder, except as provided at 2.12(c)(5) and 2.65.”

OPTION 2 – short version

“42 CFR part 2 prohibits unauthorized disclosure of these records”
# Health Center Basics – 42 CFR Part 2

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>ASSUMPTION</th>
<th>REMINDERS</th>
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<tbody>
<tr>
<td>Does the health center have Part 2 programs or providers?</td>
<td>If so, Part 2 applies to the identity of their patients and the patients' SUD records.</td>
<td>Remember that non-Part 2 providers can ask patients about SUD history and treatment, engage in Screening Brief Intervention &amp; Referral for Treatment without turning into a Part 2 provider or turning PHI into Part 2 records.</td>
</tr>
<tr>
<td>Does the Part 2 Program have a Notice of Privacy?</td>
<td>The Notice of Privacy Rights must include the required 42 CFR Part 2 language. (2.22)</td>
<td>Remember that the HIPAA Notice of Privacy Rights may not include the Part 2 elements, and the notice of Part 2 privacy must be provided at the time of admission to a Part 2 program (or as soon as the patient has capacity to understand).</td>
</tr>
<tr>
<td>Does the health center have compliant consent forms?</td>
<td>Part 2 consent language is different from HIPAA authorizations.</td>
<td>Remember that Part 2 does not allow disclosure of Part 2 information for purposes of treatment, payment or health care operations without a valid signed consent. Part 2 consents require identification of the Part 2 program making the disclosure and ‘how much’, ‘what kind’, ‘what purpose’, ‘to whom’, and revocation notice.</td>
</tr>
<tr>
<td>Is an HIE involved?</td>
<td>Some health centers may participate in health information exchanges</td>
<td>When participating in HIEs the consent can identify the HIE and generally designate the type of treating providers using the entity for exchange. The health center should have a QSOA with the HIE and ensure any disclosures of Part 2 information are with compliant consents.</td>
</tr>
<tr>
<td>Non-Disclosure Notice?</td>
<td>Each disclosure made with a consent must include non-disclosure notice</td>
<td>Short form – 42 CFR part 2 prohibits unauthorized disclosure of these records.</td>
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Qualified Service Organization (2.12(c)(4))

- A QSO is like a business associate – but a QSO can only disclose Part 2 information to agents or back to the Part 2 contracting provider.

- A QSO provides services to a Part 2 program, such as data processing, legal, accounting, “medical staffing or other professional services”, or population health management.

- Part 2 program can only share what’s necessary for QSO to perform services for the program.
Qualified Services Organization Example

Facts: What if a health center contracts with a practice group to provide overnight call-coverage?

If a Part 2 program at a Health Center enters into a QSOA with an overnight call-coverage provider, can the provider share information about the clients they treat overnight with the health center?

• Yes, with a valid QSOA.
• As is necessary to perform the on-call coverage services.
Example: QSOA language

Furthermore, [insert entity name]:

acknowledges that in receiving, transmitting, transporting, storing, processing, or otherwise dealing with any information received from [insert program name] identifying or otherwise relating to the patients in the [insert program name] (‘protected information’), it is fully bound by the provision of the federal regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 142, 160, 162 and 164;

agrees to resist any efforts in judicial proceedings to obtain access to the protected information except as expressly provided for in the regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, as amended;

agrees that it will not use or disclose protected health information except as permitted or required by the Agreement or by law;

agrees that, when the [insert entity name] uses, discloses, or request protected health information it will limit the use, disclosure, or request to the minimum necessary;

agrees that if the [insert entity name] enters into a contract with any agent, including a subcontractor, the agent will agree to comply with 42 C.F.R. Part 2 and HIPAA, and, if the [insert entity name] learns of a pattern or practice by the agent that is a material breach of the contract with the [insert entity name], to take reasonable steps to cure the breach or terminate the contract, if feasible;
Exceptions to 42 CFR Part 2
Prohibition on Disclosure of SUD Information
When Can Part 2 Records be Shared?

- Internal Communications
- Audit/Evaluation
- Medical Emergency
- Reporting suspected child abuse and neglect
- Court Order
- Qualified Service Organization Agreement
- No patient identifying information
- Written Consent
- Crime on program premises or against program personnel
- Research
What can health center staff share with health center administrative personnel?

• When a substance use disorder unit is part of a health center, specific information about a patient arising out of that patient’s diagnosis, treatment or referral to treatment can be exchanged without patient consent among the Part 2 program personnel and with administrative personnel who, in connection with their duties, need to know information (42 CFR § 2.12(c)(3)).
Practice Tip: Disclosures?

• Think about the disclosures made to support patients in their continuum of care.

• Is the disclosure covered by a patient consent?

• Is the disclosure made pursuant to an exception? What exception?

• Do your privacy notices cover your patient flow needs?
Final Rules and Legislative Changes

42 CFR Part 2 Final Rules – Effective August 14, 2020
CARES Act - Rules not drafted
42 CFR Part 2 Rules

Key Dates:

- **July 15, 2020**
  *Interim Part 2 Rules Published*

- **August 14, 2020**
  *Interim Part 2 Rules Effective*

- **Before March 27, 2021**
  *Additional Part 2 Rules Proposed*

- **After March 27, 2021**
  *Additional Part 2 Rules Effective*
CARES Act and Part 2


• The Final Part 2 rules were intended to facilitate well-coordinated care for patients with SUD
Summary of Final Rule Changes

- **Definitions** - Excludes certain oral communications and non-part 2 treatment records from the definition of “records.” To facilitate coordination of care activities between Part 2 programs and non-Part 2 providers.

- **Applicability** - Information about an SUD recorded by a non-part 2 is not automatically rendered a medical record subject to Part 2.

- **Segregated or Segmented records** - Non-Part 2 providers may record and segment or segregate information from paper or electronic Part 2 records received from Part 2 providers without its record becoming subject to Part 2. The segregated or segmented records remain subject to Part 2.

- **Prohibition on redisclosure** - Non-Part 2 providers do not need to redact information in non-Part 2 records and may redisclose with express consent.

- **Disclosures Permitted with Written Consent** - Disclosures for “payment and health care operations” are permitted with written consent; lists 18 qualifying activities, including care coordination and case management.

- **Consent Requirements** - A patient may consent to the disclosure of their information for operations purposes to certain entities without naming a specific individual.
Summary of Final Rule Changes, cont.

• **Disclosures to Prevent Multiple Enrollments** - Revises disclosure requirements to allow non-opioid treatment providers with a treating provider relationship to access central registries

• **Disclosures to Central Registries and PDMPs** - Opioid treatment programs may disclose dispensing and prescribing data to prescription drug monitoring programs (PDMPs), subject to patient consent and State law.

• **Medical Emergencies** - Authorizes disclosure of information to another Part 2 program or SUD treatment provider during State or Federally-declared natural and major disasters

• **Research** - Disclosures for research under Part-2 are permitted by a HIPAA-covered entity of business associated to those who are neither HIPAA covered entities, nor subject to the Common Rule

• **Audit and Evaluation** - Clarifies what activities are covered by the broad audit and evaluation exceptions

• **Undercover Agents and Informants** - Extends court-ordered placement of undercover agents to 12-months

• **Disposition of Records** - When an SUD patient sends an incidental message to the personal device of an employee of a Part 2 program, the employee may “sanitize” the device by deleting the message
<table>
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<tr>
<th>Record 2.11</th>
<th>Applicability 2.12(d)(2)(ii)</th>
<th>Consents (2.31)</th>
<th>Consents for payment and health care operations</th>
<th>PDMP</th>
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<tr>
<td>Definition Change to Facilitate Care Coordination</td>
<td>Change to Facilitate Care Coordination</td>
<td>“To Whom” Simplified</td>
<td>Agents and administration made easier</td>
<td>Outpatient Treatment Providers</td>
</tr>
<tr>
<td>Excludes information conveyed orally to a non-Part 2 provider for treatment purposes with a patient consent even if written down.</td>
<td>A non-part 2 treating provider may “record information about a SUD and its treatment that identifies a patient.” This is not a Part 2 record.</td>
<td>General requirement for designating recipients: Allows patients to name a person or entity to which a disclosure can be made</td>
<td>A patient consent to another entity generally for “payment and health care operations” allows entity and agents to use Part 2 information as necessary for 18 different activities.</td>
<td>Part 2 Programs are permitted to enroll in a state prescription drug monitoring program (PDMP) and report SUD medication prescribed or dispensed consistent with state law.</td>
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<tr>
<td>Means resulting medical record is not covered by Part 2</td>
<td>Part 2 records received by the non-Part 2 treating provider should be segmented, however.</td>
<td>Consent form no longer has to name a specific person at a non-treating entity.</td>
<td>Activities include “care coordination and/or case management services in support of payment or health care operations.”</td>
<td>Allows a treating provider to check a central registry to confirm the appropriateness of prescribed therapy.</td>
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“to Housing Finance Authority”
New Definition of “Record” – oral communications

Telephone call from SUD provider

A Substance Use Treatment provider treating a health center patient calls with patient consent to alert the health center PCP to the patient’s discharge from the treatment program. Health center staff writes note in primary care chart.

Rule change facilitates necessary communication about treatment between treating providers.

Are patient notes now Part 2 records?

NO! The record of the oral communication with consent does not become ‘Part 2-protected’ record merely because it’s written down. Records otherwise transmitted by a Part 2 program to health center PCP are still protected by Part 2 but may be segregated to prevent the entire medical record from special protections.
Patients can now consent to sharing Part 2 information for purposes of “payment and health care operations”.

With consent, lawful holders can disclose necessary information with their agents for such purposes.
Summary of Payment and Health Care Operations

Examples of permissible payment or health care operations activities under this section include:

• Billing, claims management, collections activities, ...related health care data processing;
• Clinical professional support services;
• Patient safety activities;
• Activities pertaining to: (i) The training of student trainees and health care professionals; (ii) The assessment of practitioner competencies; (iii) The assessment of provider or health plan performance; and/or (iv) Training of non-health care professionals;
• Accreditation, certification, licensing, or credentialing activities;
• Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits...;
• Third-party liability coverage;
• Activities related to addressing fraud, waste and/or abuse;
• Conducting or arranging for medical review, legal services, and/or auditing functions;
• Business planning and development;
• Business management and general administrative activities;
• Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
• Resolution of internal grievances;
• The sale, transfer, merger, consolidation, or dissolution of an organization;
• Determinations of eligibility or coverage and adjudication of subrogation of health benefit claims;
• Risk adjusting amounts due based on enrollee health status and demographic characteristics;
• Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
• Care coordination and/or case management services in support of payment or health care operations; and/or
• Other payment/health care operations activities not expressly prohibited in this provision.
Health Center Practice Tips – Final Rule

• Revise consents to allow for “entity(ies)” where needed to replace individual names.

• Participate in PDMPs consistent with state law.

• Review patient flow, part 2 program providers within or as part of the Health Center, and ensure appropriate record keeping practices.

• Update consents to allow for disclosures to entities for “payment and health care operations” where needed.
CARES Act Changes – 42 USC 290dd-2

• Consent still required for disclosure of SUD treatment records by a Part 2 Program.

• With a general consent, disclosures and redisclosures may be made consistent with HIPAA for treatment, payment and health care operations.

• Adopts HIPAA fines and penalties in the place of Part 2 enforcement mechanism.

• Prohibits use of SUD records in civil, criminal, legislative or administrative proceedings without a court order.

• Applies breach notification rules.

• Changes enforcement authority.
Practice Tip - CARES Act

WAIT FOR PROPOSED RULES

COMMENT ON PROPOSED RULES
Questions?
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Funded by SAMHSA, the CoE-PHI develops and disseminates resources, training, and TA for states, healthcare providers, school administrators and individuals and families to improve understanding and application of federal privacy laws and regulations, including FERPA, HIPAA, and 42 CFR Part 2, when providing and receiving treatment for SUD and mental illness.

Resources, training, technical assistance, and any other information provided through the CoE-PHI do not constitute legal advice.
### Presenters

<table>
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<th>Name</th>
<th>Title</th>
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<tr>
<td>Jacqueline Seitz, JD</td>
<td>CoE-PHI Health Privacy Lead</td>
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<tr>
<td>Caroline Waterman, MA, LRC, CRC</td>
<td>COE-PHI SUD Project Lead</td>
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<td>Christine Khaikin, JD</td>
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<td>Michael Graziano, MPA</td>
<td>CoE-PHI Project Director</td>
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Presentation Objectives

- Discuss how federal health privacy laws apply to telehealth SUD and MH services
- Describe OCR and SAMHSA guidance regarding telehealth provision during the COVID-19 pandemic
- Learn how to access resources and Technical Assistance from the CoE
Fear, shame and stigma are some of the biggest obstacles to substance use disorder treatment. Privacy protections help overcome these obstacles to care.
Telehealth During COVID-19

• Federal and State agencies have acted to facilitate the use of telehealth during the COVID-19 public health emergency

• Both OCR (HIPAA) and SAMHSA (Part 2) have issued guidance regarding privacy protections and telehealth
Poll Question #1

What methods are you currently (or considering) using to provide telehealth services?

- HIPAA-compliant video communications (e.g.; Skype for Business, Updox, Zoom Health, Webex, GoTo Meeting)
- Other video communications (e.g.; Apple FaceTime, Facebook Messenger video, Google Hangouts, Zoom, Skype)
- Encrypted text messaging
- Phone calls
- Other
Privacy Considerations for Telehealth

• How do privacy laws apply?
  – Part 2 and HIPAA do not have specific telehealth provisions

• How to protect privacy and security at:
  – Provider’s location
  – Patient’s location
HIPAA

Applies to covered entities (healthcare providers, health plans, healthcare clearinghouses) and BAs
• Protects privacy and security of general health information

Purpose: to protect health data integrity, confidentiality, and accessibility

Permits disclosures without patient consent for treatment, payment, and healthcare operations

42 CFR Part 2

Applies to SUD patient records from federally-assisted “Part 2 programs”
• Protects privacy and security of records identifying individual as seeking/receiving SUD treatment

Purpose: to encourage people to enter and remain in SUD treatment by guaranteeing confidentiality

Requires patient consent for treatment, payment, and healthcare operations, with limited exceptions
OCR Bulletin

OCR announced it will waive potential penalties for HIPAA violations arising out of good-faith use of telehealth:

• Providers may use popular video chats, like FaceTime, Messenger, Google Hangouts, Zoom, or Skype
• Providers do not need to have a BAA in place
• Does not matter whether telehealth service is directly related to COVID-19
OCR Bulletin

If possible, it is **still best practice** to use secure, HIPAA compliant services and have BAA in place

- Best way to protect patient privacy
- Guidance is temporary
- State enforcement of privacy laws still possible
Part 2 and Telehealth

• Part 2 does not have specific provisions for telehealth
• **Written consent is required** to disclose protected information, even for remote services
SAMHSA Guidance: COVID-19

**SAMHSA’s COVID-19 Part 2 Guidance** emphasizes that providers have discretion to determine whether *bona fide* medical emergency exists.
Quick Review: 42 CFR § 2.51
Medical Emergencies

Part 2 permits disclosures w/o written consent to medical personnel in order to treat a *bona fide* medical emergency

- Information may be re-disclosed for treatment purposes
- Cannot use this provision to “override” patient’s objection to a disclosure
- Part 2 program must make note in patient file regarding disclosure
Case Study #1
Part 2 and Telehealth

• Derek is a long-time patient at Sun Valley Clinic, an outpatient SUD clinic (and a Part 2 program).
• Sun Valley closed due to the COVID-19 pandemic and is referring patients to Red Hill FQHC for telehealth services to provide continuity of care.
• Derek meets with a Red Hill FQHC counselor over the phone but does not have a way to sign a written consent form authorizing his SUD clinic to share records with Red Hill FQHC.

Can the counselor access Derek’s outpatient SUD records without Derek’s written consent?
Poll Question #2

Based on the previous case study example, can the counselor access Derek’s outpatient SUD records without Derek’s written consent?

- yes
- no
- not sure
Case Study #1:
Part 2 and Telehealth

**Answer**

Yes: If the provider determines that a medical emergency exists (i.e., Derek needs SUD services and cannot get them in person due to COVID-19), then the provider can access the outpatient SUD records without written consent.

- Red Hill FQHC may also re-disclose the protected Part 2 information if necessary for *treatment purposes*.
- Sun Valley SUD clinic **must make a note of the disclosure** in Derek’s file.
Case Study #2
Part 2 and Telehealth

- Alex wants to begin treatment for Opioid Use Disorder.
- The local treatment program (a Part 2 program) is only able to provide appointments over the phone because of COVID-19.

Can the program bill Alex’s insurance without obtaining written consent authorizing the disclosure?
Poll Question #3

Based on the previous case study example, can the program bill Alex’s insurance without obtaining written consent authorizing the disclosure?

- yes
- no
- not sure
Case Study #2: Part 2 and Telehealth

**Answer**

**No**: the program needs Alex’s signed consent form; the recent SAMHSA guidance does not apply.

- Medical emergency disclosures may only be made to medical personnel – not third-party payers.
- Remember that Part 2 requires written consent to bill insurance.
Consent and Telehealth

• Part 2 allows e-signatures on consent forms, as long as state law permits.
• Consents are not needed to communicate with a patient.
• Disclosures of patient-identifying information must be accompanied by a Notice Prohibiting Redisclosure.
• Providers should obtain consent to disclose to the telehealth service if it will have access to patient information.
Key Points- Part 2 and Telehealth

Written consent is required to share Part 2 information, even for remote services.

As before, no consent is required in a medical emergency, but SAMHSA has given providers more discretion.

E-signatures and photocopied signatures are okay if state law does not prohibit.
Privacy Checklist
for Providers and Patients

✓ Password-protected device
✓ Password-protected internet
✓ If possible, encrypted communication app (e.g., Signal, WhatsApp)
✓ If not possible, make sure communication app’s privacy settings are as secure as possible
✓ Physical surroundings (minimize risk of family, roommates, or anyone else overhearing)
✓ Secure storage for physical documents
CoE-PHI Telehealth Resources

Video - Tips to Keep Your Telehealth Visit Private
ACCESSING
THE CoE-PHI
Accessing the CoE-PHI

Request TA
coephi.org/technical-assistance

Resource Library
coephi.org/resource-center

Discussing privacy protections helps the care team to provide the best possible care.
Resources

- Notice Prohibiting Redisclosure
THANK YOU!
Questions? Feedback?

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Phone: 1-844-305-7440

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  - January 27: Session 1 - Don't Block the CURES
  - February 10: Session 2 - Getting to a Common Ground
  - February 24: Session 3 - Improve Health Center Operations through Interoperability
  - March 10: Session 4 - Coordinated Care through Registries and Related Efforts
  - March 31: Session 5 - Future (and Near-Future) Visions of Data Sharing