

Substance Use Disorder Confidentiality and Updates to 42 CFR Part 2: *Phase 2*

SUD Confidentiality Rules in Practice – COVID 19, Telehealth, Hypotheticals and More

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This is Phase 2 of a two-part series - Please see Phase 1 for an introduction to 42 CFR Part 2 and recent changes!

Acknowledgment

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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.

Agenda: Substance Use Disorder (SUD) Confidentiality Primer



Telehealth and COVID
Emergency



Hypotheticals

Goals for Today

1

Consents

2

Telehealth and the COVID Emergency

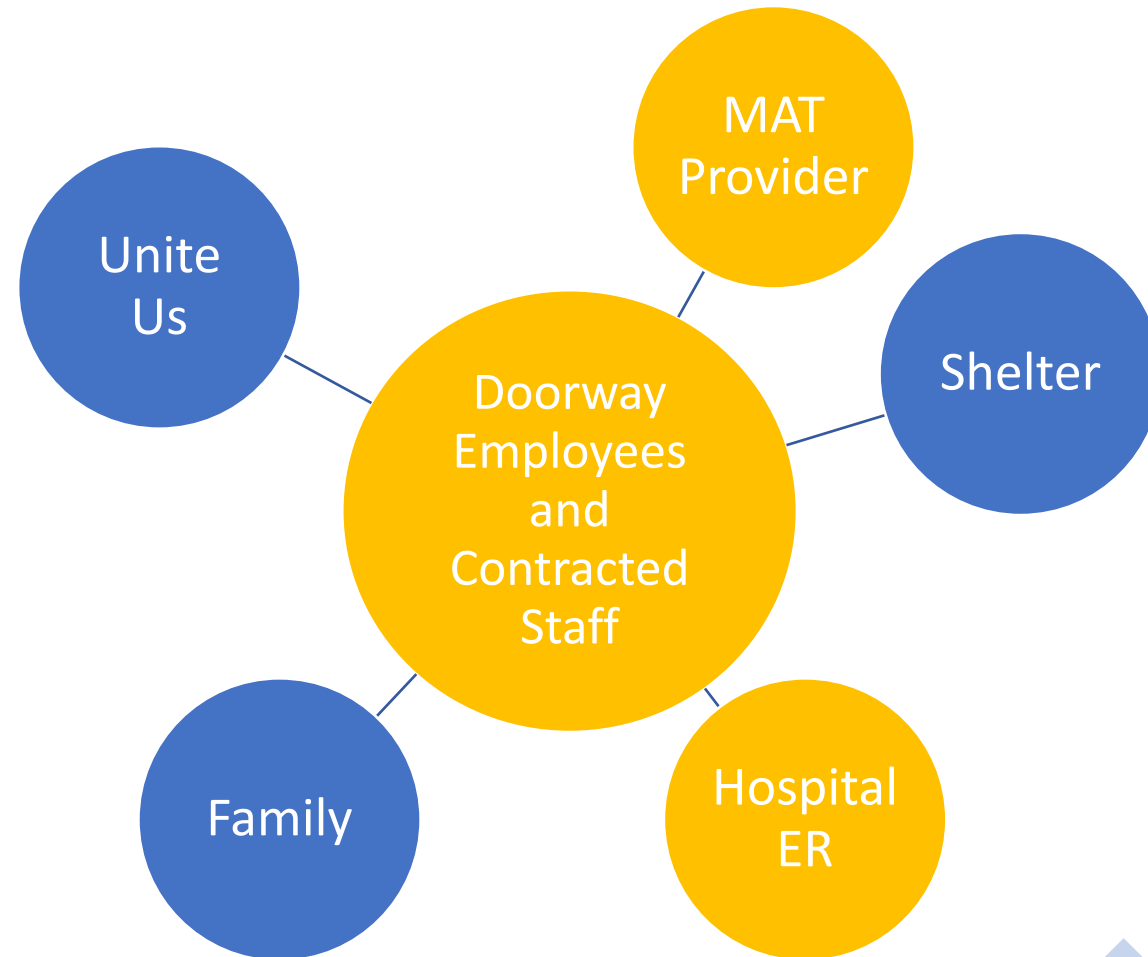
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Communicating along the Continuum of Care

4

Hypotheticals

Sharing Information while protecting privacy along the continuum of care



Part 2 is Just Part of the Many Privacy and Confidentiality Laws

Jurisdiction	Statute or Regulation	Scope
Federal	HIPAA Privacy Rules	Protects individually identifiable health information maintained by providers, payers and their contractors from disclosure. Heightened protections for psychotherapy notes.
	42 CFR Part 2	Protects the confidentiality of substance abuse patient records from disclosure without express patient consent.
	FERPA	Protects education records
New Hampshire	RSA 332-1:1	Medical information in the medical records in the possession of any health care provider shall be deemed to be the property of the patient
	RSA 318-B:12-a	Protects reports and records of treatment of minors for drug dependency as confidential
	RSA 330-A:32	Protects communications between mental health practitioners and patients as privileged
	RSA 330-C:26	Protects information held by a licensed alcohol or other drug use professional performing substance use counseling services unless permitted by 42 CFR Part 2
	RSA 135-C:19-a	Requires and/or permits disclosure of certain information by treating providers and community mental health centers to designated receiving facilities (DRFs) re: patients with SMI

42 CFR Part 2 General Rule

42 CFR Part 2 regulations (Part 2) serve to protect patient records created by federally assisted programs for the treatment of substance use disorders (SUD)

With limited exceptions, 42 CFR Part 2 requires patient consent for disclosures of protected health information even for the purposes of treatment, payment, or health care operations.

Not Every Entity is 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).



Part 2 Requirements – Check List

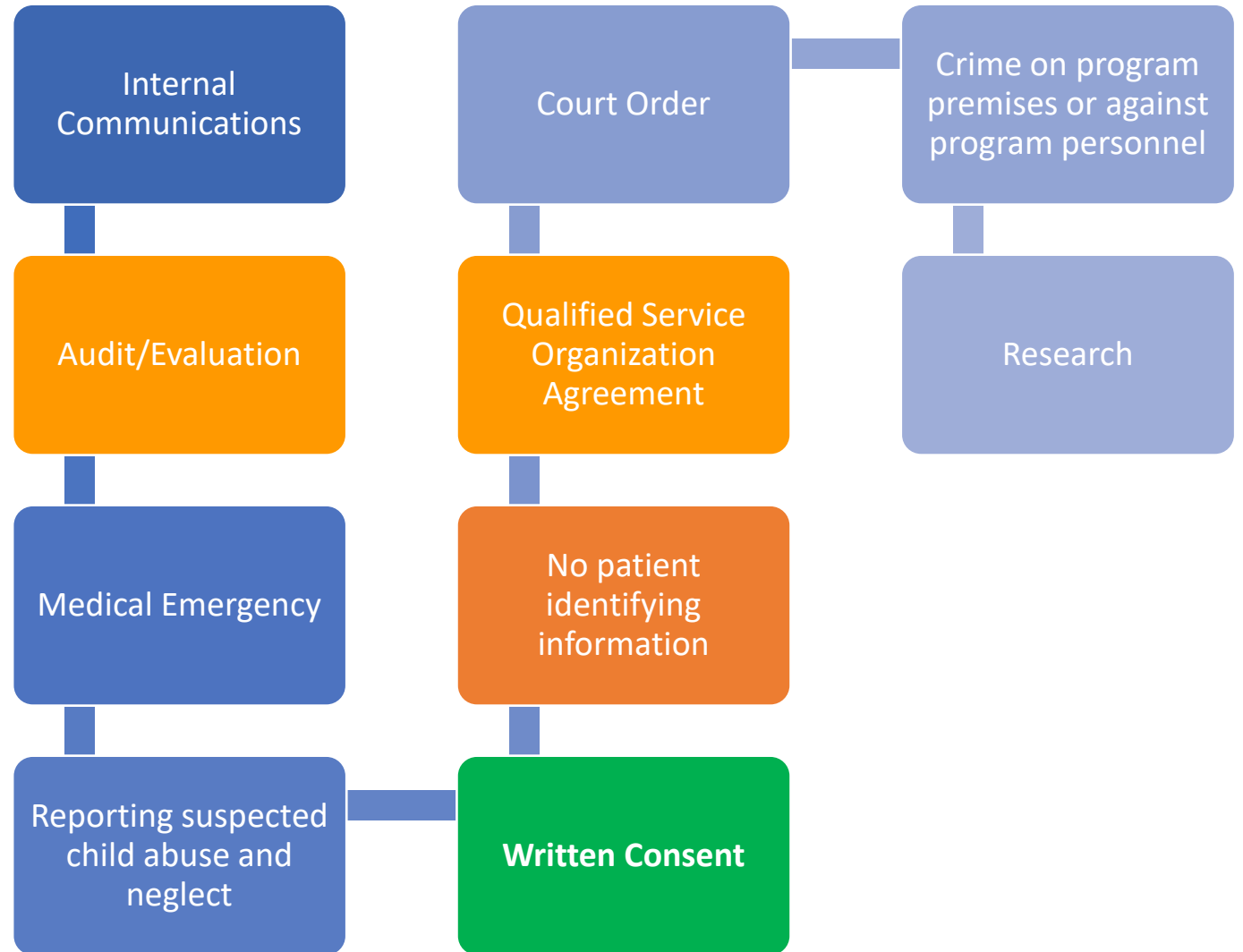
- I. Patient Records Security policies that meet the new Part 2 standards
- II. Notice of privacy rights that meet Part 2 requirements
- III. Non re-disclosure notices when Part 2 information disclosed with consent
- IV. Qualified Service Organization Agreements when necessary
- V. Compliant consent forms and disclosures pursuant to a valid exception



Consents and other Exceptions under 42 CFR Part

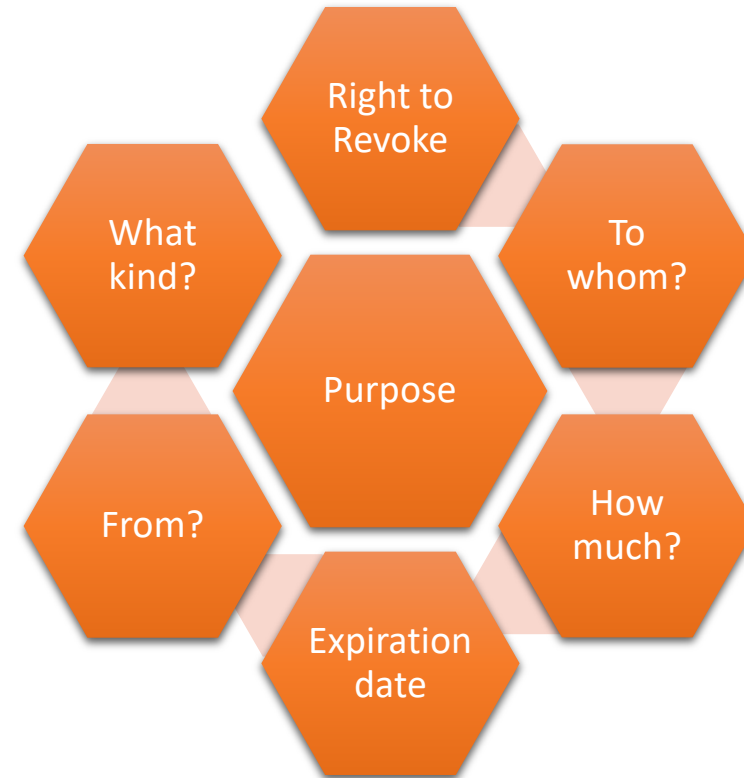


When Can Part 2 Records be Shared?

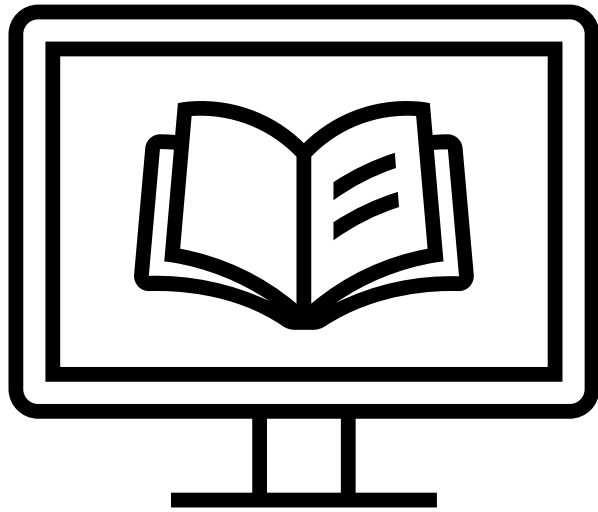


Patient Consent: Elements (2.31)

- 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.



Magic Part 2 Language



Acknowledgement of Rights

- I understand that my substance use disorder treatment records are protected under the federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), 45 C.F.R. pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I understand that if my treating providers disclose my substance use disorder treatment records pursuant to this consent, the recipient will be provided a notice of non-disclosure.

Part 2 Consent - the details matter...**NEW**

To
Whom

2021

- The name of the individual(s) or
- The name of the entity(ies)
...to whom disclosure will be made.

“From” and “To Whom” example...

I hereby authorize the disclosure of my identity and health and substance use information both orally and in writing for the purposes of my ongoing treatment, care coordination and access to needed services/supports (“my information”) as follows:			
Section II: Disclosure by			
Doorway at		Telephone Number	
Address	City	State	Zip Code
My information may be disclosed to and from the following:			
<input type="checkbox"/> Any of the participating Doorways in New Hampshire including at Concord, at Dartmouth-Hitchcock, at Androscoggin Valley Hospital, at Cheshire Medical Center, at LRH (Littleton), at LRGHealthcare, operated by Wentworth Douglas, of Greater Manchester (Catholic Medical Center, of Greater Nashua (at Southern NH Medical Center).			
<input type="checkbox"/> Entity(s):		Contact Info:	
<input type="checkbox"/> Entity(s):		Contact Info:	
<input type="checkbox"/> Entity(s):		Contact Info:	
<input type="checkbox"/> My Third Party Payer/Health insurance for payment and health care operations:			
ID:		Group #:	

What? Purpose? E.g.,

Section III	
Reason for Disclosure* [To support my ongoing treatment and coordinated care]	Health information to be disclosed*: [My identity and information about my treatment and supports]

Expiration and Understanding

Section IV	
<p>This authorization will remain in effect until revoked or shall expire on date or event specified below. I understand that I may revoke this authorization at any time by submitting written revocation in the manner specified by the disclosing entity, except to the extent that action has been taken in reliance on this authorization. If this authorization has not been revoked, it will expire on the date or completion of the event stated below. If no date or event is specified below, this authorization will expire in one year.</p>	
<p>Expiration Date or Event _____ (mm/dd/yyyy)</p>	
<ul style="list-style-type: none"> • I understand that my substance use disorder records disclosed pursuant to this Consent are protected under federal law including 42 CFR Part 2 and cannot be redisclosed without my written consent unless otherwise provided for in the regulations. Any information disclosed pursuant to this Consent other than substance use disorder records or records protected under another state law may be subject to re-disclosure by the recipient. • If I have authorized disclosure to a generally described group or class of participants in an entity which is not my treatment provider, upon my written request, I must be provided a list of entities to which my information has been disclosed pursuant to that general designation. 	
<p>Signature of Individual*</p>	<p>Date* (mm/dd/yyyy)</p>
<p>Signature of Personal Representative (if applicable)* (identify relationship to individual below)</p>	<p>Date* (mm/dd/yyyy)</p>
<p>Relationship of Personal Representative to Individual (Personal representative shall submit proof of authority to the disclosing entity)</p> <p><input type="checkbox"/> Parent <input type="checkbox"/> Legal Guardian <input type="checkbox"/> Healthcare Power of Attorney <input type="checkbox"/> Executor/Administrator <input type="checkbox"/> Other <input type="checkbox"/> N/A</p>	

Payment and Health Care Operations by Consent

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 or 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.**

Consent Language....

I authorize [my treatment team] to use, disclose and communicate both verbally and in writing my health information including substance use and mental health information to and from my health insurance company or other entity responsible for my medical bills for the purpose of eligibility, payment, audit and health care operations. *[Either insert the name of the payer or refer to your program's policy regarding notification of payment]:*

Entity:

ID No.

Group No.:

Part 2 Exception

Qualified Service Organization Agreement

Part 2

Exception

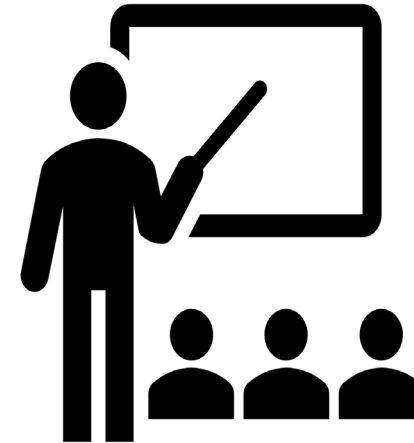
Audit/Evaluation

Doorway Practice Tip



- Simplify consent forms - only require **entity** names in “to whom” section.
- No distinction between **treating** and **non-treating** providers – entity name is sufficient
- Include space to allow for consent to disclose to entity(s) for “**payment and/or health care operations**”. Can include health insurance and/or case management organizations

- Train staff



COVID 19 and Telehealth



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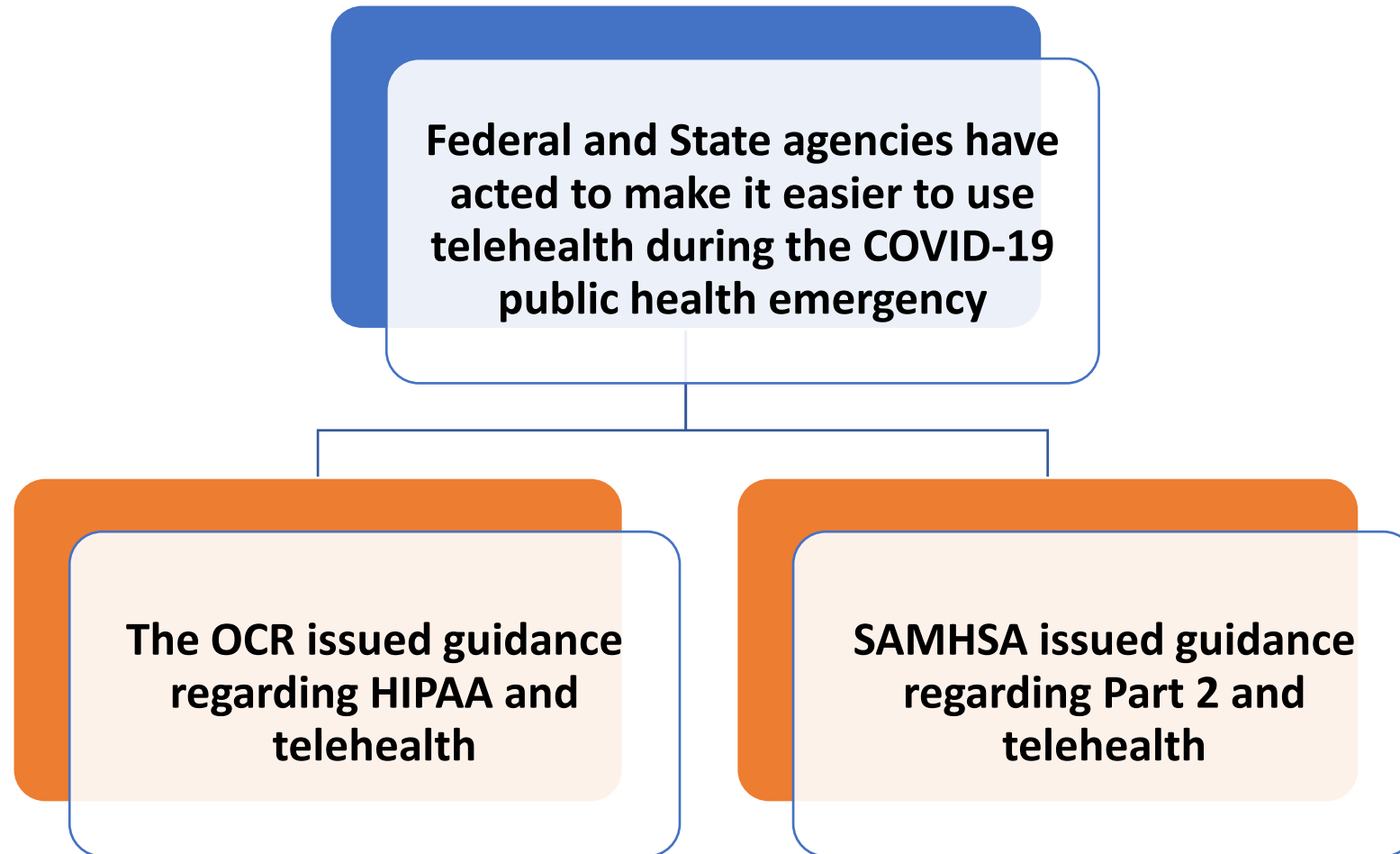
COVID 19

Federal and state orders during emergency relieved privacy restrictions to allow for new care pathways during COVID.

Federal guidance from HHS waives certain HIPAA restrictions to allow for telehealth

Federal guidance from SAMHSA clarifies emergency exception during COVID under 42 CFR Part 2

Telehealth During COVID-19



HIPAA Exceptions During Emergency

OCR Bulletin

Covered health care providers **will not be subject to penalties for** violations of the HIPAA Privacy, Security, and Breach Notification Rules that occur in **the good faith provision of telehealth** during the COVID-19 nationwide public health emergency.

Providers may use audio or video communication technology.

Telehealth may be provided for any reason, regardless of whether the telehealth service is related to the diagnosis and treatment of health conditions related to COVID-19.

Providers can use any **non-public facing** remote communication products, including:

- Popular applications like Apple FaceTime, Facebook Messenger video chat, Zoom, and Skype;
- HIPAA-compliant vendors such as Skype for Business/Microsoft Teams, Updox, VSee, Zoom for Healthcare, etc.

Providers may NOT use public facing communication applications (Facebook Live, Twitch, TikTok, etc.)

OCR will not impose penalties against providers for the lack of a BAA with video communication vendors

Part 2 Exceptions During Emergency

Under Part 2, patient identifying information may be disclosed by a part 2 program or other lawful holder to medical personnel, without patient consent, to the extent necessary to meet a **bona fide medical emergency** in which the patient's prior informed consent cannot be obtained.

SAMHSA issued guidance “to ensure that substance use disorder treatment services are uninterrupted” during COVID-19

42 CFR Part 2 prohibitions on use and disclosure of patient identifying information would not apply to the extent the provider determines that a **medical emergency exists**.

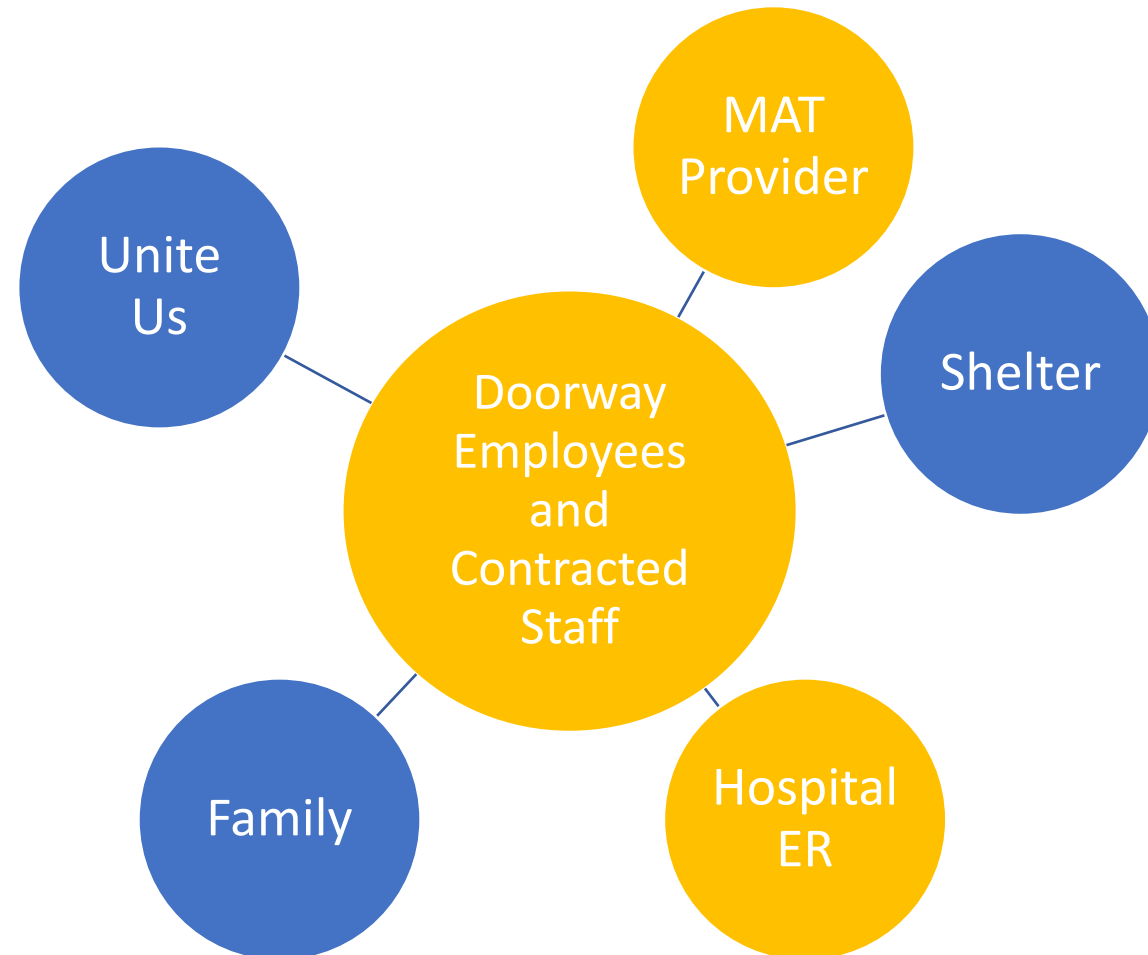
Consent and Telehealth

- Consents are still needed to for Part 2 programs to disclose Part 2 information even via telehealth
- Part 2 allows e-signatures on consent forms
- Consents are not needed to communicate with a patient.
- Disclosures of patient-identifying information must be accompanied by a [Notice Prohibiting Redisdisclosure](#)
- Providers should obtain consent to disclose to the telehealth service if it will have access to patient information.

42 CFR Part 2 in Practice – Continuum of Care




Sharing Information while protecting privacy along the continuum of care




Remember Who You Are!


Disclosure by a non-Part
2 provider: *general
privacy rules apply*



Disclosure by Part 2
provider of or about a
client: *Part 2 privacy rules
apply*



Disclosure to entity
through Unite Us or other
interoperable platform:
same as above!



Treating Provider Relationships

Claire calls and makes an appointment with a Doorway to come in for an assessment. Claire has not yet come in for her appointment. Does the Doorway have a treating provider relationship with Claire?

Treating Provider Relationships

Yes, the Doorway has a treating provider relationship with Claire.

- By making an appointment with the Doorway, Claire agreed to be assessed and diagnosed for a condition (it does not matter what type of condition).
- By scheduling Claire for an appointment, the Doorway agreed to undertake the assessment of her.
- Remember, an in-person encounter is not required to establish a treating provider relationship.

New Consent Form Requirements - entity

Alison wants her Part 2 program to coordinate transportation to and supports from Housing Helpers.

She signs a consent form authorizing certain information to be disclosed to “Housing Helpers.”

Permissible?

Quoted from the Legal Action Center Presentation, “Confidentiality & Communication of SUD Treatment Records: 42 CFR Part 2 and HIPAA” p 70 (Dec. 12, 2018 – Segment A)

Consent Form Requirements

Yes!

Under the amended rule, Alison may consent to disclosure her Part 2 treatment records to an entity (here the housing service coordinators) without naming a specific person as the recipient for the disclosure.

Modified from the Legal Action Center Presentation, “Confidentiality & Communication of SUD Treatment Records: 42 CFR Part 2 and HIPAA” p 70 (Dec. 12, 2018 – Segment A)

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.

??

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.

Rule change facilitates necessary communication about treatment between treating providers.



New Definition of “Record” – oral communications

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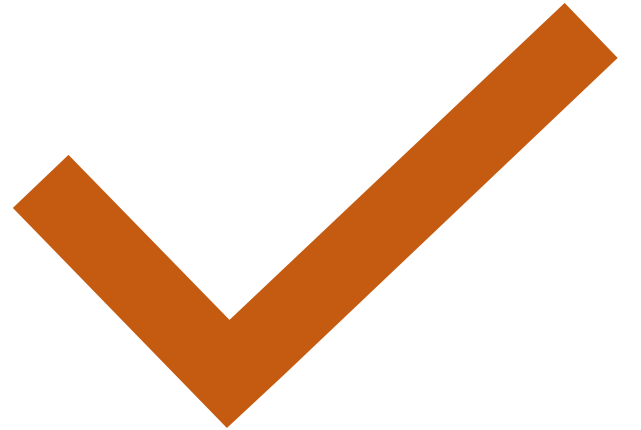
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Part 2 and Telehealth

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?

Quoted from the Legal Action Center Presentation, "Privacy Considerations for Telehealth During COVID-19" (January 19, 2021)

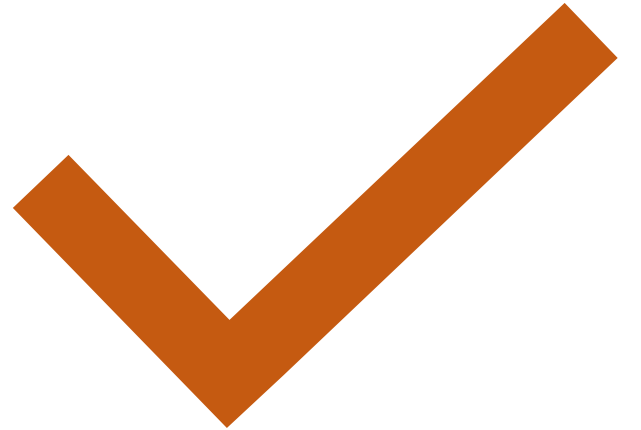
Part 2 and Telehealth

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.

Quoted from the Legal Action Center Presentation, "Privacy Considerations for Telehealth During COVID-19" (January 19, 2021)





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?

Quoted from the Legal Action Center Presentation, "Privacy Considerations for Telehealth During COVID-19" (January 19, 2021)

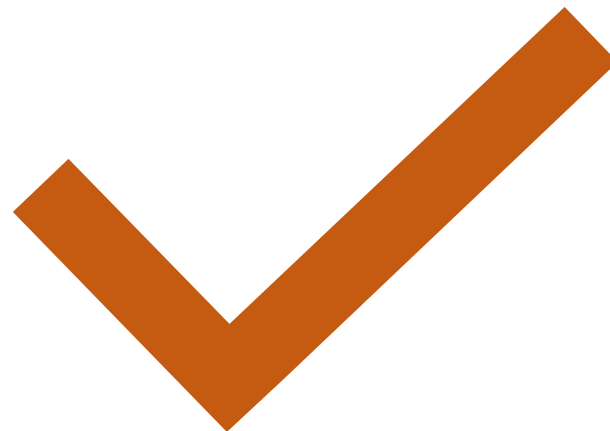
Part 2 and Telehealth

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.

Quoted from the Legal Action Center Presentation, "Privacy Considerations for Telehealth During COVID-19" (January 19, 2021)





Telehealth Services

A Part 2 Program has a QSOA with a telehealth technology service for purposes of providing remote care.

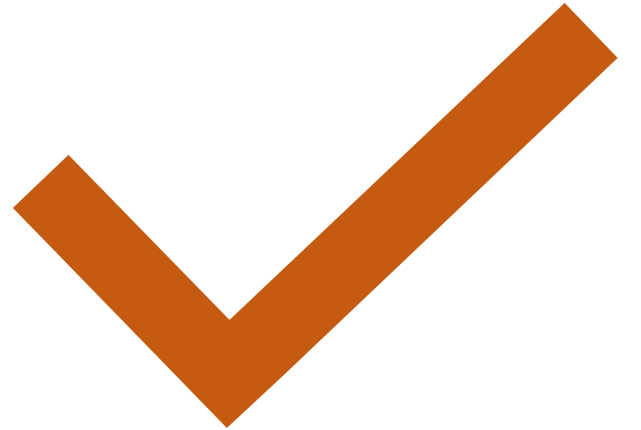
Must the Part 2 Program obtain patient consent authorizing disclosures to the telehealth service?

Focus: PHI FAQs from HITEQ Webinar – *SAMHSA 42 CFR Part 2 Revised Rule*

Telehealth Services

No: A Part 2 program does not need patient consent authorizing disclosures to the telehealth service if there is a QSOA. If the Part 2 program is also a HIPAA covered entity, the Part 2 program should use a QSOA that also meets the requirements of a Business Associate Agreement (BAA).

Focus: PHI FAQs from HITEQ Webinar – *SAMHSA 42 CFR Part 2 Revised Rule*



Part 2 Program Patient Records within a Health System



A Part 2 Program is part of a larger health system that also provides other medical and behavioral healthcare.

Do the Part 2 program's records need to be protected from providers who are not on the Part 2 program team?

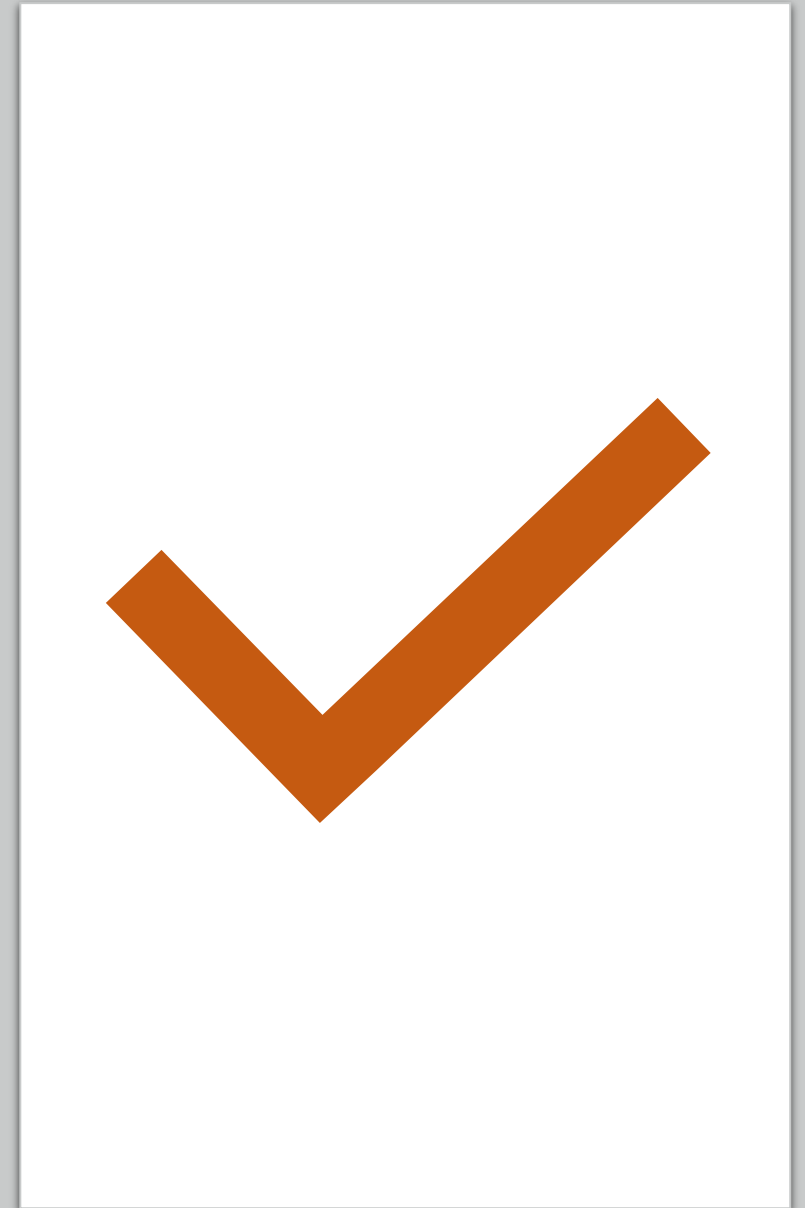
From administrators who need to know?

Focus: PHI FAQs from HITEQ Webinar – *SAMHSA 42 CFR Part 2 Revised Rule*

Part 2 Program Patient Records within a Health System

Yes: If the SUD program team meets the definition of a Part 2 program, then the SUD program team needs written patient consent to share records outside the program, unless one of Part 2's limited exceptions apply. **No:** A SUD program does not need consent to share records for administrative purposes.

Again, the “internal communications” exception permits the Part 2 program to share information with the larger entity for billing or administrative purposes related to the patient’s substance use disorder treatment, so long as the larger entity has “direct administrative control” of the Part 2 program. 42 CFR 2.12. In addition, Part 2 also permits information to be shared without patient consent in order to treat a bona fide medical emergency. 42 CFR 2.51.



Communications between Doorways

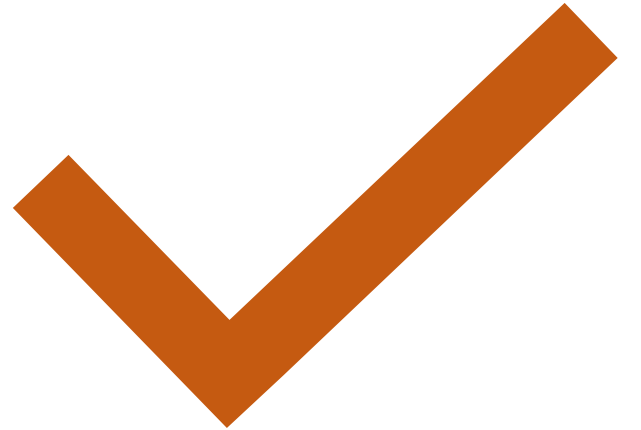


A client comes to the Doorway at Dover-Wentworth Douglass for an intake but has housing in Concord. The client would like to coordinate services and supports through the Doorway at Concord.

Can the Doorway at WWD share the client's information with the Doorway at Concord?

Communications between Doorways

Yes: with appropriate written consent. The Doorway at Concord must be identified as an entity to whom the information will be shared on the consent signed by the client at the WWD Doorway.



Communications during a Medical Emergency



Can the Part 2 medical emergency exception be invoked to head off a potential medical emergency such as a potential drug interaction?

From SAMHSA FAQs Q 9

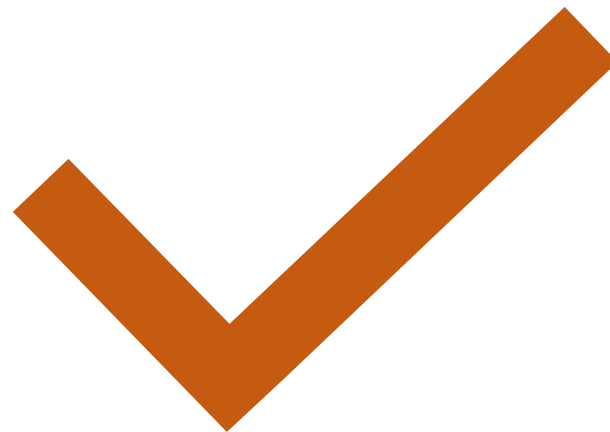
<https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>

Communications during a Medical Emergency

Yes: If a health care provider treating an individual determines that a medical emergency exists as defined in Part 2, i.e., “a condition which poses an immediate threat to the health of any individual [not just the patient], and which requires immediate medical intervention,” and in treating the medical emergency the health care provider needs information about potential drug interactions, then that information and any other information contained in the Part 2 record that the treating health care provider determines he or she needs to treat the medical emergency can be disclosed. If no such determination exists, SAMHSA recommends trying to obtain consent from the patient.

From SAMHSA FAQs Q 9

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





Does Part 2 prohibit
one Social Service
Agency from sharing
information with
another Social Service
Agency?

No!



Questions?

Appendix

**Summary of 42 CFR Part 2 Rule Changes Effective
August 2020**



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Health Law & Policy

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