

Training on the Privacy of Health and SUD Records:

Important Changes on the Federal and State
Level Coming to HIPAA/Part 2 that are
Important to Substance Use Privacy



September 7, 2021

A Little HIPAA, FERPA

And a lot 42 CFR Part 2

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Pole Question

The increase in COVID cases this season makes me:

- a. Very anxious and frustrated
- b. Concerned but hopeful we will get through it
- c. Committed to supporting our clients through this difficult time
- d. All of the above



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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. 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.

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Three Part Series

Session 1: Confidentiality of Substance Use Disorder Patient Records: 42 CFR Part 2 Highlights – What do you need to know?

June 4

Session 3: Important Changes on the Federal and State Level Coming to HIPAA/Part 2 that are Important to Substance Use Privacy

September 7

30 June

Session 2: Sharing Information while protecting privacy as we communicate along the continuum of care

Goals for Session 1 (June 7)

- 1 Reminder about basics of 42 CFR Part 2
- 2 Differences between HIPAA, FERPA and 42 CFR Part 2
- 3 How do you know if you are subject to 42 CFR Part 2 confidentiality? What if you are not?
- 4 Hypotheticals and Questions

Goals for Session 2: June 30

1

Deeper Dive into Consents and Exceptions

2

Part 2 and non-Part 2 Providers - Communications

3

The Impact of COVID on Best Practices – Telehealth and more..

4

Team Based Approach to Implementing Privacy Practices – Bob Fagen, Live Free Recovery

Goals for Today: September 7

1

Privacy and COVID 19 – Focusing on Schools

2

Telehealth and PHE

3

National landscape changes in patient information access

4

The future of technology supports and exchanges

Sharing Information while protecting privacy along the continuum of care



Potential Sources of Confidentiality/Privacy Restrictions

Grants/Contracts

Professional Responsibilities / Codes of Ethics

Employer Policies

Statutes and Regulations

Client Requests

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

Age of Consent - NH

Substance Use	STDs	Medicaid Family Planning	Seriously Mentally Ill
Minor age 12 or older may consent to treatment for drug dependency or any problem related to the use of drugs without the consent of a parent or legal guardian. RSA 318-B:12-a	Minor age 14 or older may voluntarily consent for medical diagnosis and treatment for sexually transmitted diseases, and a licensed physician may diagnose, treat or prescribe for the treatment of sexually transmitted diseases in a minor age 14 or older without the knowledge or consent of the parent or guardian. RSA 141-C:18	Adolescent minors who are eligible for Medicaid may receive confidential family planning services funded by Medicaid	Treatment information regarding seriously or chronically mentally ill person receiving services from community mental health program or state facility may be disclosed to a family member who lives with the person or provides direct care after the facility has received the written consent of the patient or, if consent cannot be obtained, has notified the patient in writing as to what is being disclosed, the reason for its disclosure

LDACs/MDLACs

330-C:26 Privileged Communications Between Licensees and Certificate Holders and Their Clients.

– A person licensed or certified under this chapter or an employee of such person, shall not disclose any confidential information that the licensee, certificate holder, or employee may have acquired while performing substance use counseling services for a patient unless in accordance with the federal regulation regarding the Confidentiality of Alcohol and Drug Abuse Patient Records pursuant to 42 C.F.R. section 2.1 et seq.

- Source. 2008, 189:1, eff. July 1, 2008.

Peer Recovery Support Specialists - Ethics

- National Certified Peer Recovery Support Specialist (NCPRSS) Code of Ethics [d PDF of NCPRSS Code of Ethics](#)
- 10. Protect the privacy and confidentiality of persons served in adherence with Federal Confidentiality, HIPAA laws, local jurisdiction and state laws and regulations. This includes electronic privacy standards (Social Media, Texting, Video Conferencing etc).

Work with Your Team

Think about your patient flow

What do you want to be able to share?

With whom?

When?

Why?

Create pathways to support integrated care.

Schools, students, SUD services and COVID19



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FERPA Umbrella

- K-12 school nurses and their records are typically protected by FERPA
- School nurses can receive information as treating providers from HIPAA covered entities and ask questions about diagnosis and treatment of their student
- However, unless there's an emergency, educators need consents to talk to outsiders about their students.

HIPAA Umbrella

- Health care providers who submit claims electronically can share medical information for treatment purposes without the patient's authorization
- This includes sharing information with other providers to refer a patient.
- This includes information about a patient's mental health.

42 CFR Part 2 Umbrella

- 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.

Examples of Part 2 “Programs”

- A freestanding drug/alcohol treatment program
- Primary care providers who provide drug/alcohol services as their principal practice
- A detox unit
- Outpatient or inpatient drug program within a general medical facility
- An addiction specialists working in a primary care practice
- A LDAC working in a peer support program in New Hampshire

Remember Who You Are - What if?

If I am covered by 42 CFR Part 2? Check List

1. Security policies for patient information that meet the new Part 2 standards
2. Notice of privacy rights that meet Part 2 requirements
3. Non re-disclosure notices when Part 2 information disclosed with consent
4. Magic Part 2 language in your agreements
5. Compliant consent forms and disclosures pursuant to a valid exception

If I'm not covered?

1. What privacy rules apply to information about my clients/patients?
2. Am I sharing information with a Part 2 Program?
3. Am I receiving information from a Part 2 Program?

How familiar are you with 42 CFR Part 2 requirements?

1. Very familiar
2. Somewhat familiar
3. Lots of questions
4. Totally confused

https://chhs.unh.edu/institute-health-policy-practice/health-law-policy#collapse_2907

Sharing COVID Information: Students and Schools

Question: If a student has COVID-19, what information from education records can the school share with the community? With teachers? Classmates?

Question: If a school suspects that a student may have COVID-19, can school officials contact the student's primary care physician? Peer counselor?

Privacy Public Health Emergency Telehealth



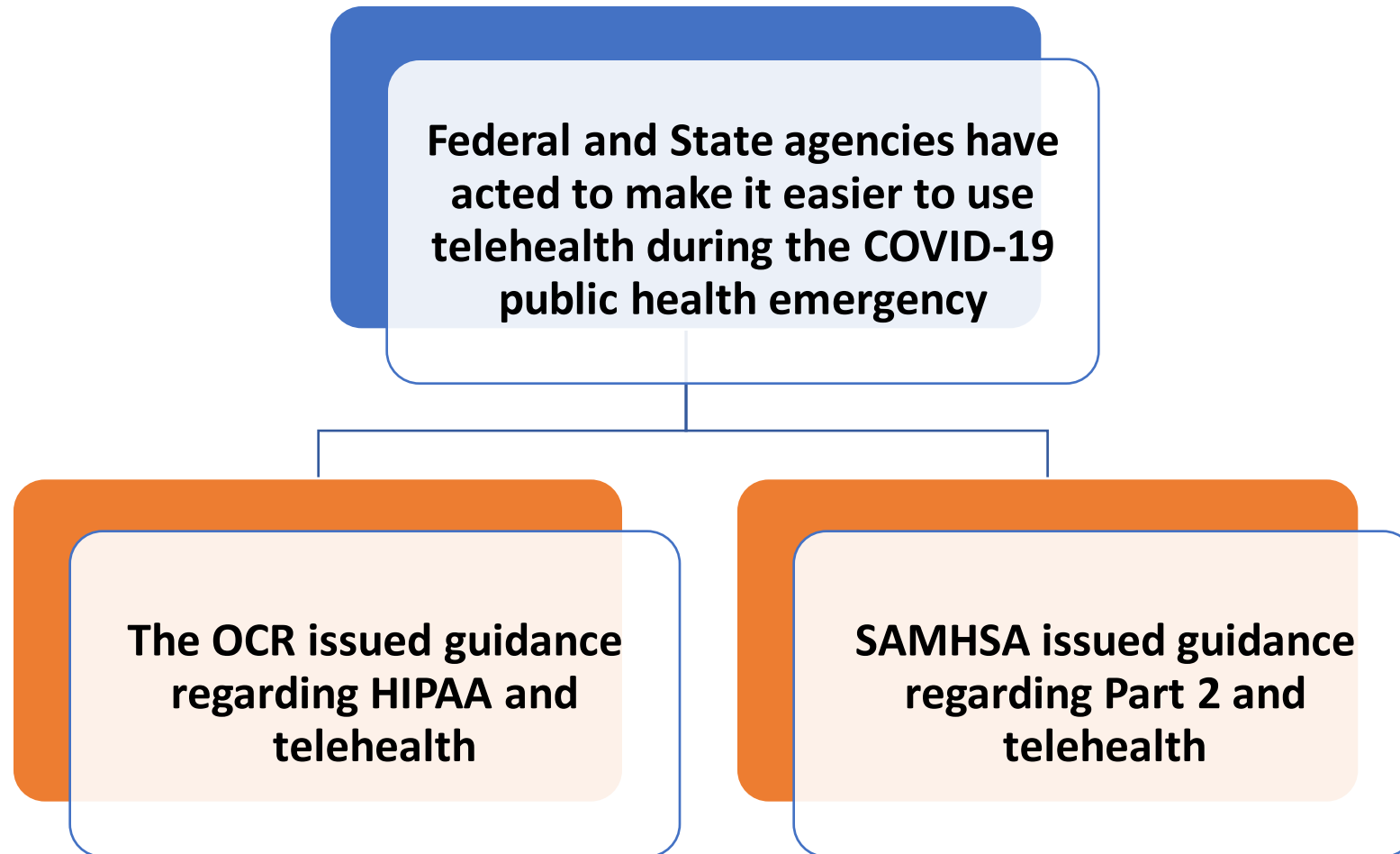
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Question

Question: Did privacy regulations change during the state or federal public health emergency?

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

Telehealth During COVID-19



HIPAA Providers

- [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 can not use public facing technology like Facebook!
- Providers do not need to have a BAA in place with technology providers who make telehealth possible
- *Does not matter whether telehealth service is directly related to COVID-19*

42 CFR Part 2 Providers

- If a SUD provider needs to support a client via telehealth – they can!
- Consents can be secured via electronic signature
- If your office is closed because of COVID and the client needs services due to a medical emergency, no consent is required.

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 Redislosure](#)

Providers should obtain consent to disclose to the telehealth service if it will have access to patient information.

Question

Question: When will the PHE terminate?

Answer:

- Federal Public Health Emergency is “likely” to last through 2021
- State public emergency declaration ended Friday, June 11

Technology Enabling Referrals



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Care Coordination and Supported Referrals

- What are they?** A supported referral is one that successfully secures the right resources for patients at the right time, ensuring that the patients' needs are met.
- How do they work?** Care teams need confirmation that patients have seen the correct organizations for their needs.
- Why Is Care Coordination Important?** Care coordination ensures patients are able to navigate a complicated system of care to achieve better outcomes and avoid duplication of or lost services.
- What information is shared?** Information shared is what is necessary to allow providers and care managers to change the course of action for patient, if needed.
- How is the loop actually closed?** Whether patients are able to connect to recommended care and treatments outside the traditional health care delivery system.

Tech Enabled Referrals

The "closed-loop referral" is a tech-enabled workflow that provides real-time view of the status of the patient, while also exchanging data amongst the team, assigning tasks, and reporting on outcomes.



Technology allows for:

Development of a network of available supports and services

Access by patients to real-time referrals

Supported care and transitions



Providers comply with HIPAA and other privacy rules that support patient access, information exchange and care coordination

What about technology vendors?

- Let's talk about technology vendors who support referrals to services!
- What rules apply?

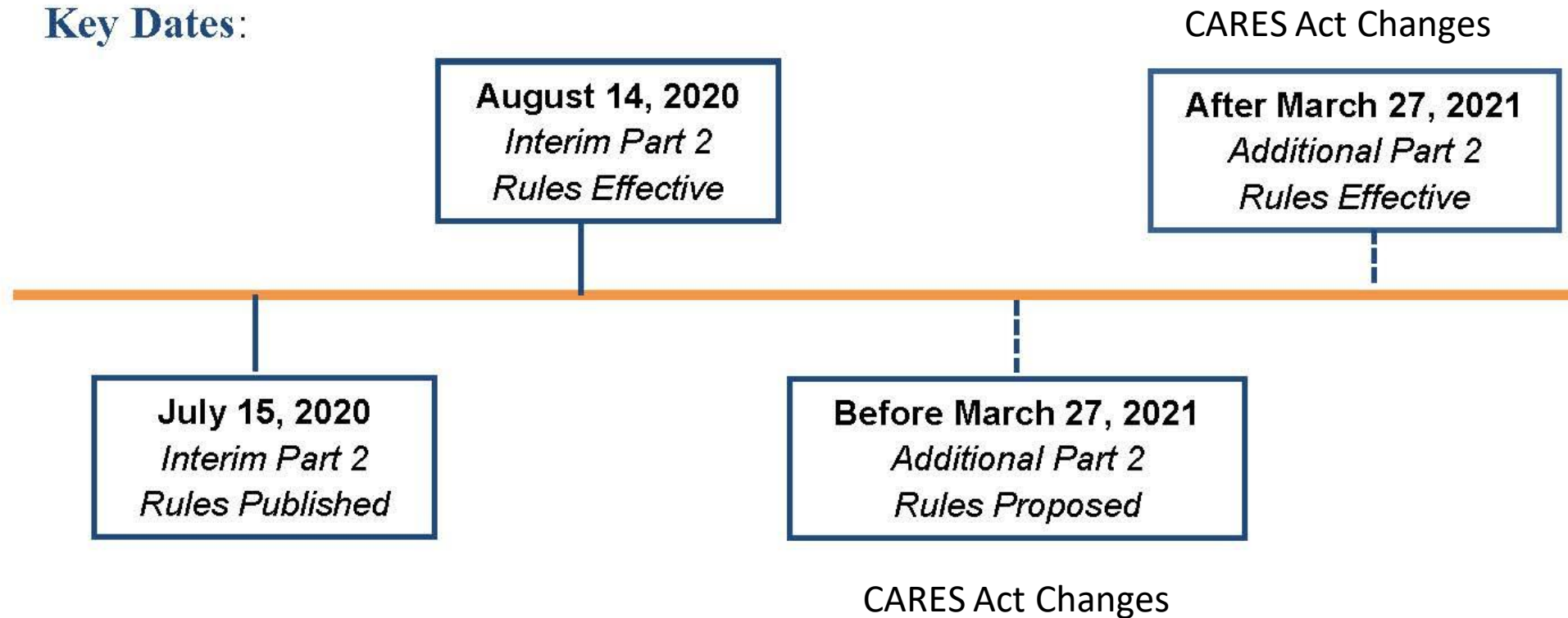
Big Picture Federal Activity



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42 CFR Part 2 Rules – CARES Act

Key Dates:



Note on Timing of CARES Act changes

SAMHSA is working with the HHS Office for Civil Rights on a Notice of Proposed Rulemaking to address the changes required by the CARES Act, to the 42 CFR part 2 regulations governing the confidentiality of substance use disorder patient records. We intend to publish these amendments later this year in the Federal Register, and we will be seeking comments from the public. Until new regulations are promulgated, the current 42 CFR part 2 regulations remain in effect. We know that many stakeholders are eagerly awaiting these revisions and appreciate your patience as we work to provide a thoughtful and thorough review of these provisions and amendments.

Last Updated

Last Updated: 04/09/2021

HIPAA Changes

December 2020: Notice of proposed rulemaking re. HIPAA privacy rules

- Minor tweaks to strengthen patient access to PHI, facilitate data sharing, and ease the administrative burden on HIPAA covered entities.
- Defines “health care operations” to include care and case management enabling improved access to information
- Improves patient transparency by allowing 15 days to provide PHI on request

March and April 2020: Notice of Enforcement Discretion easing HIPAA requirements during COVID19 Public Health Emergency

- Good faith provision of telehealth for diagnosis and treatment
- Community based testing sites
- Business Associates responding to public health agencies
- Web based scheduling for vaccines

```
mirror_mod = modifier_ob.  
set mirror object to mirror.  
mirror_mod.mirror_object  
operation == "MIRROR_X":  
mirror_mod.use_x = True  
mirror_mod.use_y = False  
mirror_mod.use_z = False  
operation == "MIRROR_Y":  
mirror_mod.use_x = False  
mirror_mod.use_y = True  
mirror_mod.use_z = False  
operation == "MIRROR_Z":  
mirror_mod.use_x = False  
mirror_mod.use_y = False  
mirror_mod.use_z = True  
  
#selection at the end -add  
mirror_ob.select= 1  
modifier_ob.select=1  
context.scene.objects.active  
("Selected" + str(modifier_ob.  
mirror_ob.select = 0  
= bpy.context.selected_object  
data.objects[one.name].select  
  
print("please select exactly  
  
--- OPERATOR CLASSES ---  
  
types.Operator):  
on X mirror to the selected  
object.mirror_mirror_x"  
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context):  
context.active_object is not
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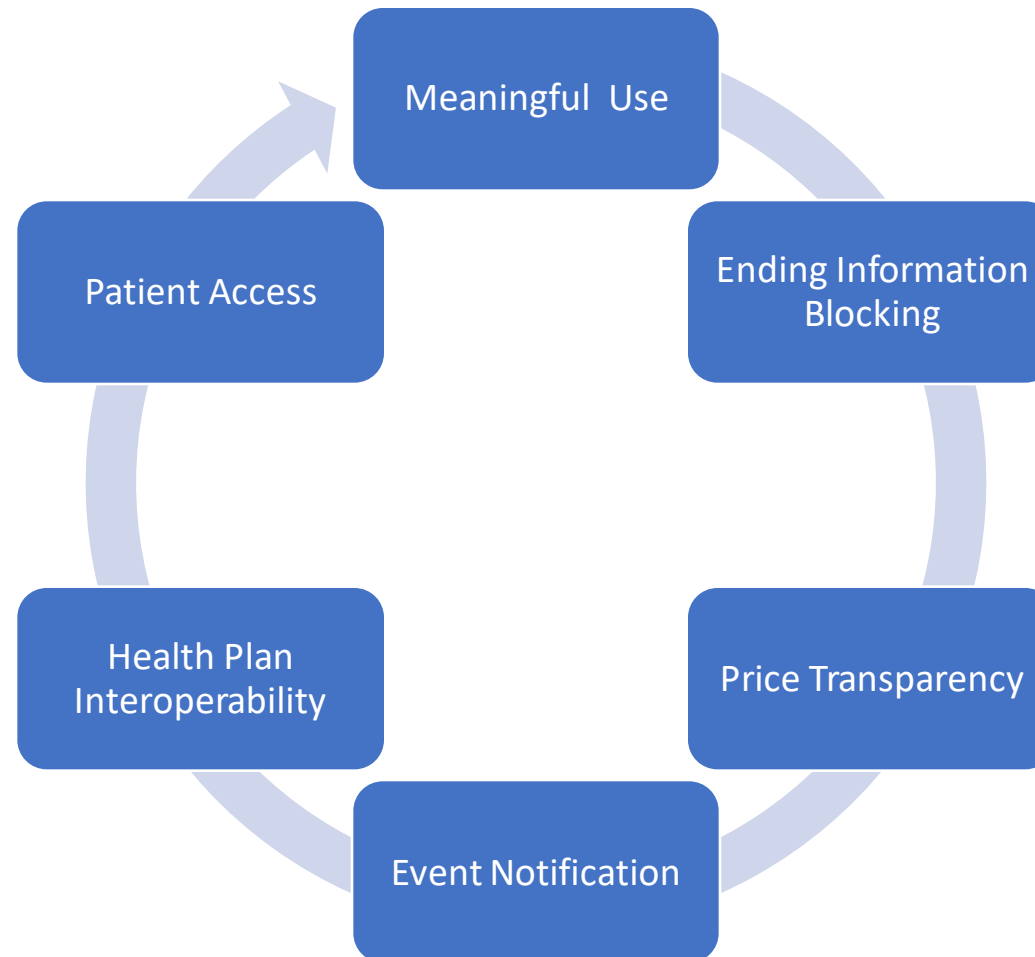
Interoperability, Access, Transparency

From Meaningful Use to Interoperability Programs

History of Federal Requirements

- HIPAA rules established that plans and providers needed to provide patients with access to their records
- Claims data, events and data sets were standardized
- Providers were incentivized to implement standardized electronic health records
- CMS and ONC (National Coordinator for Health Information Technology), through the Cures Act issued rules:
 - ONC: Established interoperability data and technology standards
 - CMS: Required patient access, provider directory, payer-to-payer exchange
 - CMS/ONC: Enhanced payer to payer data exchange to include prior authorizations

Promoting Interoperability Programs



What's Going On?

Beginning April 5, 2021, the program rule on Interoperability, Information Blocking, and ONC Health IT Certification, which implements the 21st Century Cures Act, requires that healthcare providers give patients access without charge to all the health information in their electronic medical records “without delay.”

Goals of 2020-2021 Interoperability Rules

“ We believe patients should have the ability to move from payer to payer, provider to provider, and have both their clinical and administrative information travel with them throughout their journey.”

- CMS May 1, 2020, Interoperability and Patient Access Final Rule



CMS INTEROPERABILITY & PATIENT ACCESS FINAL RULE

my
health
data

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

2019

- Draft 2 TEFCA released
- CMS publishes **Interoperability and Patient Access Proposed Rule**
- ONC publishes 21st Century Cures Act Proposed Rule

2018

- Draft TEFCA released
- White House Executive Forum on Interoperability
- CMS made data available to researchers through the Virtual Research Data Center

JAN 2019

Providers are required to use **2015 Edition Certified EHR Technology**

Promoting Interoperability program requirements take effect for all providers

LATE 2020

Public reporting of clinician or hospital data blocking and providers without digital contact info in NPPES

JAN 1 2021*

Patient Access API

Patient health care claims and clinical info made available through standards-based APIs for Medicare Advantage, Medicaid and CHIP FFS, Medicaid and CHIP managed care, and QHPs on the FFEs

Provider Directory API

Payer Provider Directories made available through standards-based APIs

* both requirements will not be enforced until July 2021

SPRING 2021

Hospitals send **event notifications** regarding admission, discharge, and transfer to other providers

JAN 1 2022

Payer-to-Payer data exchange

Payers required to exchange patient USCDI data upon request

APRIL 2022

Improved benefits coordination for dually eligible individuals

March 2018

MyHealthEData and Blue Button 2.0 launched

2019

2020

2021

2022

Information Blocking – 21st Century Cures Act

- Penalize healthcare providers (among others) who engage in ***information blocking***.
- ***Information Blocking*** prohibits healthcare providers from interfering with access, exchange, or use of electronic health information.
- It **does not** prohibit healthcare providers from protecting information covered by a stricter privacy law, such as 42 CFR Part 2.

Examples: Patient Info Blocking

- **A healthcare provider's internal procedures require a patient's written consent before sharing any of the patient's electronic health information with unaffiliated providers for treatment purposes.**
- If the healthcare provider is a Part 2 program, or if the electronic health information is otherwise protected by Part 2, this is NOT "information blocking." A patient's written consent is required before sharing Part 2 records with unaffiliated providers for treatment purposes.
- See ONC Information Blocking Exceptions; 42 CFR 2.31.

Focus PHI: CFE

http://coephi.org/sites/default/files/31741026_21st_century_cures_act_final_rule_-_final_version.pdf

Examples – Info Blocking

- A healthcare provider directs its EHR developer to configure its technology so that users cannot easily send electronic patient referrals and associated electronic health information to unaffiliated providers, even when the user knows the direct address or National Provider Identifier of the unaffiliated provider.
- Even if the healthcare provider is a Part 2 program or the records are protected by Part 2, ***this is “information blocking.”*** Part 2 does not require EHRs to impose barriers to sending electronic patient referrals and associated electronic health information to unaffiliated providers; the only Part 2 requirement is that the patient consent before sending referral information or electronic health information.

Focus PHI: CFE

http://coephi.org/sites/default/files/31741026_21st_century_cures_act_final_rule_-_final_version.pdf

Price Transparency

Hospital price transparency – Posted January 2021

- Post yearly charges for standard services including negotiated rates

Health Insurance Price Transparency: January 2022 (maybe)

- Rules require health insurers to provide personalized information about consumers' out-of-pocket costs for covered services via an online, self-service tool.
- An initial set of 500 “shoppable services” are supposed to be available to consumers in 2023 and more in 2024.
- Information on negotiated rates paid to health care providers, historical charges for things like health services, Rx drug costs and out-of-network providers

What is Price Transparency?

- Hospital common items and services
- Machine readable
- Include all payers: name of payer and plan type
- All “charges”:
 - gross charge,
 - discount cash price,
 - payer-specific negotiated charges,
 - de-identified minimum and maximum charges, and
 - descriptions of, and codes for, the items and services provided by hospitals.

What does it all mean?

Hope for rebalancing costs, reimbursements and resources for care

More data aggregation

Technology engagement across systems of care

Heightened issues with privacy compliance and likely updates to HIPAA and 42 CFR Part 2.

Conflicts between federal and state guidance.

Hope for mental health parity compliance

Now What?

We are seeing?

- SUD and mental illness continue to be major problems for Americans
- Cannabis use and Methamphetamine use significantly increasing in adults
- Rising SUD and trauma in families and communities

What do we do?

- Improve support for you and evidenced based treatment
- Expand and improve access to crisis services
- Enforce mental health parity so that our “health care” resources are shared across mind and body

Appendix

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



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	HIPAA (health information) 45 CFR 164.508 “Authorization”	42 CFR Part 2 (substance use disorders), 42 CFR 2.31, 2.32 “Consent”	Family Education Rights Privacy Act (FERPA), 34 CFR 99.30, 99.33 “Consent”
Required Core Elements			
Whose information?	Name of Patient	Name of Patient	Name of student
What information – describe?	<p>Must describe information in “specific and meaningful” way</p> <p>Remuneration: If purpose involves remuneration (e.g. marketing, sale of data), must state that disclosure will result in remuneration to covered entity</p>	<p>Must describe how much and what kind of information may be disclosed, including an explicit description of what substance use disorder information may be disclosed; must be limited to that information necessary to carry out the purpose of the disclosure</p>	<p>Must specify the records that may be disclosed</p>
Who is disclosing the information?	Must include the name or other specific identification of person(s) or classes of persons authorized to make the disclosure	Must include the specific name(s) or general designation(s) of Part 2 program(s), entity(ies), or individual(s)	Must state the educational agency or institution disclosing the information

	HIPAA (health information) 45 CFR 164.508 “Authorization”	42 CFR Part 2 (substance use disorders), 42 CFR 2.31, 2.32 “Consent”	Family Education Rights Privacy Act (FERPA), 34 CFR 99.30, 99.33 “Consent”
Required Core Elements			
“TO WHOM” may the disclosure be made?	Authorization can be made without written consent to other covered entities for purposes of treatment, payment and health care operations. Written authorizations must identify the persons or class of person to whom disclosure it to be made	Must include the names of the individual(s) to receive the information, or for the following types of recipients: <ul style="list-style-type: none"> • Name of person or entity • Entities that facilitate health information exchange: the name of the entity or the name of the entity’s participant(s) that has a treating provider relationship with the patient 	Must identify the party or class of parties to whom the disclosure may be made

	HIPAA (health information) 45 CFR 164.508 “Authorization”	42 CFR Part 2 (substance use disorders), 42 CFR 2.31, 2.32 “Consent”	Family Education Rights Privacy Act (FERPA), 34 CFR 99.30, 99.33 “Consent”
Required Core Elements			
Purpose(s) for which the information may be disclosed	Must describe each purpose of disclosure When initiated by individual, “at the request of the individual” is sufficient	Must describe each purpose of disclosure, as specific as possible	Must state the purpose of the disclosure
Signature of Individual	Must include signature of patient or authorized representative; if representative signs, must also include description of authority to act	Must include signature of patient or authorized representative	Must include signature of signature of parent or individual with authority to consent; a signature in electronic form must identify and authenticate a particular person as the source of the electronic consent and indicates such person’s approval of the information contained in the electronic consent
Signature of witness	None required	None required	None required
Date Signed	Must include date signed	Must include date signed	Must include date signed

Summary of Most Recent Changes to 42 CFR Part 2

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 Part 2 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

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.**