



# HIPAA PASS Privacy and Security Solutions

## HIPAA Series: “The Path to 42 CFR, Part 2, Past, Present and Future”

Presented by Susan Clarke

Health Care Information Security and Privacy Practitioner

Thursday, June 25, 2020 | 11 AM – 12 PM



# Zoom tips and tricks!

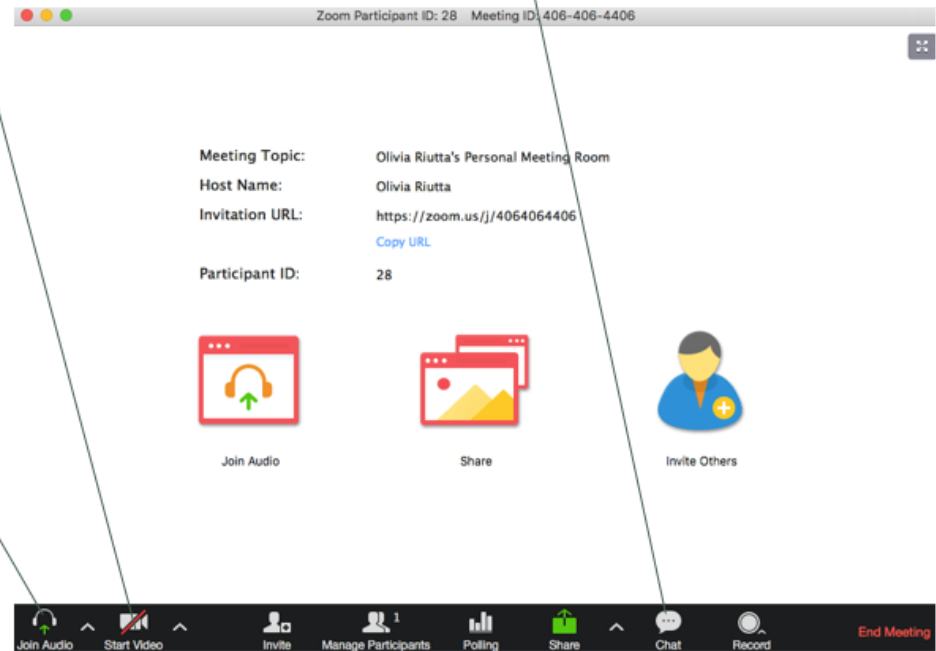
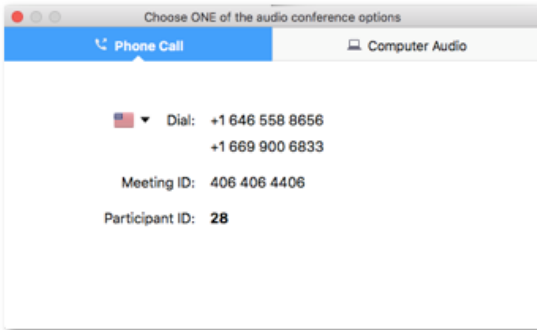
**CHAT:** Please jump in if you have something to share, but we also have this nifty chat function.

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**MUTE/UNMUTE:** \*6 or click the mic on the bottom left of your screen.



# Susan Clarke, HCISPP



(ISC)<sup>2</sup> Healthcare Information Security and Privacy Practitioner and Computer Scientist at Mountain-Pacific Quality Health.

Conducts privacy and security risk analysis in addition to HIPAA and 42 CFR, Part 2 training.

20 years' experience in health care operations.

10 years' design and coding EHR software including HL7 Healthcare application development.

Served on IT security, disaster recovery and joint commission steering committee at Mayo Clinic-affiliated health care system.

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# Acronyms

**BA:** Business Associate

**BAA:** Business Associate Agreement

**CE:** Covered Entity

**CEHRT:** Certified Electronic Health Record Technology

**CMS:** Centers for Medicare & Medicaid Services

**EHR:** Electronic Health Record

**ePHI:** Electronic Protected Health Information

**HHS:** Department of Health and Human Services

**HIPAA:** Health Insurance Portability and Accountability Act

**HIT:** Health Information Technology

**IT:** Information Technology

**NIST:** National Institute of Standards and Technology

**OCR:** Office for Civil Rights

**PHI:** Protected Health Information

**QSO:** Qualified Service Organization

**SP:** Special Publication

**SRA:** Security Risk Analysis

# Learning Objectives

**PAST**

Overview of 42 CFR, Part 2

**PRESENT**

Recent changes, August 14, 2020, to be aware of

**FUTURE**

42 CFR, Part 2, March 27, 2021, the CARES Act



Enacted in 1975

# 42 CFR PART 2 THE PAST



# 42 CFR, Part 2

## Title 42 of the Code of Federal Regulations (CFR) Part 2:

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Confidentiality of Substance Use Disorder Patient Records (Part 2) was first enacted in 1975 to address concerns about the potential use of Substance Use Disorder (SUD) information in non-treatment-based settings such as administrative or criminal hearings related to the patient.



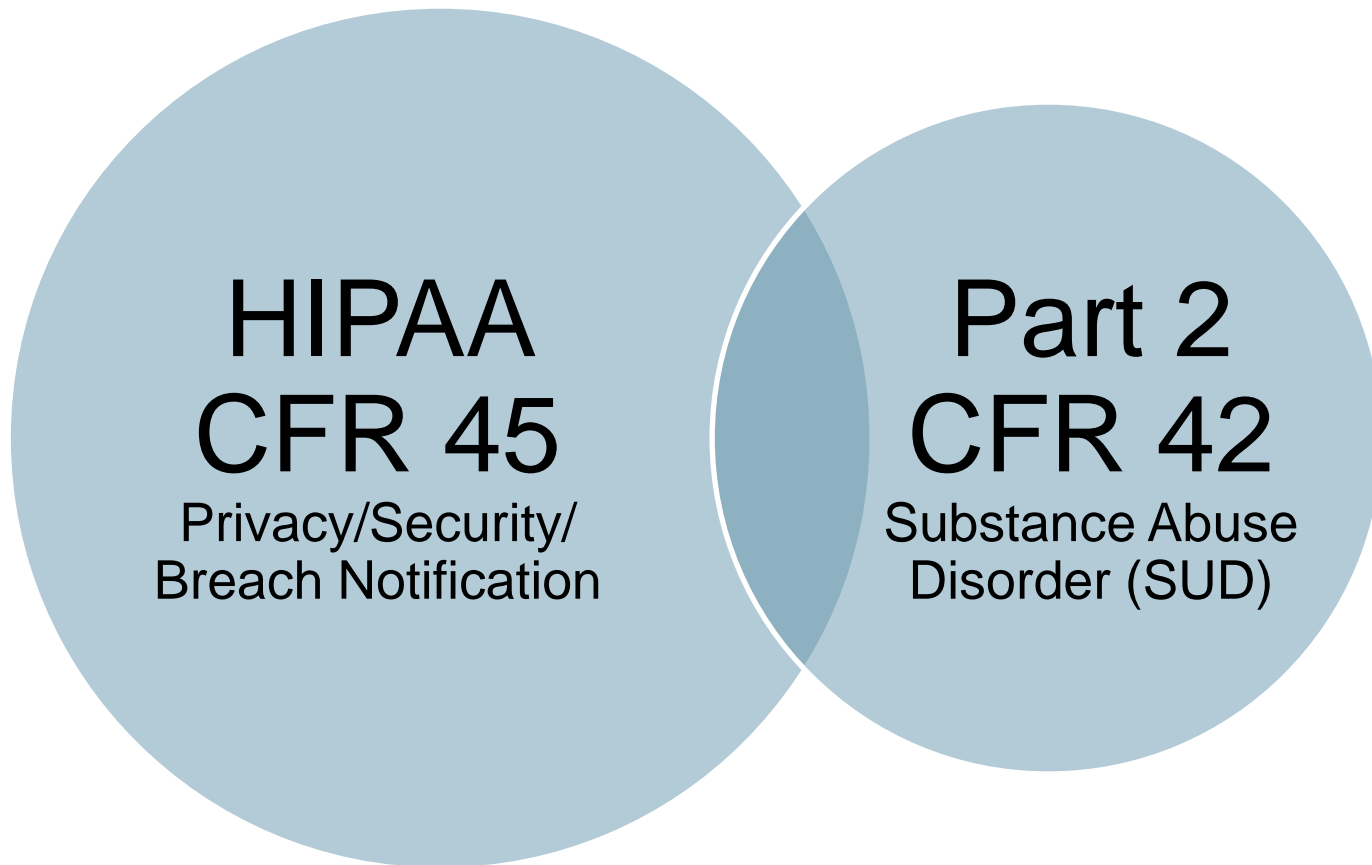
# Doctors Responding to Opioid Crisis



HIPAA allows sharing health information in emergency

Misunderstandings create obstacles to family support during crisis situations, e.g., opioid overdose

# HIPAA and Part 2



The vast majority of alcohol/drug treatment programs are covered by both.

# HIPAA versus Part 2

Both laws address the confidentiality and security of health information.

## HIPAA

- Protects PHI maintained by providers, payers and their contractors from disclosure without consent permitted for treatment, care coordination
- Business Associate Agreements (BAAs)
- Applies to almost all providers
- Enforcement Office for Civil Rights (OCR)

## Part 2

- Protects confidentiality of SUD patient records from disclosure without express patient consent (unless emergency)
- Qualified Service Organizations (QSOs)
- Applies to Part 2 providers
- Enforcement Department of Justice (DOJ)

# Enforcement and Penalties

## HIPAA

- OCR
- Civil penalties of \$112 to \$55,910 per violation
- Mandatory penalties of \$11,182 to \$55,910 if act with willful neglect (possible patient gets %)
- Criminal penalties \$50,000 to \$250,000; up to 10 years in prison

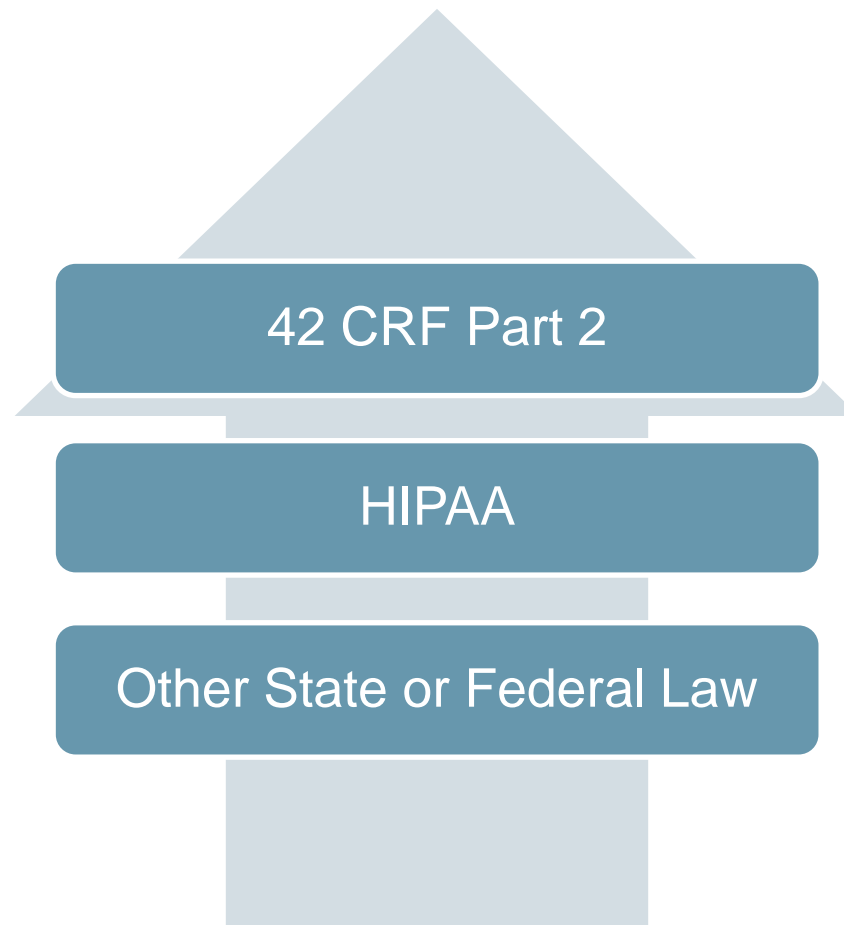
## 42 CFR Part 2

- DOJ criminal fines of \$500 for first offense; \$5,000 for subsequent offenses

Note: Might be used as basis for private lawsuit

# Comply with Most Restrictive Law

Follow the law that gives more privacy protection.



# Important Points About Part 2

- Narrower but significantly stricter than HIPAA
- General rule: patients must authorize disclosures of their Part 2-records, unless an exception applies
- Consent form must describe information to be disclosed, purpose of disclosure and include name of entity (new)



# Part 2 Rule

Part 2 protects patients from any unintended bias associated with substance use disorders (SUDs). These regulations protect the confidentiality of SUD treatment records.

Part 2 prohibits the disclosure and use of SUD patient records except with the patient's specific written consent or under certain limited exceptions.

# Two Parts in determining Part 2

## 1 Part 2 applies to federally assisted SUD programs

Provider federally assisted if

- Medicare or Medicaid,
- Registered to dispense controlled substances,
- Receives any federal grants or
- nonprofit

2 **Program:** Any *individual* or *entity* that “holds itself out as providing education, treatment or prevention to individuals in need of alcohol or drug abuse treatment”



# Almost All Fall under Federally Assisted

- Recipients of federal financial assistance
- Federal financial assistance = assistance of any kind
- Licensed, certified, registered or authorized by federal government
- Tax-exempt
- Conducted with federal funds; can be used for SUD programs

*Exception: Part 2 does not apply to the Department of Veterans Affairs or Armed Forces*

# “Holds itself out as...”

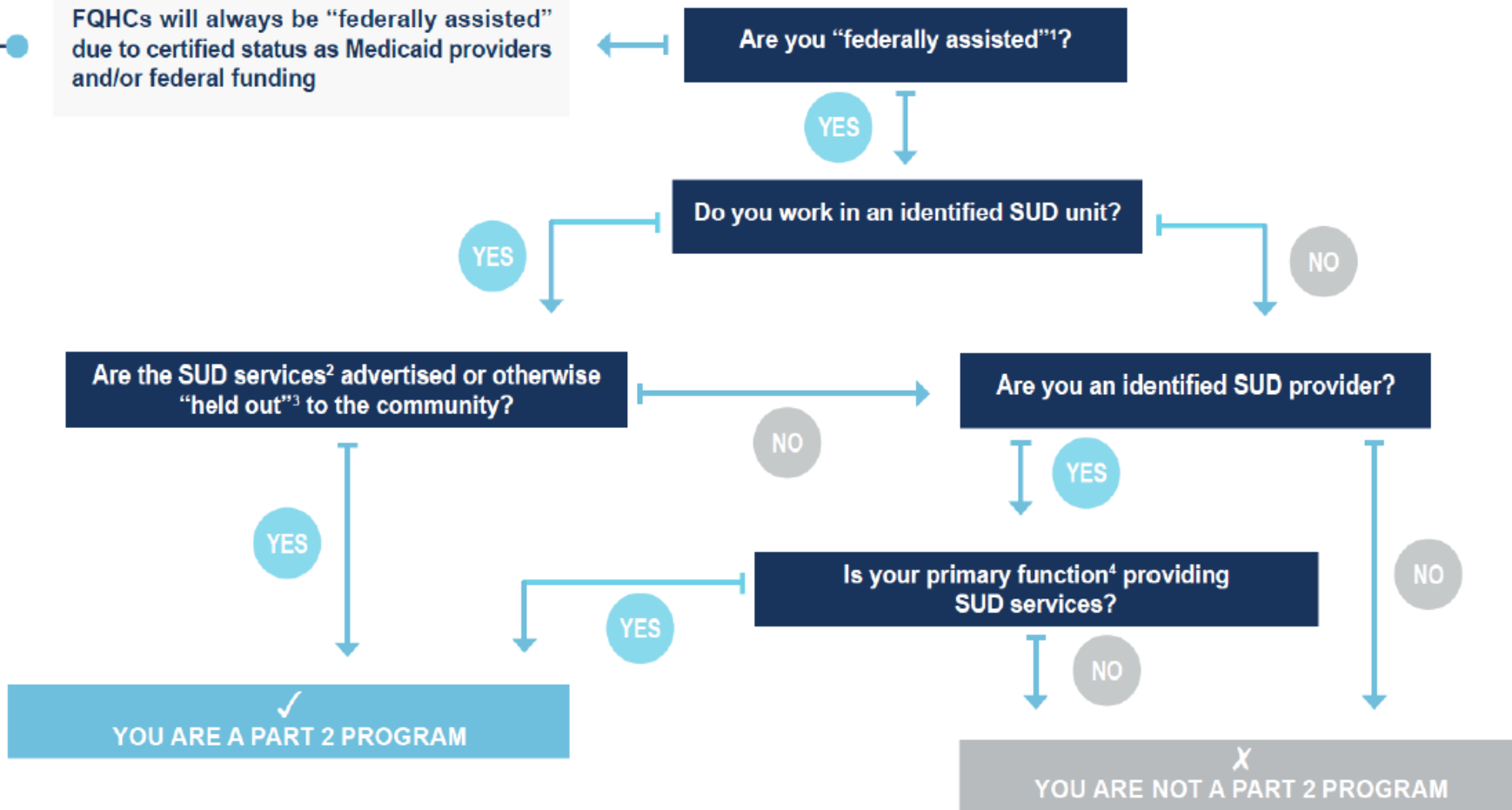
## **Part 2, a Medical personnel or staff member who:**

- ✓ Holds themselves out as providing/does provide SUD treatment, diagnosis or referral for treatment; or
- ✓ Practices in a general medical facility whose primary function is SUD treatment, diagnosis or referral for treatment and is identified as such; or
- ✓ Is a Licensed Alcohol and Drug Counselor (LADC) providing LADC services

# I Provide SUD Services in an FQHC: Does Part 2 Apply to Me?

Use the flowchart below to determine if Part 2 applies to you

**NOTE:**  
FQHCs will always be “federally assisted” due to certified status as Medicaid providers and/or federal funding



For more information & resources, or to request technical assistance, please visit [coephi.org](http://coephi.org).

Resources, training, technical assistance, and any other information provided through the Center of Excellence for Protected Health Information do not constitute legal advice. For legal advice, including legal advice on other applicable state and federal laws, please seek out local counsel.

# State Laws Limit Disclosure of Behavioral Health Records

## **For general health:**

Most states allow disclosure of health information for purposes of treatment without consent.

## **For mental health:**

Variation in state laws as to whether mental health information can be disclosed.

## **For SUD:**

Many states have statutes or regulations that mirror Part 2 and/or allow the state to enforce Part 2 compliance.

View the state minimum necessary laws:

<https://www.healthit.gov/sites/default/files/State%20Mental%20Health%20Laws%20Map%201%20Minimum%20Necessary%20-%20revised%202-23-17.pdf>

# Case Study #1

## Meet Jackie, a nurse



- Works in a Federally Qualified Health Center (FQHC)
- Works in SUD treatment unit that meets Part 2 program definition
- Her patient needs referral to specialist in another practice area of Federally Qualified Health Center

# Poll Question #1

**Q:** Does Jackie need to obtain the patient's written consent before making the referral?

Yes

No

# Case Study #1 (Answer)

**A: YES, Jackie needs patient consent to make the disclosure.**

If Jackie did NOT work in an SUD treatment unit, she may make the referral without written consent, because HIPAA permits disclosures for “treatment.”

*Note: Other privacy laws may also apply, in which case Jackie should follow whichever law is most protective of privacy.*

# Internal Communications: For Larger Entity (e.g., FQHC)



Part 2 program can share patient information for administrative purposes with larger entity (e.g., billing)



Disclosures for treatment purposes (e.g., with primary care provider) still need consent



# Internal Communications: The “Need to Know” Rule



Can share/receive patient information within Part 2 program, if necessary, to provide SUD services



Information should be limited to minimum necessary

# Case Study #2

## Meet Tom, a nurse



- Works at opioid treatment program (OTP)
- Patient collapses suddenly and loses consciousness
- Paramedics arrive and ask Tom questions

# Poll Question #2

**Q:** Can Tom share patient information with the paramedics?

Yes

No

# Case Study #2 (Answer)

**A: YES, Tom can share patient information with paramedics to address this medical emergency.**

Tom can share SUD information and basic information (patient's name, age, date of birth, emergency contacts).

# Medical Emergencies

**Part 2 permits disclosures without written consent to medical personnel to treat a bona fide medical emergency:**

- ✓ Information may be re-disclosed for treatment purposes
- ✓ If patient has capacity to consent and chooses not to authorize the disclosure, you may not use the medical emergency exception
- ✓ Part 2 program must make note in patient file regarding disclosure



August 14, 2020

# 42 CFR PART 2 TODAY



# Changes to 42 CFR, Part 2

July 15, 2020

SAMHSA amended regulations – transitional only

Effective: August 14, 2020

# What Changed

<b>42 CFR §</b>	<b>Provision</b>
2.11	Definition of “records”
2.12	Applicability and re-disclosure
2.31	Requirements for written consent forms
2.32	Notice of prohibition on re-disclosure
2.33	Disclosures permitted with written consent (P/HCO)
2.34	Disclosures by central registries
2.36	Disclosures to prescription drug monitoring programs
2.51	Medical emergencies
2.52	Research
2.53	Audit and evaluation
2.67	Court orders for undercover agents and informants
<b>Guidance</b>	<b>Disposition of records on employees’ personal devices, data segmentation</b>

Source: The Center of Excellence for Protected Health Information.  
[https://www.coephi.org/sites/default/files/SAMHSA%2042%20CFR%20Part%202%20Fact%20Sheet%20\\_1.pdf](https://www.coephi.org/sites/default/files/SAMHSA%2042%20CFR%20Part%202%20Fact%20Sheet%20_1.pdf)





# Consent Requirements

## Why Changed

SUD patient may consent to disclosure of Part 2 treatment records to entity (e.g., Social Security Administration) without naming specific person as disclosure recipient.

## What Changed

SUD patient may consent to disclosure of Part 2 treatment records to entity (e.g., Social Security Administration) without naming specific person as disclosure recipient; **optional update** “recipient” description to permit naming entity



# Re-Disclosure

## Update Prohibition on Re-Disclosure Notice

New language can be found here:

<https://www.federalregister.gov/documents/2020/07/15/2020-14675/confidentiality-of-substance-use-disorder-patient-records#p-644>



March 27, 2021

# 42 CFR PART 2 FUTURE



# Changes to Law 42 USC § 290dd-2

On March 27, 2020  
Congress amended statute, required new  
regulations

Effective: March 27, 2021

# CARES Act Does Not Repeal Part 2



Makes some changes  
to SUD privacy law;  
will require future  
changes to Part 2  
regulations



Goes into effect  
March 27, 2021

# Changes in CARES Act

- Still requires initial patient consent to disclose protected SUD records
- After initial consent, some re-disclosures permitted:
  - For treatment/payment/health care operations (TPO) by HIPAA-covered entities, business associates and Part 2 programs
  - Patient still has right to revoke initial consent

# Conclusion

## Substance Abuse and Mental Health Services (SAMHSA)

Making SUD information  
available for legitimate  
purposes  
(ACOs, health information  
exchanges, etc.)

Safeguarding information  
from improper uses,  
harmful disclosures,  
adverse legal  
consequences



# Special Thanks

## Center of Excellence for Protected Health Information (CoE-PHI)

Funded by SAMHSA, CoE-PHI develops and disseminates resources, training and technical assistance for states, health care providers, school administrators, individuals and families to improve understanding and application of federal privacy laws and regulations, **including Family Educational Rights and Privacy Act (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.*

<http://www.coephi.org/>



# SAMSHA Supporting Material

- [SAMSHA Fact Sheet: Does Part 2 Apply to Me?](#)
- [SAMSHA FAQ: Applying the Substance Abuse Confidentiality Regulations](#)
- [Fact Sheet SAMHSA 42 CFR Part 2 Revised Rule](#)





Please let me know how I can help.

**For assistance, please contact:**

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**Thanks for your  
valuable time today!**

