

## RECONCILING PART 2 & HIPAA: HOW TO PROTECT YOUR SUD PATIENTS' RECORDS

1

### UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

Differentiate between HIPAA regulations and Part 2 privacy regulations

Apply strategies to ensure your organization is compliant with Part 2 and HIPAA regulations

Adapt to upcoming Part 2 regulation changes that will impact your privacy program

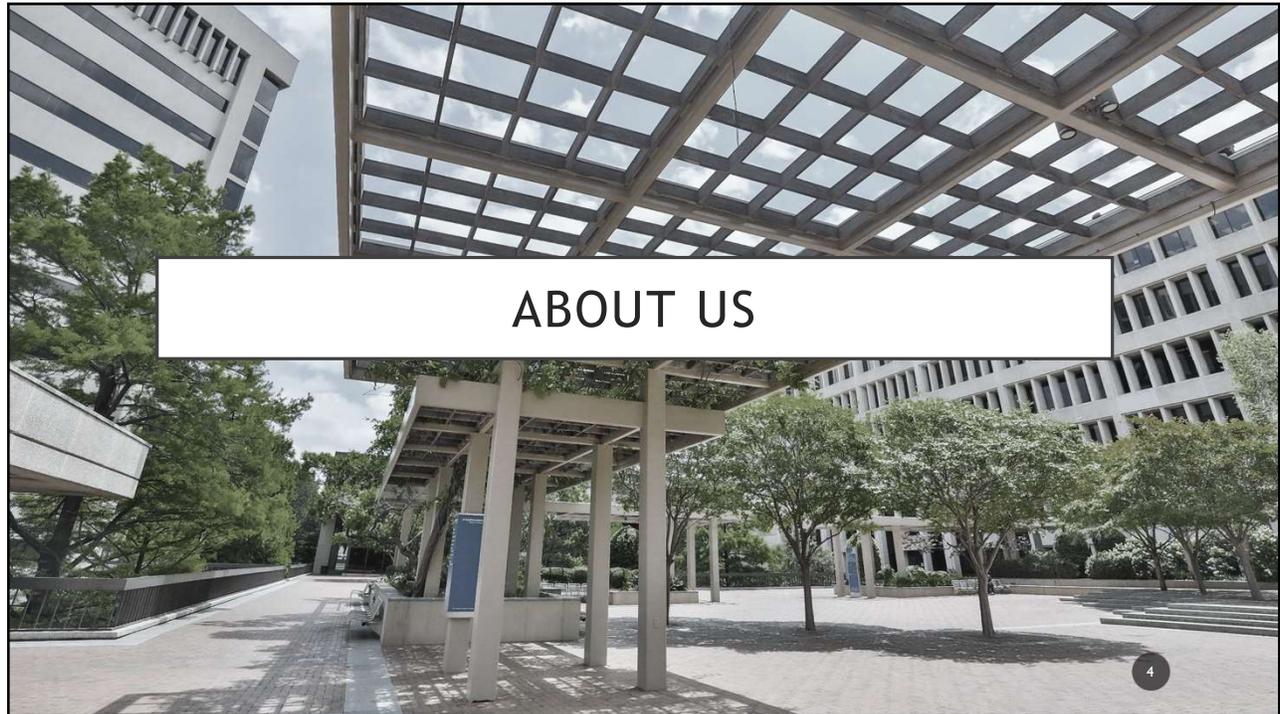
2

## KNOW THE AUDIENCE

- COMPLIANCE/PRIVACY OFFICERS
- AUDITORS/CONSULTANTS
- PRIVATE PRACTICE PERSONNEL
- HEALTH SYSTEM
- ACADEMIC MEDICAL CENTERS

 POLLING QUESTION - 1

3



4

# UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER

## WHO WE ARE



5

## OFFICE OF INSTITUTIONAL COMPLIANCE

Expect to encounter willing partners, ready to provide support, with awareness of potential risks and knowledge of best practices to maintain compliant business units.



6

6

## UTSW MISSION & VALUES

Promoting health and a healthy society that enables individuals to achieve their full potential.

We:

EDUCATE-Physicians, scientists, and caregivers optimally prepared to serve the needs of patients and society  
DISCOVER-Research that solves for unmet needs by finding better treatments, cures, and prevention with a commitment to ensuring real world application

HEAL-Best care possible today, with continuous improvement and innovation for better care tomorrow

Excellence ★ Innovation ★ Teamwork ★ Compassion

### Office of Institutional Compliance

The Mission of the Office of Institutional Compliance at UT Southwestern is to partner with stakeholders to foster a culture of honesty and integrity that allows for successful and elevated patient experiences in each facet of our medical, academic and research communities.

Knowledge Sharing ★ Collaborative Community ★ Proactive Awareness



7

DOES YOUR ORGANIZATION HAVE A SUD PROGRAM?

- YES
- NO
- WORKING TO IMPLEMENT ONE

 POLLING QUESTION - 2

8



## PART 2 OVERVIEW

9

### THE WHY BEHIND PART 2

- Enacted in the 1970s at a time when individuals seeking treatment for substance use disorders faced significant consequences, even legal problems, because they sought help.
- Persons with substance use disorders continue to be subject to discrimination in such areas as employment and housing.

10

## HISTORY OF PART 2

### Original Part 2 Regulation

- Drug Abuse Office and Treatment Act of 1972 (21 USC § 1175) and Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 USC § 4582) authorized confidentiality for patient records.
- Promulgated on July 1, 1975
- Statute is now at 42 USC § 290dd-2

### Substantive Revisions

- 1987
- 2017
- 2018
- Substance Abuse and Mental Health Services Administration (SAMHSA) substantially revised the regulations in 2017 and 2018. While patient privacy is a critical concern, equally important is the need for individuals with substance use disorders to get the safest and most effective treatment possible when they experience medical illnesses.
- 2020
- *Expected Revisions 2021*

11

## STATE LAW & PART 2

- 42 CFR part 2 does not preempt more stringent state laws (See § 2.20)
- A compilation of state laws may be found at:  
<https://www.nasmhpd.org/content/tac-assessment-working-paper2016-compilation-state-behavioral-health-patient-treatment>

12

## WHAT IS 42 C.F.R. PART 2?

“Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States” shall be confidential.

May be disclosed as permitted by prior written consent of the patient.

Subject to certain exceptions/exclusions

13

## EXCEPTIONS TO PART 2

### Exceptions to Consent Requirement

To medical personnel to the extent necessary to meet a bona fide medical emergency

To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluation but individual patients cannot be identified by those personnel in any report or otherwise disclosed

If authorized by a court order showing good cause (e.g., need to avert a substantial risk of death or serious bodily harm)

Except as authorized by court order, no record may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient

14

## DISCLOSURE UNDER PART 2

- Even when exceptions to Part 2 exist or a patient consents to disclosure, absent a court order disclosures by program are not compulsory:
- “The regulations in this part prohibit the disclosure and use of patient records unless certain circumstances exist. If any circumstance exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstances.

15

## PENALTIES FOR PART 2 VIOLATIONS

- Violations to be fined under Title 18 of US Code (Crimes and Criminal Procedure).
- Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute
- Penalty is enforced by DOJ
- Reports of violations to US Attorney in district where violation occurs
- No enforcement cases to date but due to criminal penalty regulation and statute likely to be “strictly construed” by courts
- While there is no federal private right of action, may be other penalties accreditation issues, bad public relations, licensing issues for health professionals, perhaps state law claims (e.g., negligence)

16

**IF YOU HAVE A SUD PROGRAM, WHICH DEFINITION OF PROGRAM DOES YOUR ORGANIZATION USE?**

- INDIVIDUAL/ENTITY
- IDENTIFIED UNIT WITHIN A GENERAL MEDICAL FACILITY
- MEDICAL PERSONNEL OR OTHER STAFF

**POLLING QUESTION -3**

17



18

## PART 2 V. HIPAA

Confidentiality of Substance Use Disorder Patient Records, 42 CFR part 2 (“Part 2”)

Health Insurance Portability & Accountability Act (HIPAA), 42 CFR part 164

PART 2

HIPAA

Both Part 2 and HIPAA protect patient privacy by regulating how and in what forms patient information can be used and disclosed.

**WHERE PART 2 AND HIPAA CONFLICT, YOU MUST COMPLY WITH THE MOST RESTRICTIVE LAW.**

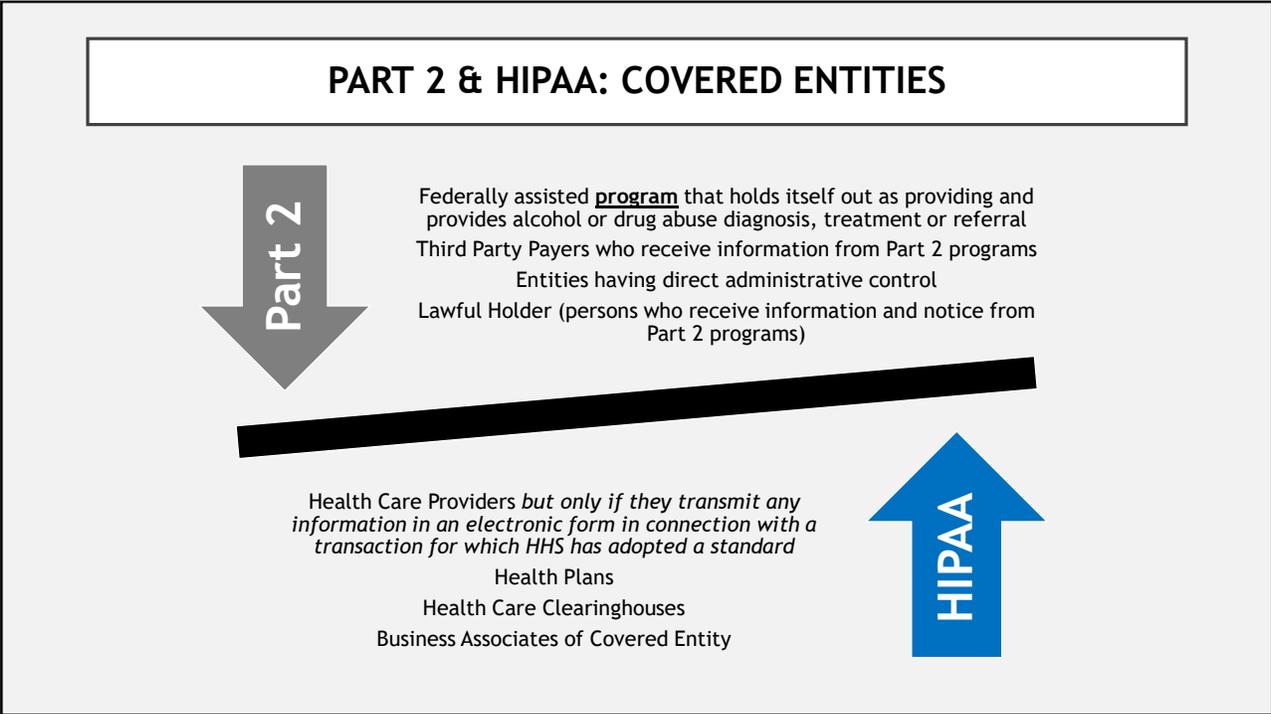
19

## PART 2 & HIPAA: SIMILARITIES

Both Part 2 and HIPAA involve:

- Disclosures to third parties with written agreements
  - ✓HIPAA → Business Associates
  - ✓Part 2 → Qualified Services Organizations
- Minimum Necessary Rule
- Allowance of Patient Access to Records
- Notice of Confidentiality Protections to Patients
- Accounting of Disclosures
- Criminal Penalties for violations

20



21

## PART 2 & HIPAA: KEY DIFFERENCES

	Part 2	HIPAA
Covered Information	Information <b>must</b> identify patient as having SUD, been diagnosed with SUD, or referred for SUD treatment (limited list of demographic elements)	Includes more demographic data (even those that don't indicate a SUD patient)
Definition of Disclosures	The communication of any information from the record of a SUD patient who has been identified, which captures anything that might be in the SUD records (more inclusive than a Designated Record Set)	Limited to Designated Record Sets
Permitted Disclosures	Permits disclosures <b>with</b> patient consent or under specific exceptions  Requires a specific court order to authorize the disclosure of SUD records for criminal and civil legal proceedings	Permits disclosures <b>without</b> patient consent for treatment, payment, or health care operations or under specific exceptions  Requires a court order or valid subpoena from a party to the litigation requesting medical records for criminal and civil legal proceedings

22

## PART 2 & HIPAA: KEY DIFFERENCES

	Part 2	HIPAA
Re-Disclosures	<p>Require that any legal recipient of Part 2 records <b>must</b> follow Part 2 protections</p> <p>Disclosing entity must include a written statement outlining the requirements with each disclosure</p>	<p>Only requires recipients of PHI to abide by laws/regulations that apply to the recipient*</p> <p><i>*Business Associates must abide by the language outlined within the Business Associate Agreement executed with the Covered Entity</i></p>
Reporting Breaches	<p>Reports of Part 2 violations <b>may*</b> be directed to the United States Attorney for the judicial district in which the violation occurs</p> <p><i>*Subject to change upon Part 2 being revised in March 2021</i></p>	<p>Reports of HIPAA violations are <b>required</b> by HIPAA Covered Entities and Business Associates</p>

23

23



## SETTING UP A COMPLIANT PART 2 PROGRAM

24

24

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### Key Questions:

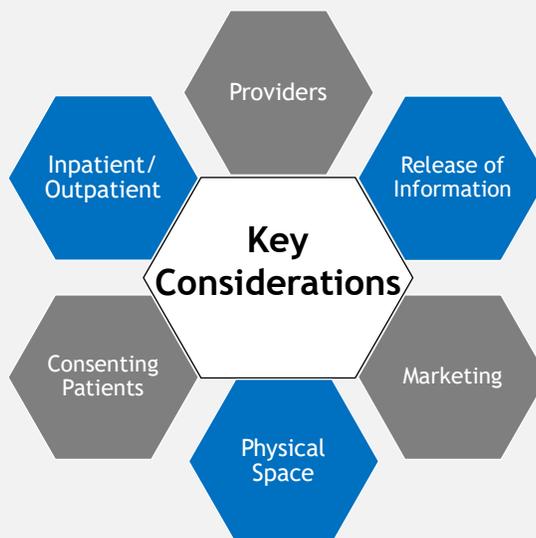
- Is your program federally assisted?
- Do you “hold yourself out” as providing diagnosis/treatment/referral for SUD?

### Defining Your Program:

- An individual or entity (other than a general medical facility) who holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment;
- An identified unit within a general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

25

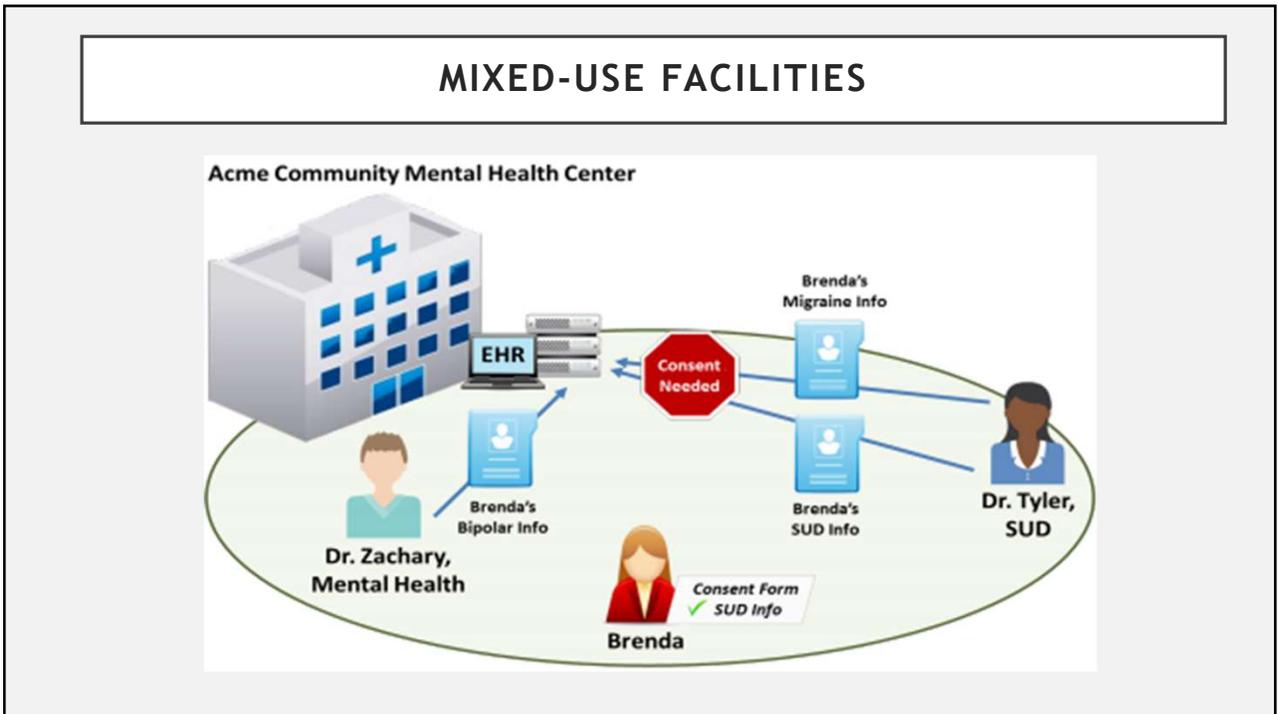
## SETTING UP A COMPLIANT PART 2 PROGRAM



26



27



28

## CONSIDERATIONS FOR MIXED-USE FACILITIES

### PROVIDERS

**PART 2 PROGRAM PROVIDERS' RECORDS FALL UNDER THE SCOPE OF PART 2, EVEN IF NOT ALL RECORDS REFERENCE SUD.**

### SEGREGATION OF RECORDS

**PART 2 REQUIRES THAT SUD RECORDS BE SEGREGATED WITHIN THE EMR, EVEN IN A MIXED-USE CLINIC.**

### PATIENT PERCEPTION

**PATIENT PERCEPTION OF WHAT RECORDS ARE PROTECTED UNDER PART 2 AND/OR HIPAA IS IMPERATIVE.**

### RELEASE OF SUD RECORDS

**HIM STAFF MUST HAVE THE ABILITY TO DIFFERENTIATE BETWEEN PART 2 RECORDS AND NON-PART 2 RECORDS.**

### PHYSICAL SPACE

**PHYSICAL SPACE WITHIN CLINIC SHOULD BE SET UP TO HONOR THE INTENT OF PART 2.**

29



30

## PART 2 IN THE NEWS

### **Headline: Addiction treatment employees charged for refusing police admission to facility**

*Two employees of Bridgeway Behavioral Health (St. Charles, Mo.) have been charged in St. Charles County Court with “interference with legal process” for actions they took in November when, under provisions of 42 CFR Part 2 – the law that protects the confidentiality of patients involved in designated substance abuse treatment facilities - they refused to admit St. Peter Mo. police armed with a search warrant to a Bridgeway facility.*

*Despite the insistence of police to enter the treatment facility, Chernof maintains that the Bridgeway personnel who refused them did nothing wrong. “The confidentiality requirements are often not understood or are misunderstood, even by police,” he explained, pointing to an inch-thick guide to federal drug and alcohol confidentiality law published by the Legal Action Center. “42 CFR Part 2 requires personnel in a designated program to protect the confidentiality of a client unless they receive a specific court order that makes reference to the law and compels them to breach it,” he continued. Chernof points out that the statute does not require a treatment program or its personnel “to offer forcible resistance to police” to protect a client. On the other hand, he added, “Ordinarily, personnel aren’t arrested and charged” for their efforts to comply with this complicated law, which was drafted in the 1970s to protect information about patients participating in addiction treatment programs from being released to others without patient consent.*

31



32

## PART 2 JULY 2020 REVISIONS

### Applicability & Re-Disclosure

Treatment records created by non-Part 2 providers based on their own patient encounter(s) are not covered by Part 2, unless any SUD records received from a Part 2 program are incorporated into such records.

### Disposition of Records

Incidental messages from SUD patients sent to a SUD Program employee's personal device may be "sanitized" from the device by deleting that message.

### Consent Requirements

SUD Patients may consent to disclosures of their Part 2 records to an entity (without naming a specific person).

33

## PART 2 JULY 2020 REVISIONS

### Permitted Disclosures (With Consent)

Disclosures for "payment and health care operations" are permitted with written consent (as constituted by the list of 18 payment and health care operations activities).

### Central Registries & PDMPs

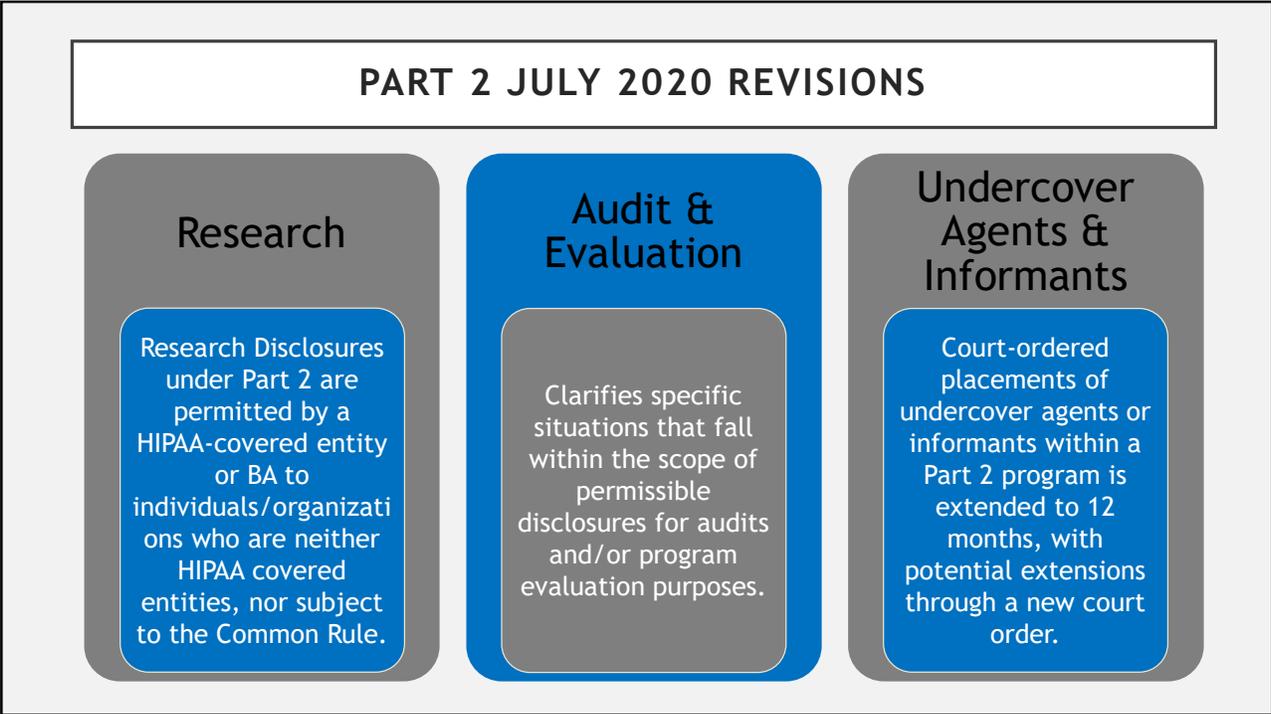
Non-OTP & non-central registry treating providers are now eligible to query a central registry.

OTPs can enroll in & can report data to the PDMP when prescribing or dispensing Schedule II-V medications, consistent with applicable state law.

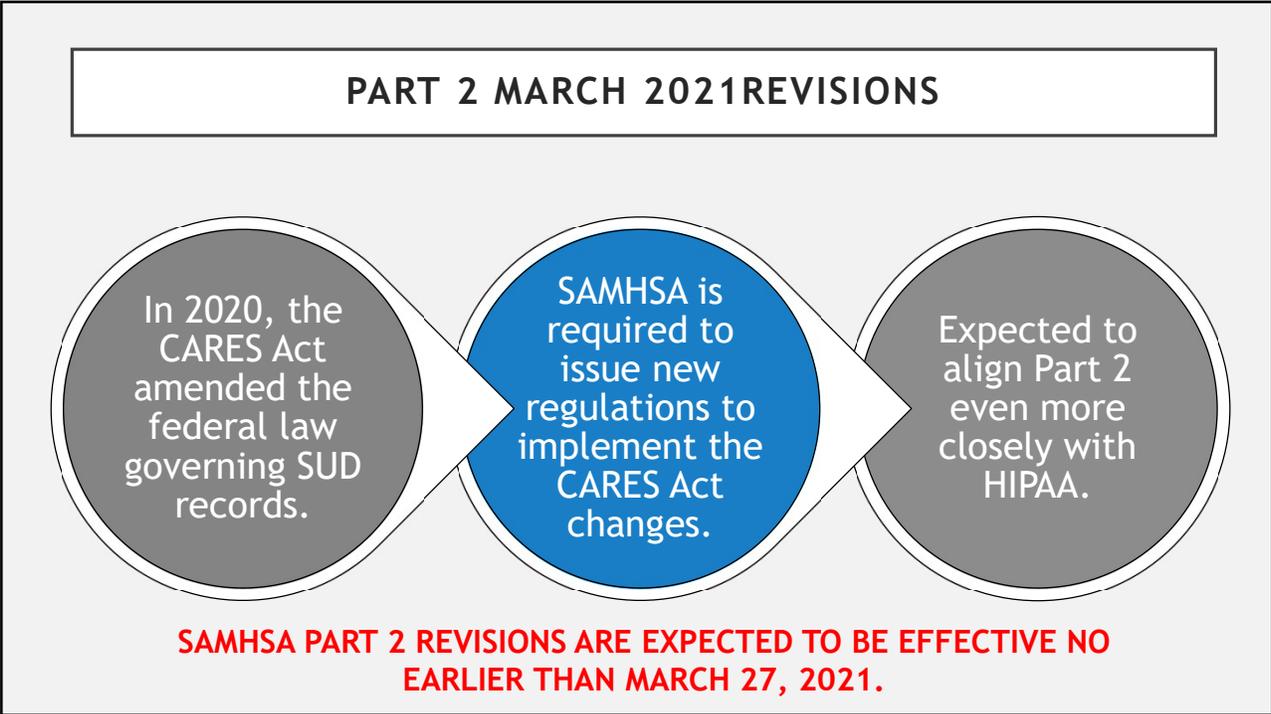
### Medical Emergencies

Declared emergencies resulting from natural disasters that disrupt treatment facilities/services for the purpose of disclosing SUD records without patient consent under Part 2.

34



35



36

## CARES ACT MODIFICATIONS

- Part 2 records can be used and disclosed for Treatment, Payment, & Health Care Operations, pursuant to a single prior written patient consent (revocable in writing).
- Part 2 records can be used to create de-identified information for disclosures to public health authorities.
- Part 2 records can not be used/disclosed for civil, criminal or legislative proceedings.

37

## CARES ACT MODIFICATIONS

- Recipients of Federal funds can not discriminate against patients based on Part 2 records.
- Part 2 programs not covered by HIPAA must comply with HIPAA breach notification requirements if a Part 2 records breach occurs. Breaches are also subject to the same CMPs as HIPAA.
- Covered Entities must update their NPPs to clarify patients may specifically request restrictions of their Part 2 records and describe each purpose of the use/disclosure of their Part 2 records without the patient's written authorization.

38

**HOW COMFORTABLE ARE YOU WITH YOUR  
CURRENT PART 2 COMPLIANCE?**

- VERY CONFIDENT
- FAIRLY CONFIDENT
- MEH (NEED TO REVIEW)
- FAIRLY INSECURE (NEEDS SOME WORK)
- VERY INSECURE (NEEDS A LOT OF WORK)

**POLLING QUESTION - 4**

39



40

**CONTACT INFORMATION**



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