# The Pathway of Part 2 Data in Research: Opioids, Covered Entities, and IRBs, Oh My!

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# Agenda

1. Overview of Part 2 regulations
2. Recent changes to Part 2
3. Using Part 2 data in research
4. Education: Researchers and the IRB
5. Questions



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# Background Information



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## Evolution of Part 2

- The original regulations were promulgated in 1975
- First significant update was in 1987.
- The next revision occurred in January 2017
- Another revision occurred in January 2018
- There is a proposed revision published in August 2019 but not yet final
- The CARES Act made revisions to the regulations



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# Part 2 Key Definitions

- 42 CFR Part 2 Applies to a program that is federally assisted and holds itself out as providing, and provides, SUD diagnosis, treatment, or referral for treatment.
- **Program** means:
  - 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; or
  - 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.
  - 42 C.F.R. § 2.11



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# Part 2 Key Definitions

- *Federal assistance*. A program is considered to be federally assisted if: (1) It is conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the United States (but see paragraphs (c)(1) and (2) of this section relating to the Department of Veterans Affairs and the Armed Forces);
- (2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including but not limited to:
  - (i) Participating provider in the Medicare program;
  - (ii) Authorization to conduct maintenance treatment or withdrawal management; or
  - (iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of substance use disorders;
  - 42 C.F.R. § 2.12(b)



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# Part 2 Key Definitions

- *Federal assistance (cont.)*
- (3) It is supported by funds provided by any department or agency of the United States by being:
  - (i) A recipient of federal financial assistance in any form, including financial assistance which does not directly pay for the substance use disorder diagnosis, treatment, or referral for treatment; or
  - (ii) Conducted by a state or local government unit which, through general or special revenue sharing or other forms of assistance, receives federal funds which could be (but are not necessarily) spent for the substance use disorder program; or
- (4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.
  - 42 C.F.R. § 2.12(b)





# Part 2 Key Definitions

- **Substance Use Disorder** means a cluster of cognitive, behavioral, and psychological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For the purpose of the regulations in this part, this definition does not include tobacco or caffeine use.
- ***Records*** means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient (*e.g.,* diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts). For the purpose of the regulations in this part, records include both paper and electronic records.
  - 42 C.F.R. § 2.11
  -

# Part 2 Key Definitions

- **Patient identifying information** means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information. The term does not include a number assigned to a patient by a part 2 program, for internal use only by the part 2 program, if that number does not consist of or contain numbers (such as a social security, or driver's license number) that could be used to identify a patient with reasonable accuracy from sources external to the part 2 program.
  - 42 C.F.R. § 2.11
  -



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# Part 2 Key Provisions

- Restrictions on disclosure:
  - (a) *General*—(1) *Restrictions on disclosure*. The restrictions on disclosure in the regulations in this part apply to any information, whether or not recorded, which:
  - (i) Would identify a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person; and
  - (ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972 (part 2 program), or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (part 2 program); or if obtained before the pertinent date, is maintained by a part 2 program after that date as part of an ongoing treatment episode which extends past that date; for the purpose of treating a substance use disorder, making a diagnosis for that treatment, or making a referral for that treatment.
  - 42 C.F.R. § 2.12(a)(i)&(ii)



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# Part 2 Key Provisions

- *Restrictions on disclosures*—(i) *Third-party payers, administrative entities, and others*. The restrictions on disclosure in the regulations in this part apply to:
  - (A) Third-party payers with regard to records disclosed to them by part 2 programs or under §2.31(a)(4)(iii)(A);
  - (B) Entities having direct administrative control over part 2 programs with regard to information that is subject to the regulations in this part communicated to them by the part 2 program under paragraph (c)(3) of this section; and
  - (C) Individuals or entities who receive patient records directly from a part 2 program or other lawful holder of patient identifying information and who are notified of the prohibition on re-disclosure in accordance with §2.32.
  - 42 C.F.R. § 2.12(d)(2)



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# Part 2 Key Provisions

- *Required elements of patient's written consent*
  - Patient name
  - Specific name or general designation(s) of the part 2 program(s), entity(ies) or individual(s) permitted to make the disclosure
  - How much & what kind of information is to be disclosed w/explicit description of the SUD info to be disclosed
  - Name of the individual(s) to whom a disclosure is made or
  - Name of the entity with a treating provider relationship w/patient or
  - 42 C.F.R. § 2.31



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# Part 2 Key Provisions

- *Required elements of patient's written consent (cont.)*
  - Name of 3rd party payer w/o treating relationship with the patient
  - If not a 3rd party payer and is an HIE or research institution
    - Name of individual participants or
    - Name of any entity with treating relationship with the patient or
    - General designation of an individual or entity or class of participants that must be limited to participants with a treating relationship with the patient
      - If a general designation is used the patient or their representative must confirm that they may ask for a list of entities to whom their data was disclosed
  - Purpose of the disclosure-must be minimum necessary
  - Revocation language
  - Expiration date, event, or condition which must ensure the consent will not last longer than reasonably necessary
  - Signature of the patient or representative and the date signed.
  - 42 C.F.R. § 2.31



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# 2 Recent Changes to the Part 2 regulations



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# Changes Published in 2018

- Abbreviated language regarding re-disclosure
  - "Federal law/42 CFR Part 2 prohibits unauthorized disclosure of these records"
- Permitted disclosures with written consent
  - If patient consented to disclosures for payment and healthcare operations then the recipient entity can re-disclose to is contractors for payment or healthcare operations
  - Cannot share with contractors for treatment, care coordination or case management
- Lawful holder of Part 2 information must have contact in place with with contractors specifically requiring them to comply with Part 2 with language that
  - Requires reasonable safeguards against unauthorized uses and disclosures
  - Part 2 must be explicitly listed
- Can also disclose to contactors for Medicare, Medicaid or CHIP audit or investigation



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# Proposed Changes Published in 2019

- Clarification regarding the status of SUD information created in a record of a lawful holder who has also received Part 2 information and included it in the same record
- Allows non-Part 2 providers with treating relationship to access Part 2 central registries to prevent multiple enrollments
- Allows Part 2 providers or other lawful holders to disclose information with patient consent to a prescription drug monitoring program (PDMP) if required by law.
- Changes to consent to allow Part 2 patients to consent to disclosure to entities without a treating relationship without naming specific individual to whom the data is being disclosed (SS Admin)
- Specifics that the general designation option for future consent is specific to HIEs and research institutions



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# Proposed Changes Published in 2019 (cont.)

- Expands bona fide medical emergency to include natural disasters if Part 2 program is closed or unable to provide services.
- Moves examples of types of activities under payment and healthcare operations for which a lawful holder can share Part 2 data with contractors, subcontractors, or legal representatives from Preamble to the regulatory language.
- Expands who can get Part 2 data without consent for research
  - Under current rule can only disclose to qualified personnel conducting research at a covered entity or business associate with authorization or waiver of authorization or
  - The recipient is subject to the HHS protections for human subjects under the Common Rule
  - Proposed regulation allows disclosure from HIPAA covered entity or business associate to individuals or organizations that are not subject to HIPAA or the Common Rule if the data is disclosed in compliance with HIPAA



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# Proposed Changes Published in 2019 (cont.)

- New proposed regulatory language would allow Part 2 data to be disclosed for research to a CE workforce member for employer sponsored research if the CE requires all research to be conducted in compliance with HIPAA and/or the Common Rule.
- New proposed regulatory language that would allow Part 2 data to be disclosed for research to recipients covered by the FDA regulations for the protection of human subjects.



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# Changes Under the CARES Act

- Once written consent has been obtained, Part 2 records can be used or disclosed pursuant to HIPAA for treatment, payment, and healthcare operations by covered entities or business associates
- Must still account for the disclosures including disclosures from the EHR
- Must comply with the request for restrictions including those under HITECH associated with the patient paying in full
- The terms covered entity, business associate, treatment, payment, and healthcare operations have the same meaning as under HIPAA
- Only need to obtain patient consent once for all future uses and disclosures for TPO



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# Changes Under the CARES Act

- Part 2 information can be shared with public health authorities if it is de-identified.
- Penalties for unauthorized uses or disclosures of Part 2 information were aligned with the HIPAA civil monetary penalties
- New protections for discrimination based on SUD diagnosis or treatment for records inadvertently or intentionally disclosed
- HIPAA breach notification rule applies to SUD records of a Part 2 program regardless if entity is otherwise subject to HIPAA
- Requires the notice of privacy practices for Part 2 programs be updated to make patients aware of their rights.



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# Changes Under the CARES Act

- KEY FACTORS:
  - CARES Act is immediately effective
  - Current regulations are effective based on January 2018 final rule.
  - There is a disconnect between the two.
  - CARES Act directs SAMSHA to issue regulations to be effective March 21, 2021.
  - It is a way and see.



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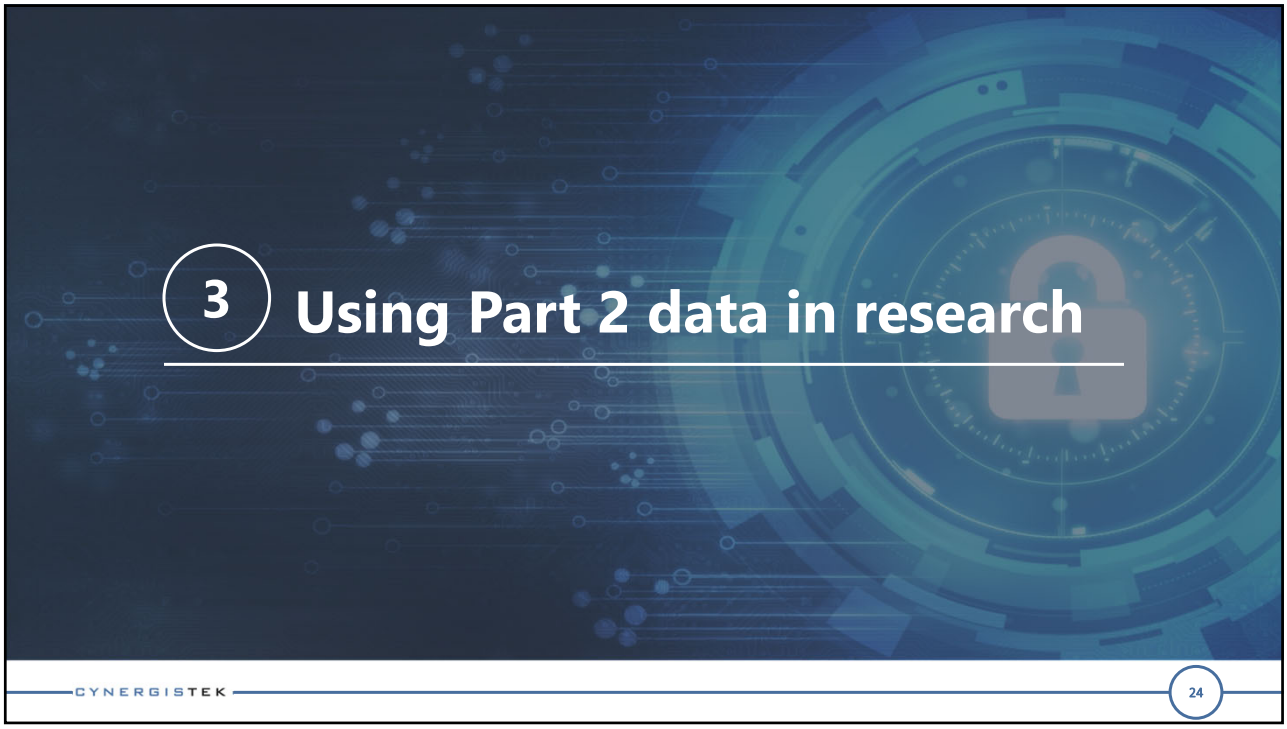




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## Compliance Considerations

- Compliance with re-disclosure requirements
- Contract language if contractors are used
- Ensuring appropriate protections
- Breach notification obligations



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## Re-disclosure

- Make sure
  - The notice is going with data used for research
  - Researchers are only redisclosing to appropriate individuals
  - Any authorization used for Part 2 SUD information is very clear about who might be getting the information
  - Any waiver of authorization is clear on the uses and disclosures for the Part 2 SUD information and
    - Has an adequate plan to protect the information



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## Contract language if contractors are used

- Do agreements include language regarding the need to protect Part 2 information shared with the contractor
- While a BAA is uncommon in research, make sure your BAA specifically mentions Part 2 data if applicable



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## Appropriate Protections

- Evaluate the security measures for research involving Part 2 information
- Reassess the incident response plan to encompass obligations for Part 2 data



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## Breach notification obligations

- Part 2 programs may ask that lawful holders of Part 2 SUD information agree to the breach notification provisions of the CARES act



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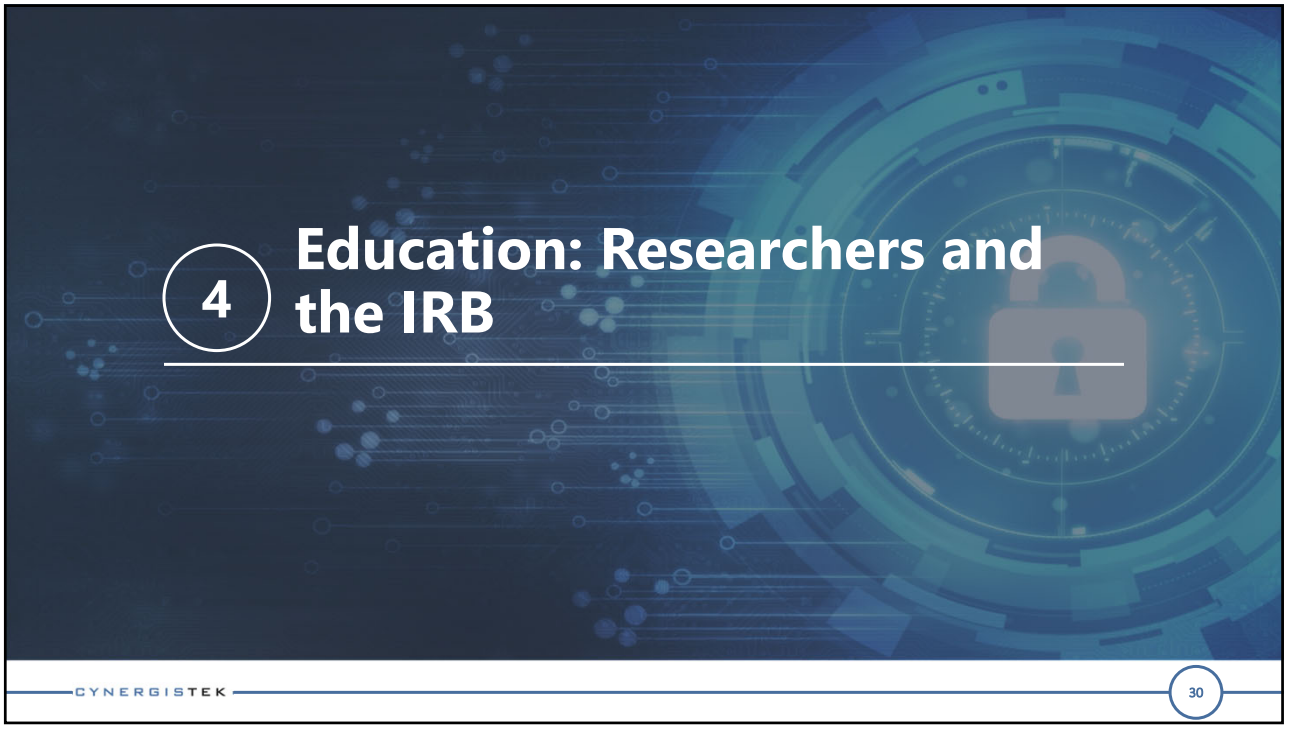


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## Making sure researchers are aware

- The Part 2 regulations promulgated in January 2018 are still in effect
- Not significant changes for the use of Part 2 data in research
- The CARES Act appear to add
  - Breach notification obligations to researchers receiving Part 2 data
  - Penalties applicable for unauthorized uses and disclosures of Part 2 data by a researcher.



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## IRB actions

- Understands when Part 2 data might be involved
  - The entity using or disclosing the information is a Part 2 program
  - The entity using or disclosing the information is involved in SUD treatment and could have Part 2 data in its records
- Evaluating the risk when Part 2 data is involved
  - Re-disclosure issues
- Evaluating the plan to protect the Part 2 data when a waiver of authorization is requested by the researcher



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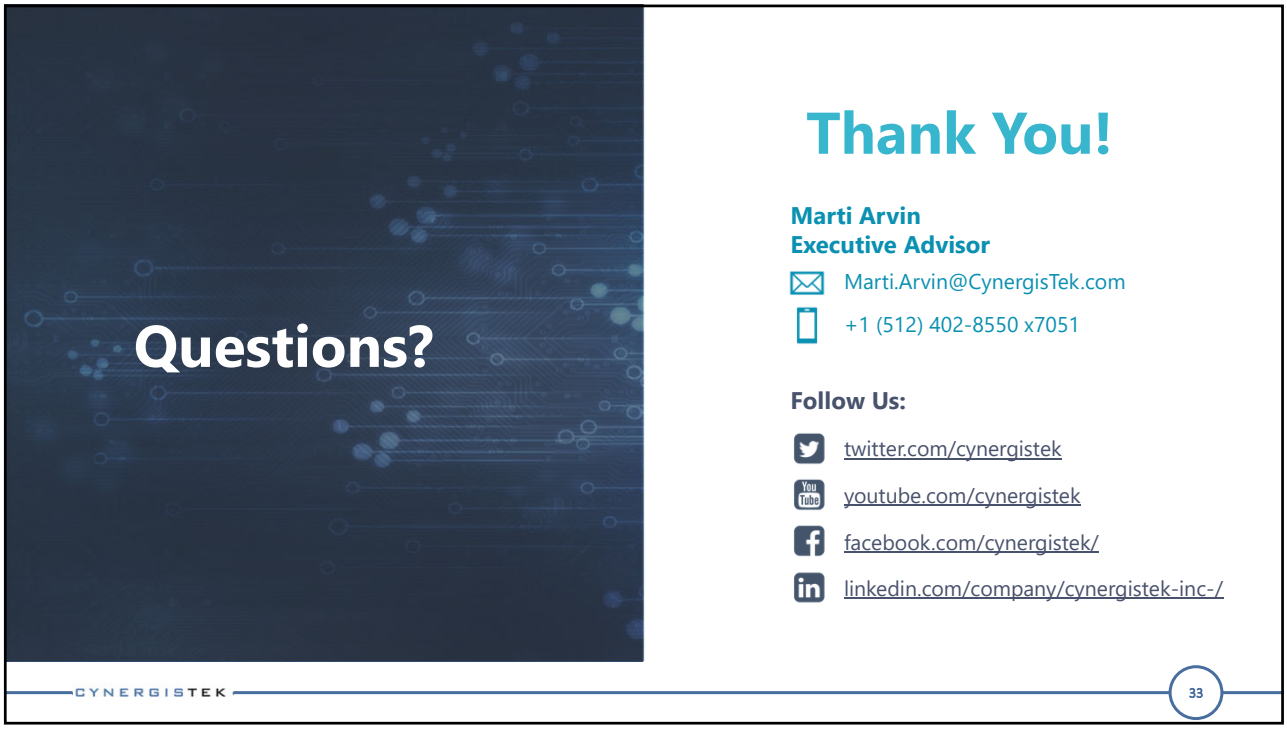
Questions?
Thank You!
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