42 CFR Part 2 & Final Rule: 2020 Update

What is 42 CFR Part 2?

- CFR Title 42 - Public Health is one of fifty titles comprising the United States Code of Federal Regulations (CFR). Title 42 is the principal set of rules and regulations issued by federal agencies of the United States regarding public health
- The purpose of 42 CFR Part 2 is to allow patient identifying information to be disclosed to medical personnel in a medical emergency [42 CFR § 2.51].
- 42 CFR Part 2’s general rule places privacy and confidentiality restrictions upon substance use disorder treatment records.

What is the difference between HIPAA and 42 CFR?

- There are two main differences between Part 2 substance abuse disorder disclosure limitations and the HIPAA Privacy Rule disclosure limitations.
- The HIPAA Privacy Rule permits disclosures without patient consent for treatment, payment, or healthcare operations. However, for patients with substance abuse disorders, such disclosures may lead to stigma and discrimination by healthcare providers, the potential loss of insurance, and even loss of employment.
- Part 2 substance use disorder treatment regulations require either that a patient consent, or that the disclosure be permitted under a specific exception.

What is the difference between HIPAA and 42 CFR? (Cont.)

- The two regulations also differ in the amount of privacy protections afforded or patient records in criminal and civil legal proceedings.
- Under HIPAA, a HIPAA-covered health care provider or health plan may share protected health information if it has a court order, or, if it receives a valid subpoena from a party to the litigation requesting medical records.
- Part 2's requirements are much stricter. Part 2 requires that a specific court order authorize disclosure of SUD records. Persons having a legally recognized interest in the disclosure – and only those persons- may apply for the court order.

What is the difference between HIPAA and 42 CFR? (Cont.)

- When one regulation imposes a stricter standard than the other, the covered entity must follow the stricter standard. Generally, 42 CFR Part 2 imposes more strict standards than HIPAA does.
- 42 CFR Part 2's general rule places privacy and confidentiality restrictions upon substance use disorder treatment records.

Who does 42 CFR Apply to?

- 42 CFR Part 2 applies to any individual or entity that is federally assisted and holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment (42 CFR § 2.11).
- Most drug and alcohol treatment programs are federally assisted.

Changes to 42 CFR Part 2

- The Substance Abuse and Mental Health Services Administration (SAMHSA) released a final rule on July 13, 2020, to go into effect on Friday, August 14th, 2020.
- The CARES Act of 2020 approved by Congress and signed into law made several changes to 42 CFR Part 2's enabling legislation.
- Additional regulations will be needed to implement the changes, which can go into effect no earlier than March 27, 2021.

CARES Act Modifications to 42 U.S.C § 290dd-s

- 42 U.S.C. § 290dd-2 is statutory basis for 42 CFR Part 2 – the Confidentiality of Substance Use Disorder Patient Records regulations
- Federal Coronavirus Aid, Relief, and Economic Security (CARES) Act signed March 27, 2020 amends 42
- U.S.C. § 290dd-2 to align more closely with Health Insurance Portability and Accountability Act (HIPAA)
- Requires general consent for disclosure of substance use disorder (SUD) treatment records
- Allows disclosure of covered records for treatment, payment and health care operations.

CARES Act Modifications to 42 U.S.C § 290dd-s (cont.)

- Recipients include Part 2 programs, HIPAA covered entities and business associates
- May be redisclosed in accordance with HIPAA
- Allows for disclosure of de-identified SUD records to public health authorities
- Prohibits use of SUD records in civil, criminal, legislative, or administrative proceedings other than by Court order or patient consent
- Adopts HIPAA fines and penalties in place of old Part 2 criminal enforcement mechanism
- Obligation to comply with HIPAA breach notification requirements
- Protections against discrimination based on intentional or inadvertent disclosure of SUD records

Part 2 Regulations

- CARES Act amended statute on which Part 2 is based
- Part 2 regulations were not directly amended by CARES Act
- Questions raised regarding enforceability
- HHS has stated that the final regulations incorporating the CARES Act revisions will not be effective prior to March 2021

Part 2 - Disclosures

- Part 2 Programs must still obtain consent in order to disclose:
  - Uses and disclosures only for treatment, payment, and certain health care operations
  - Only to other Part 2 programs, HIPAA covered entities or business associates
- Ability of recipients to redisclose pursuant to HIPAA
- Accounting of disclosures requirement under HITECH Act now applies
- Right of individual to request restriction on use or disclosure under HITECH Act

Part 2 - Consent

- Consent
  - Must be obtained prior to disclosure
  - Must be in writing
  - May obtain consent once for all future uses or disclosures until revoked
- Revocation
  - Once revoked, how will it impact downstream recipients?

Part 2 – Model Notice of Privacy Practices

- Model notice to be issued by the Secretary not later than 1 year after enactment of the CARES Act
  - Must be easily understandable and in plain language
  - Must include:
    - Statement of the patient's rights with respect to protected health information (including for self-pay patients)
    - Brief description of how the individual may exercise their related rights
    - Description of each purpose for which the covered entity is permitted or required to use or disclose protected health information without the patient's written authorization

Part 2 – Breach Notification

- Breach – the acquisition, access, use, or disclosure of protected health information in a manner not permitted under applicable regulations which compromises the security or privacy of the protected health information.
- Disclosure in a manner not permitted by regulations is presumed to be a breach, unless:
  - Good faith but unintentional acquisition, access or use by workforce member or person under the authority of a covered entity or business associate if no unpermitted use or disclosure
  - Inadvertent disclosure by and to person with authorized access at covered entity or business associate if no further unpermitted use or disclosure
  - Covered entity can demonstrate through risk assessment that there is a low probability that the protected health information has been compromised

Part 2 – Breach Notification (cont.)

- In case of a breach, covered entity must notify everyone whose unsecured protected information has been, or is reasonably believed to have been, accessed, acquired, or disclosed as a result of such breach.
- Business associates notify covered entities of breach
- Breach is considered discovered as of the first day on which it is known to the covered entity, or by which the covered entity would have known had it exercised reasonable diligence
- Must notify patient without unreasonable delay and no more than 60 calendar days after discovery

Part 2 – Breach Notification (cont.)

- Notice must be written in plain language and must include, to the extent possible:
  - Brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;
  - Description of the types of unsecured protected health information involved in the breach (e.g., full name, SSN, DOB, home address, account number, diagnosis, disability code, etc.);
  - Steps individuals should take to protect themselves from potential harm resulting from the breach;

Part 2 – Breach Notification (cont.)

- Brief description of the covered entity s actions to investigate the breach, mitigate harm to individuals, and protect against further breaches;
- Contact procedures for questions or additional information
- Must notify HHS within 60 days if 500 or more individuals; within 60 days of end of calendar year for others
- Must notify media if more than 500 individuals in state or jurisdiction

Part 2 – Anti-Discrimination

- Adds explicit protections against discrimination based upon Part 2 records or information about the patient disclosed under Part 2 – either inadvertently or intentionally. Specifically, no entity may discriminate against a patient about whom the Part 2 records relate in:
- Admission, access to, or treatment for health care
- Hiring, firing, or terms of employment, or receipt of worker's compensation
- Sale, rental, or continued rental of housing
- Access to Federal, State, or local courts
- Access to, approval of, or maintenance of social services and benefits provided or funded by
- Federal, State, or local governments
- No recipient of Federal funds may discriminate against the patient based upon the Part 2 records in affording access to the services provided with such funds

Part 2 – Use in Proceedings

- Except with a valid court order or patient consent, Part 2 records or testimony about such records may not be disclosed or used in any civil, criminal, administrative, or legislative proceeding conducted by any Federal, State, or local authority, against a patient, including that:
- The record or testimony shall not be entered into evidence in any criminal prosecution or civil action before a Federal or State court
- The record or testimony shall not form part of the record for decision or otherwise be considered in any proceeding before a Federal, State, or local agency
- The record or testimony shall not be used by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation

Part 2 – Penalties and Enforcement

- Part 2 has historically been enforced criminally by the US Attorney (42 CFR § 2.4) and penalties under Title 18 of the U.S. Code (42 CFR § 2.3)
- Penalties now set forth under sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5 and 42 U.S.C. 1320d–6), which are the penalties imposed for HIPAA violations
- Penalties for civil violations
- HIPAA violation: Unknowing - Penalty range: $100 - $50,000 per violation, with annual maximum of $25,000 for repeat violations
- HIPAA violation: Reasonable Cause - Penalty range: $1,000 - $50,000 per violation, with annual maximum of $100,000 for repeat violations

Part 2 – Penalties and Enforcement (cont.)

- HIPAA violation: Willful neglect but violation is corrected within the required time period - Penalty range: $10,000 - $50,000 per violation, with an annual maximum of $250,000 for repeat violations
- HIPAA violation: Willful neglect and is not corrected within required time period - Penalty range: $50,000 per violation, with an annual maximum of $1.5 million Criminal penalties
- “Knowingly" obtain or disclose individually identifiable health information, in violation of the Administrative Simplification Regulations, face a fine of up to $50,000, as well as imprisonment up to 1 year
- Offenses committed under false pretenses allow penalties to be increased to a $100,000 fine, with up to 5 years in prison
- Offenses committed with the intent to sell, transfer or use individually identifiable health information for commercial advantage, personal gain or malicious harm permit fines of $250,000 and imprisonment up to 10 years

Part 2 – Sense of Congress

It is the sense of the Congress that—

1. Any person treating a patient through a Part 2 program or activity with respect to which the SUD confidentiality requirements apply is encouraged to access the applicable State-based prescription drug monitoring program when clinically appropriate
2. Patients have the right to request a restriction on the use or disclosure of a SUD record for treatment, payment, or health care operations
3. Covered entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding such use or disclosure

Part 2 – Sense of Congress (cont.)

4. For purposes of SUD confidentiality protections,
   "health care operations " shall have the meaning given such term in the HIPAA regulations except that this term shall not include the creation of "de- identified health information or a limited data set, and fundraising for the benefit of the covered entity"
5. Programs creating protected SUD records should receive positive incentives for discussing with their patients the benefits to consenting to share such records.

42 CFR Part 2 Final Rule Published 7/15/20

- Final Rule amending 42 CFR Part 2 was published July 15, 2020
- Effective August 14, 2020
- Based on Notice of Proposed Rulemaking of August 2019
- Does NOT include CARES Act provisions

Summary of July 2020 Final Rule

- Definitions (§ 2.11)
  - Revises the definition of “Records” to create an exception so that information communicated orally by a Part 2 program to a non-Part 2 provider for treatment purposes with consent does not become a “record” subject to Part 2 merely because it is reduced to writing by that non-Part 2 provider
- Applicability (§ 2.12)
  - Provides that the recording of information about an SUD and its treatment by a non- Part 2 provider does not, by itself, render a medical record subject to Part 2, provided that the non-Part 2 provider segregates any specific SUD records that it receives

Summary of July 2020 Final Rule (cont.)

- Consent requirements (§ 2.31)
  - Permits patients to consent to the disclosure of their information for operations purposes to certain entities without naming a specific individual and includes special instructions for health information exchanges (HIEs) and research institutions
- Prohibition on redisclosure (§ 2.32)
  - Clarifies that non-Part 2 providers do not need to redact information in their or another non-Part 2 record and confirms that redisclosure is permitted if expressly permitted by written consent of the patient or permitted under Part 2 regulations

Summary of July 2020 Final Rule (cont.)

- Disclosures permitted with written consent (§ 2.33)
  - Allows disclosure to specified entities and individuals for 18 types of payment and health care operational
  - activities, including for care coordination and case management
- Disclosures to prevent multiple enrollments (§ 2.34)
  - Permits non-opioid treatment providers with a treating provider relationship to access central registries
- Disclosures to Prescription Drug Monitoring Programs (§ 2.36)
  - Permits opioid treatment programs (OTPs) to disclose dispensing and prescribing data, as required by applicable state law, to prescription drug monitoring programs (PDMPs), subject to patient consent
- Medical Emergencies (§ 2.51)
  - Authorizes disclosure of information to another Part 2 program or other SUD treatment provider during
  - State or Federally-declared natural and major disasters

Summary of July 2020 Final Rule (cont.)

- Research (§ 2.52)
  - Permits research disclosures of Part 2 data by a HIPAA covered entity to individuals and organizations who are neither HIPAA covered entities, nor subject to the Common Rule. Also now permits research disclosures to recipients who are covered by Food and Drug Administration (FDA) regulations
- Audit and evaluation (§ 2.53)
  - Clarifies that federal, state and local governmental agencies and third-party payors may conduct audits and evaluations to identify actions necessary to improve care; that audits and evaluations may include medical necessity and utilization reviews; and that auditors may include quality assurance organizations as well as entities with direct administrative control over a Part 2 program or a lawful holder. Also updates language related to quality improvement organizations (QIOs), and allows for patient identifying information to be disclosed to federal, state, or local government agencies, and to their contractors, subcontractors, and legal representatives for audit and evaluations required by law

Summary of July 2020 Final Rule (cont.)

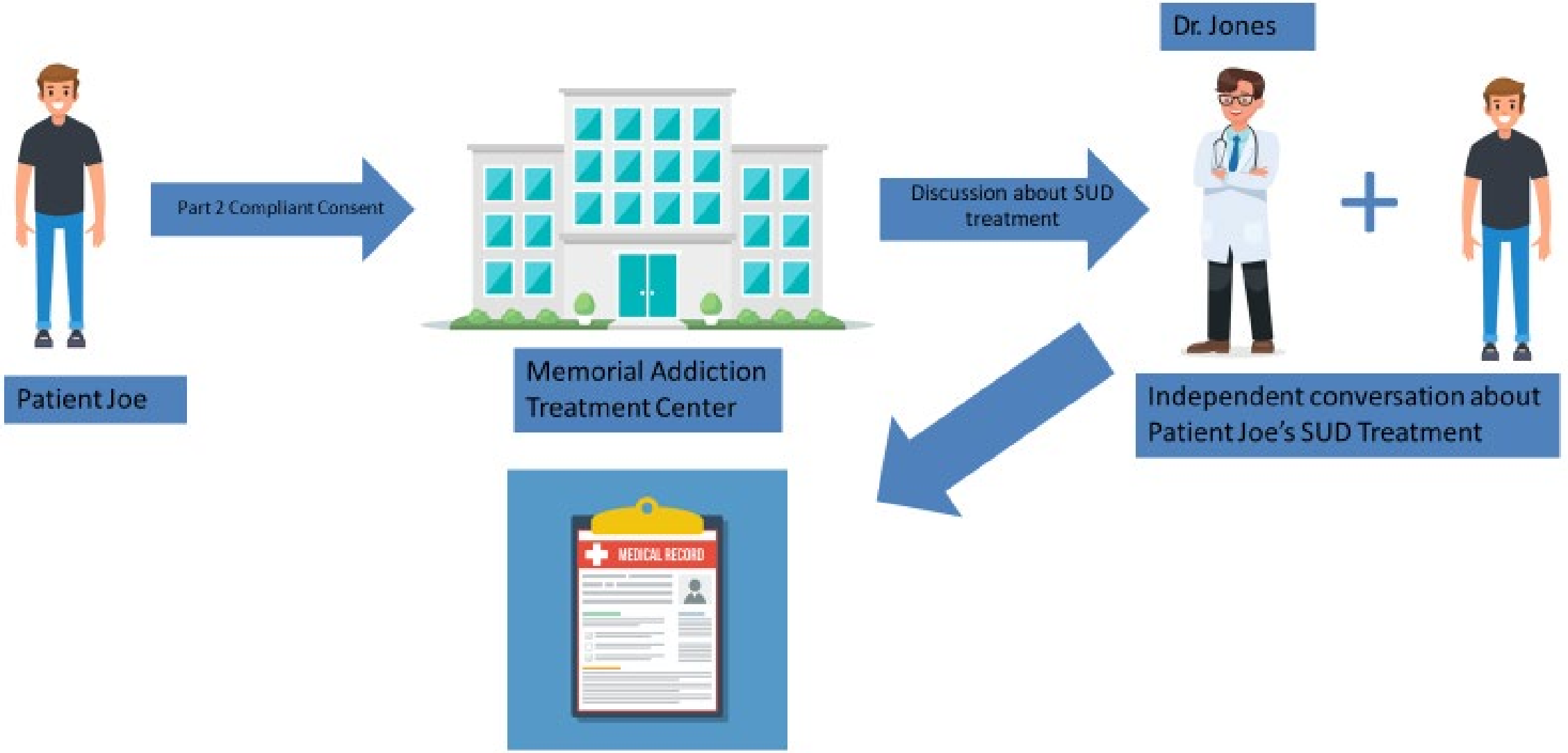
- Orders authorizing use of undercover agents and informants (§ 2.67)
  - Amends the period for court-ordered placement of an undercover agent and informant within a Part 2 program to 12
  - months that starts when an undercover agent or informant is placed in the Part 2 program

Changes to 42 CFR Part 2 Regulations: Clinical Perspective

- Applications
  - Application 1: Applicability and re-disclosure for non-part 2 providers
  - Application 2: Disclosures permitted with written consent for care.
  - Application 3: OTP disclosures to Prescription Drug Monitoring Programs (PDMPs).

Application 1: Applicability and Re-Disclosure for Non-Part 2 Providers

- What: Clarifies that treatment records created by non-Part 2 providers based on their own patient encounter(s) are not covered by Part 2. Segregation of a Part 2 patient record previously received can be used to ensure that new records created by non-Part 2 providers will not become subject to Part 2.
- Why: To facilitate coordination of care activities by non-part-2 providers by alleviating fear among non-part 2 providers of inadvertently violating Part 2, as a result of receiving and reading a protected SUD patient record and then providing care to the patient.


Dr. Jones
Part 2 Compliant Consent
Discussion about SUD treatment
Patient Joe
Memorial Addiction Treatment Center
Independent conversation about Patient Joe's SUD Treatment
MEDICAL RECORD

Application 2: Disclosure Permitted with Written Consent for Care Coordination and Case Management

- What: Disclosures for the purpose of “payment and health care operations” are now explicitly listed as permitted with written consent under regulatory provisions. Further, the list has been expanded to include care coordination and case management activities.

- Why: In order to resolve lingering confusion under Part 2 about what activities count as “payment and health care operations.”

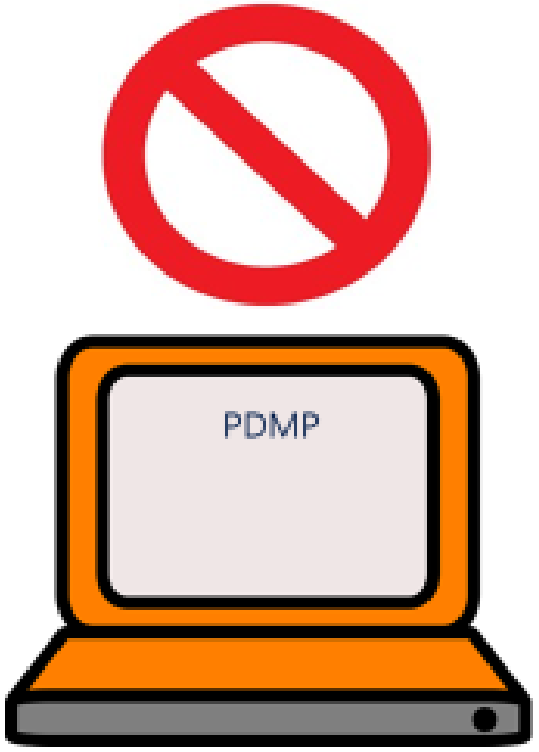
Application 2: Disclosure Permitted with Written Consent for Care Coordination and Case Management

- Patients may consent to disclosures of Part 2 information to organizations without a treating provider relationship.
- Patients may consent to share their information with a contractor or subcontractor that performs care coordination or case management, if the consent form specifies the contracted organization name in the ‘‘to whom’’ section, describes the specific types of activities to be undertaken in the ‘‘purpose’’ section; and meets all other required elements outlined in § 2.31.

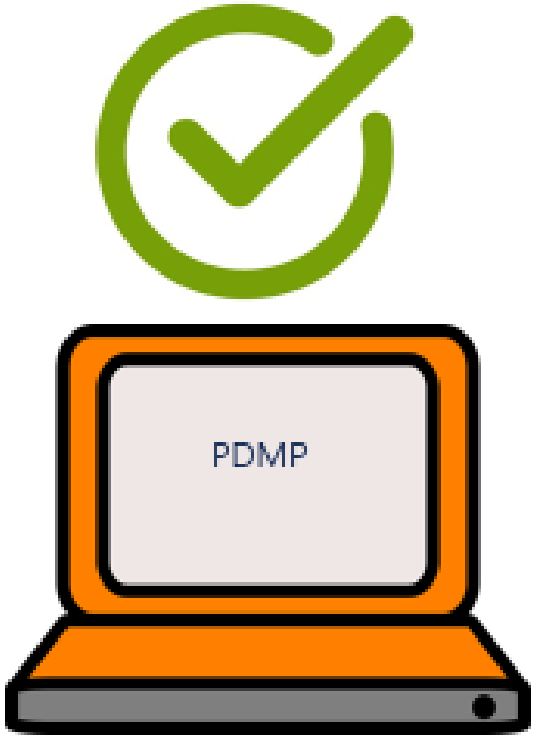
Application 3: OTP Disclosures to PDMPs

- What: OTPs are permitted to enroll in a state PDMP and permitted to report data into the PDMP when prescribing or dispensing medications on Schedules II to V, consistent with applicable state law.
- Why: To prevent duplicative enrollments in SUD care, duplicative prescriptions for SUD treatment, and adverse drug events related to SUD treatment.

Prescription Drug Monitoring Program (PDMP)



Before



After with patient consent and consistent with state law

Resources

- Substance Abuse and Mental Health Services Administration: https://www.samhsa.gov/
  - The Center of Excellence for Protected Health Information: https://www.coephi.org/
- American Psychiatric Association: https://www.psychiatry.org/
  - 42 CFR Part 2 webpage
- American Academy of Addiction Psychiatry: https://www.aaap.org/
- American Society of Addiction Medicine: https://www.asam.org/
  - 42 CFR Part 2 webpage

Thank You