The Revised Substance Use Disorder Privacy Regulations of 42 C.F.R. Part 2

DISCLAIMER

• This presentation is for informational purposes only. The information contained in this presentation is not intended to be, and should not be relied upon, as legal advice.
• The views and opinions included in this presentation are solely those of the presenters and do not necessarily represent the views or opinions of their associated entity.
**WHAT IS 42 C.F.R PART 2?**

- 42 CFR Part 2 was enacted in 1975 to protect confidentiality of patient records pertaining to substance abuse disorder treatment
- The goal was to ensure that individuals seeking alcohol or drug abuse treatment are not made more vulnerable than individuals who do not seek treatment

**REASONS FOR UPDATES**

- Prior to 2017, last substantive revision was in 1987
- Part 2 became outdated due to changes in health care industry
- Limited ability to coordinate care for patients with substance use disorders
UPDATES

• Two rounds of updates: 2017 and 2018
• Purpose:
  – Update the regulation in response to significant changes in information system capabilities
  – Better align the regulation with HIPAA
  – Reduce substance abuse and misuse

KEY CHANGES

2017
• Where to report violations (§2.4)
• Definition consolidation/additions (§2.11)
• Clarifies applicability (§2.12)
• Security Standards (§2.16)
• Patient Notice of federal laws (§2.22)
• Clarifies consent requirements, consent form revisions, and general designation for “To whom” (§2.31)
• Clarifies prohibition on re-disclosure (§2.32)
• Clarifies research (§2.52) and medical emergency exception (§2.51), and disclosures for audit and evaluation (§2.53)

2018
• Abbreviated notice for prohibition of re-disclosure for electronic use (§2.32)
• Clarifies disclosure to facilitate payment and healthcare operations (§2.33)
• Clarifies disclosure for Medicare, Medicaid, or Chip audit/evaluation (§2.53)
**APPLICABILITY**

Coverage under 42 CFR Part 2 depends on whether the program:

1. Receives Federal Assistance
   **AND**
2. Qualifies as a Part 2 program

**APPLICABILITY: FEDERALLY ASSISTED**

- Conducted by any U.S. department/agency
- License, certification, registration, or other authorization by any U.S. department/agency, including but not limited to:
  - Participation in Medicare program
  - Authorization for maintenance treatment/withdrawal management
  - DEA registration, if controlled substance is used for substance use disorder treatment
APPLICABILITY: FEDERALLY ASSISTED CONT.

- Supported by funds from any U.S. department/agency, if
  - A recipient of federal financial assistance
  - Conducted by state/local government unit and receives federal funds which could be spent on substance use disorder programs.
- Assisted by IRS through income tax deductions or the granting of tax exempt status

APPLICABILITY: PART 2 PROGRAM

- Individual/Entity or identified unit in general medical facility that holds itself out as providing substance use disorder diagnosis or treatment (including referral), or
- Medical personnel/staff in general medical facility with primary function to provide substance use disorder diagnosis or treatment (including referral)
### Applicability: Examples

<table>
<thead>
<tr>
<th>Applicable</th>
<th>Not Applicable</th>
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<tbody>
<tr>
<td>• If receive federal assistance and holds out as providing substance use disorder diagnosis and treatment/referral:</td>
<td>• If primary function is not, or does not advertise providing, substance use disorder diagnosis and treatment/referral:</td>
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<tr>
<td>– School, rehabilitation, employee assistance, or general hospital programs</td>
<td>– Emergency room overdose treatment (including referral to ICU for overdose)</td>
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<tr>
<td>– Private practitioners</td>
<td>– Private for-profit program with no federal assistance.</td>
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### What Does It Mean If Part 2 Is Applicable?

Patient written consent must be obtained before disclosing any records containing the patient’s “identity, diagnosis, prognosis, or treatment” relating to substance abuse disorder.

42 U.S. Code § 290dd–2(a)
EXCEPTIONS TO CONSENT REQUIREMENT

Disclosures may be made without consent:
• To medical personnel if medical emergency;
• To qualified personnel for purpose of:
  – Scientific research
  – Management or financial audits
  – Program evaluation;
• If authorized by court order

EXCEPTIONS TO CONSENT REQUIREMENT

Part 2 Regulations are not applicable to:
• Department of Veteran Affairs
• Communications between armed forces and armed forces and the VA

Disclosure requirements do not apply if Part 2 program/personnel:
• Report suspected child abuse/neglect
• Communicate with other personnel in Program
• Communicate to entity with administrative control over Program
• Communicate with qualified service organizations
• Report crime on Program premises or crime against Program personnel
## CONSENT FORMS

- May be electronic or paper
- Must include:
  1. Patient Name;
  2. Name or general designation of disclosing Part 2 program/entity/individual;
  3. Amount and kind of information to be disclosed;
  4. Name or general designation to whom a disclosure may be made
  5. Purpose of disclosure;
  6. Statement that consent is subject to revocation and explanation of when consent will expire if not revoked; and
  7. Patient signature (may be electronic) and date consent is signed

## CONSENT FORMS: GENERAL DESIGNATIONS

- “From Whom” general designation is still allowed
- “To Whom” general designation is now allowed, if:
  - General designation is for treating providers
  - Consent form includes a statement that patient has a right to list of disclosures upon request
**CONSENT FORMS: AMOUNT/_KIND AND EXPIRATION**

- **Amount and kind of information**
  - Must include an explicit statement of “how much” and “what kind” of substance use disorder information may be disclosed

- **Expiration statement**
  - “Date, event, or condition” when consent will expire if not revoked. Must be no longer than reasonably necessary to serve purpose.

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**ACCOMPANYING NOTICE FOR DISCLOSURES**

Disclosures, permitted by written consent, must be accompanied by:

- “This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies 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 unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65;”

  OR

- “42 CFR part 2 prohibits unauthorized disclosure of these records.”
OTHER LAWFUL HOLDERS OF INFORMATION

Restrictions on disclosing patient information/records also applies to:
• 3rd party payers who hold records disclosed by Part 2 programs;
• Entities with admin. control over part 2 programs;
• Individuals/entities who receive records from Part 2 programs; and
• Other lawful holders, if notified of the prohibition on re-disclosure

OTHER LAWFUL HOLDERS: ALLOWABLE RE-DISCLOSURE

Records disclosed to lawful holder under consent for payment and/or health care operation purposes may be disclosed to downstream contactor/subcontractor/legal representative to carryout the disclosure purpose, if:
  – Contract/legal instrument binding downstream entities to Part 2 provisions
  – Lawful holder verifies additional safeguards
## SECURITY STANDARDS

Part 2 program/lawful holder of patient identifying information must have polices and procedures addressing:

<table>
<thead>
<tr>
<th>Paper Records</th>
<th>Electronic Records</th>
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| • Transferring, removing, and destroying  
  – Sanitizing hard copy media  
• Maintaining in a secure area  
• Access to and use of areas that use and store records  
• Rendering patient identifying information as non-identifiable | • Creating, receiving, maintaining, transmitting, and destroying  
  – Sanitizing electronic media  
• Use and access of electronic records/media  
• Rendering patient identifying information as non-identifiable |

### QUESTIONS?