Taking a Closer look at Substance Use Disorder and Confidentiality

Presented by: Susan Clarke,
Health Care Information Security and Privacy Practitioner

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Learning Objectives

• Understanding the importance of care coordination and impact of Part 2.
• The nuts and bolts of Part 2.
• Differences between HIPAA and Part 2.
• 21st Century Cures Act and ONC and CMS proposed rules, key word Interoperability.
• Data Blocking, the good, bad and the ugly.
Title 42 of the Code of Federal Regulations (CFR) Part 2: Confidentiality of Substance Use Disorder Patient Records (Part 2) was first promulgated 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.
Coordination of Care Challenges

1) More treating providers need access to confidential SUD treatment records to provide services.

2) The opioid crisis has focused on the need for treatment and services, and the need for more integrated care for patients.

3) Compliance with HIPAA and Part 2.

4) To improve care coordination we need to have statutory change to align with HIPAA.
• HIPAA applies to Protected Health Information (PHI)
• HIPAA permits providers, health plans, health care clearinghouses to disclose PHI for treatment purposes without patient authorization
• Authorization is required for disclosure of psychotherapy notes, which document the content of conversations with mental health professionals
• The minimum necessary standard does not apply to the following disclosures to or requests by a health care provider for treatment purposes
Important points about HIPAA

• Mostly speaking HIPAA is Not a Barrier to Coordinating SUD Care.
• HIPAA does not preempt stricter federal and state privacy laws.
• In response to the Opioids Crisis--HIPAA regulations allow health professionals to share health information with a patient’s loved ones in emergency or dangerous situations (see link below)

42 CFR Part 2 are the federal substance use disorder (SUD) confidentiality regulations issued by the Department of Health & Human Services Substance Abuse and Mental Health Services Administration (SAMHSA). These regulations protect the confidentiality of SUD treatment records. The Part 2 rules were recently amended with the first substantial update to the Confidentiality of Alcohol and Drug Abuse Patient Records (Part 2) regulations since 1987. Final rule published Jan 18, 2017, then, Jan 3, 2018 another final rule issued.
Why did Part 2 Change?

- To encourage care integration and information exchange,
- To address healthcare technology changes,
- To address prohibition against re-disclosures and accounting for disclosures,
- To address research uses of data, and
- To address security of records.

“SAMHSA wants to ensure that patients with substance use disorders have the ability to participate in, and benefit from health system delivery improvements, including from new integrated health care models while providing appropriate privacy safeguards.”
Intended Purpose of Part 2?

The purpose of Part 2 is to protect patients from any unintended bias associated with substance use disorders. The goal is to encourage people to seek SUD treatment, rather than not, because they can do so without fear of their information being shared. To accomplish this, Part 2 prohibits the disclosure and use of SUD patient records except with the patient’s specific written consent or under certain limited exceptions. The lawful recipient of SUD records is also prohibited from re-disclosing the information except with written patient consent or when another Part 2 exception applies.
Important points about Part 2

• Narrower but significantly more strict than HIPAA.

• Unlike HIPAA, Part 2 program must obtain patient consent in order to disclose for purposes of treatment, unless a medical emergency.

• Consent form must describe information to be disclosed, purpose of disclosure, and include name of recipient(s) (general designation allowed through intermediaries such as HIEs).
More Important Points

• No Part 2 exception that allows for disclosure to prescription drug monitoring programs.
• As a result, practitioners sometimes fear prescribing certain drugs (e.g., Xanax) because they do not know if their patient has an SUD.
• On the other hand, many practitioners do not realize that they can participate in MAT without being subject to Part 2.
Two Parts in determining Part 2.

1) Part 2 applies to federally assisted substance use disorder (SUD) programs
   Provider is federally assisted if it participates in Medicare or Medicaid, is registered to dispense controlled substances, receives any federal grants, or is a non-profit.

2) A “program” is defined as 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 is assistance of any kind, even if it does not directly fund the SUD treatment, diagnosis, or referral for treatment services.
- Licensed, certified, registered, or authorized by the federal government to conduct business;
- Tax-exempt through the IRS; or
- Conducted by the federal government or a state or local government that receives federal funds, which could be used for SUD programs.

Exception: Part 2 does not apply to the Department of Veterans Affairs or Armed Forces
Part 2 does not apply to all providers of SUD care

A Medical personnel or staff member who:
- Holds themselves out as providing and 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;

Examples of Part 2:
An entity (other than a general medical facility) that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment; or
A unit within a general medical facility that holds itself out as providing and does provide SUD treatment, diagnosis, or referral for treatment.

Note: Emergency rooms generally not subject to Part 2 and some providers of Medication-Assisted Treatment (MAT) not subject to Part 2.
Examples

An internist who provides occasional advice about substance abuse to patients as part of their primary care practice

**NO:** Internist does not “hold himself/herself out” as providing specialized substance abuse treatment services

A Community health clinic that is not licensed as a substance abuse treatment provider but advertises its expertise in serving patients with substance abuse disorders

**PROBABLY:** If the clinic promotes its substance abuse treatment services capacity and provides or makes referrals for substance abuse services, probably subject to Part 2
## HIPAA versus Part 2

### HIPAA
- Protects PHI maintained by providers, payers, and their contractors from disclosure. Disclosure w/o consent permitted for treatment, care coordination.
- Business Associate Agreements, BAA.
- Applies to almost all providers.

### Part 2
- Protects the confidentiality of substance use disorder (SUD) patient records from disclosure without express patient consent. (unless emergency)
- Qualified Service Organizations (QSO).
- Applies to Part 2 providers.
Qualified Service Organizations (QSO)

- Under Part 2 a qualified service organization (QSO) is an individual or entity providing a service to Part 2 treatment programs pursuant to a written agreement.
- QSO services include EHR vendor, Health Information Exchange, network data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting or other professional services.
- QSOs are exempt from Part 2 restrictions on disclosure of SUD information, however, QSOs agree in their contract with the provider to be bound by Part 2 requirements.
Part 2 Impact to HIEs

Previously, Part 2 did not permit a patient to authorize disclosure to a class of organizations. Previously, lawful holders, such as other treating providers or HIEs, struggled with whether they had the ability to further disclose Part 2 information to their contractors.

Generally speaking, the new Final Rule allows the patient to consent to disclosure to a Health Information Exchange (HIE) or Accountable Care Organization (ACO) network.
Consent Example

The Patient may consent to disclosure on the Consent form to a third-party entity with whom the patient does not have a treating provider relationship (e.g., a health information exchange) and,

On the same consent form, the patient can permit this third-party entity to redisclose his or her Part 2 information to other named individuals or entities with whom the patient does have a treating provider relationship:

(e.g., “I consent to disclosure of my Part 2 information to the Western Frontier Information Exchange, and agree to permit the HIE to redisclose my information to my current provider and all future providers with whom I have a treating provider relationship.”).
Compliance can be difficult

• Consents must be tracked and shared. One provider may have consent but others may not be aware. A patient is entitled to receive a list of all entities to which his or her information has been disclosed pursuant to a general designation.

• Consents must contain all required information. Often difficult to meet the Part 2 requirements of listing all information recipients by name.

• Provider holding data may have little motivation to obtain consent on behalf of other providers or honor another’s consent.
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.

State minimum necessary laws
Part 2 requires that a notice prohibiting redisclosure accompany disclosures of Part 2 information.

Under the 2018 Final Rule, SAMHSA has adopted an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems.

It reads “Federal law/42 CFR part 2 prohibits unauthorized disclosure of these records.”
<table>
<thead>
<tr>
<th>State</th>
<th>Citation of Statute or Regulation</th>
<th>Narrative Description of State Law</th>
<th>Definition or Scope of Information/Material Covered by Application of Minimum Necessary Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>MT</td>
<td><strong>Mont. Code. Ann. § 53-21-166</strong></td>
<td>Montana authorizes health care providers to disclose a patient's health care information, without authorization, to any health care provider has previously provided services to the patient. Such disclosures must be limited to the extent the necessary to provide treatment and are prohibited if a patient requests that their provider not make such disclosures.</td>
<td>Records and information obtained and maintained while providing services to persons with serious mental illness in accordance with Montana's mental health law (Mont. Code. Ann. § 53-21-166). Health care information. Defined as information related to a patient's health care that either identifies the patient or can identify the patient (Mont. Code Ann.§ 50-16-50 et seq.).</td>
</tr>
<tr>
<td>WY</td>
<td><strong>W.S.1977 § 9-2-125</strong></td>
<td>Wyoming permits a treatment facility to disclose an individual's mental health treatment records in connection with the individual's transfer to another facility. The transferring facility must limit disclosure to only the records necessary to enable the receiving facility to provide mental health services and any records required by law.</td>
<td>Registration and treatment records regarding patients receiving mental health treatment at a treatment facility that is under contract with the Department of Health (W.S.1977 § 9-2-125).</td>
</tr>
</tbody>
</table>
1. Part 2 programs should update their patient consent forms to address the release of SUD Information for payment and health care operations purposes.

2. Part 2 should evaluate whether to update their patient consent forms to include the abbreviated notice regarding re-disclosure and, if they do, they should consider how to assure that their Subcontractors are aware of the scope of re-disclosure restrictions.

3. Part 2 programs, health systems, ACOs and other integrated care models treating Part 2 patients will need to carefully evaluate their relationships with Subcontractors (third party) to determine what information may be shared with each of them, and they then must amend or enter into appropriate contracts with each applicable Subcontractor (third party) no later than February 2, 2020.
Conclusion

SAMHSA is trying to balance between making SUD Information available to those who need it for legitimate purposes to enable individuals who seek treatment for SUDs to participate in and benefit from ACOs, health information exchanges, and other innovative care models, while safeguarding that information from improper uses and disclosures that may result in reputational harm or adverse legal consequences to patients.
Washington — The U.S. House on Tuesday approved bills meant to combat the opioid epidemic, including Jessie's Law — named for an Ann Arbor woman.

Jessie's Law passed the U.S. Senate in response to the 2016 overdose death of Jessica Grubb. Since that time, her family has pushed for the legislation to be brought to the House for consideration.

Grubb, 23, was seven months after treatment in Michigan for her heroin addiction. She died of a fentanyl overdose at St. Joseph Mercy Hospital in Ann Arbor days after having hip surgery for a running injury.

Her parents have been vocal about her condition, but that message allegedly never made it into the patient’s medical record. They were discharged her. He prescribed her 50 Oxycodone pills. She died that night in March 2016, according to her family.

"The worst tragedy is that Jessie's addiction history was recorded eight times in her medical records, yet the discharging doctor was somehow unaware," said her father, David Grubb.

"Hopefully, this legislation will make a real difference ... and save lives."
FOR IMMEDIATE RELEASE  
February 11, 2019

Contact: HHS Press Office  
202-690-6343  
media@hhs.gov

HHS Proposes New Rules to Improve the Interoperability of Electronic Health Information

New innovations in technology promote patient access and could make no-cost health data exchange a reality for millions

The U.S. Department of Health and Human Services (HHS) today proposed new rules to support seamless and secure access, exchange, and use of electronic health information. The rules, issued by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), would increase choice and competition while fostering innovation that promotes patient access to and control over their health information. The proposed ONC rule would require that patient electronic access to this electronic health information (EHI) be made available at no cost.

Page 30--In collaboration with ONC, the Substance Abuse and Mental Health Services Administration (SAMHSA) developed the Consent2Share application to address the specific privacy protections of patients with substance use disorders who are covered by HIPAA.

Consent2Share is an open source application for data segmentation and consent management. Consent resource to capture a record of a health care consumer’s privacy preferences.
Health IT Legislation

21st Century Cures Act

There are many provisions of the 21st Century Cures Act (Cures Act) that will improve the flow and exchange of electronic health information. ONC is responsible for implementing those parts of Title IV, delivery, related to advancing interoperability, prohibiting information blocking, and enhancing the usability, accessibility, and privacy and security of health IT. ONC works to ensure that all individuals, their families and their health care providers have appropriate access to electronic health information to help improve the overall health of the nation’s population.

In addition to supporting medical research, advancing interoperability, clarifying HIPAA privacy rules, and supporting substance abuse and mental health services, the Cures Act defines interoperability as the ability exchange and use electronic health information without special effort on the part of the user and as not constituting information blocking.
How are HIPAA, SUD, and Information Blocking Regulations Related?

- HIPAA
  - Patient Access
  - CFR 45

- Substance Abuse (SUD)
  - CFR 42

- Data Blocking
  - CFR 45
What is Information Blocking?

Information blocking occurs when a person or entity – typically a health care provider, IT developer, or EHR vendor – knowingly and unreasonably interferes with the exchange and use of electronic health information, which is a right protected by the HIPAA.

“A new rule issued today by the Office of the National Coordinator for Health Information Technology involves the patient, not as a person being “acted upon,” said Elise Sweeney Anthony, director of Office of Policy for the ONC, but as someone in control of his or her electronic health records.

If a patient requests their record, and it’s not given to them electronically and for free, that’s information blocking, Sweeney said during HIMSS19.

The Centers for Medicare and Medicaid Services would also require that healthcare providers and plans implement open data sharing technologies to support transitions of care as patients move between these plan types”
Examples of Information Blocking

- Fees that make data exchange cost prohibitive.
- Organizational policies or contract terms that prevent sharing information with patients or health care providers.
- Technology is designed or implemented in non-standard ways that inhibit the exchange of information.
- Patients or health care providers become “locked in” to a specific technology or health care network because data is not portable.
Example: Health care providers restrict access to a patient’s sensitive test results until the clinician who ordered the tests, or another designated health care professional, has reviewed and appropriately communicated the results to the patient.

(Keeping with the HIPAA Privacy Rule, the restriction does not apply to the patient or to anyone else to whom the patient has requested in writing to provide this information.)
Patient Safety Comes First

• Some actions that impede the exchange of electronic health information do not constitute information blocking. For example, when an act or course of action is necessary to protect patient safety, privacy, or other compelling interests.

• As long as the restrictions imposed by the health care provider were based on the health care provider’s patient assessment of their patient’s best interests (rather than a blanket policy) and were not an excuse for restricting health information exchange.
21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

A Proposed Rule by the Health and Human Services Department on 03/04/2019

This document has a comment period that ends in 39 days. (05/03/2019)

Understanding Some of HIPAA’s Permitted Uses and Disclosures

• Health records are used and share to provide good care to patients, to evaluate the quality of care and to assure proper payment from health plans.

• Relevant players in the health care system – including the patient – need to be able to quickly and easily access health records to make decisions, and to provide the right care at the right time

• The Privacy, Security, and Breach Notification Rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) were intended to support information sharing by providing assurance that sensitive health records would be maintained securely and shared only for appropriate purposes or with express authorization of the patient.

• Although the regulations have been in effect for quite some time, health care providers frequently still question whether the sharing of health information, even for routine purposes like treatment or care coordination, is permissible under HIPAA.

• Confusion about the rules has been cited by many as a potential obstacle to interoperability of digital health information.
Please let me know how I can help?

For assistance please contact:

Susan Clarke: sclarke@mpqhf.org, (307) 248-8179
Questions