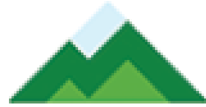

Montana Primary Care Association

The Intersection of HIPAA and Part 2, How Does SUD Privacy Fit?

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

July 10, 2019, 11AM-12PM

Susan Clarke, HCISPP

- (ISC)² Certified Healthcare Information Security and Privacy Practitioner and Computer Scientist.
- 20+ years of Healthcare Experience.
- 10 years design and coding EHR software including HL7 Healthcare application development.
- Served on IT Security, Disaster Recovery and Joint Commission steering committee at Mayo Clinic-affiliated Healthcare system.
- Served as communications unit lead during Healthcare system's ready and complete alerts.

Mountain-Pacific Quality Health

Mountain-Pacific Quality Health (Mountain-Pacific) is a private, non-profit, community-based organization that has dedicated more than three decades to improving health and health care in Alaska, Hawaii (including some U.S. Pacific Territories), Montana and Wyoming. Our goal is to increase access to high-quality health care that is affordable, safe and of value to the patients we serve.

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Learning Objectives

- The Opioid Crisis today.
- Overview of HIPAA and Part 2.
- Part 2 Drill down and Scenarios.
- MT State Law.
- Case Study.
- In the works and next steps.

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130

AMERICANS

die every day from an opioid overdose

(including Rx and illicit opioids).

CDC.GOV

- Drug overdose deaths continue to increase in the United States.
- From 1999 to 2017, more than 700,000 people have died from a drug overdose.
- Around 68% of the more than 70,200 drug overdose deaths in 2017 involved an opioid.
- In 2017, the number of overdose deaths involving opioids (including prescription opioids and illegal opioids like heroin and illicitly manufactured fentanyl) was 6 times higher than in 1999.
- On average, 130 Americans die every day from an opioid overdose

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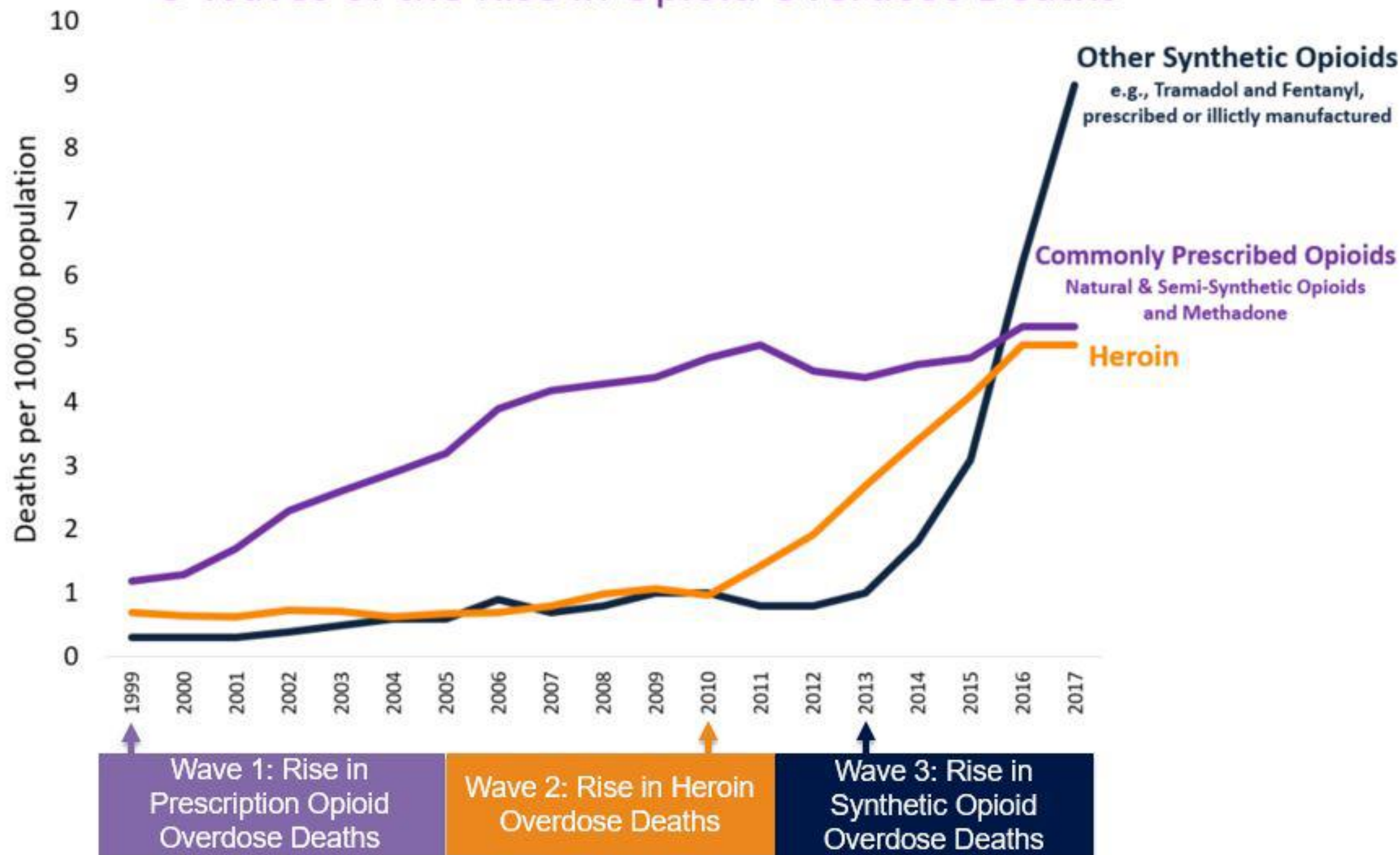

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Doctors Responding to Opioid Crisis

HIPAA regulations allow health professionals to share health information with a patient's loved ones in emergency or dangerous situations – but misunderstandings to the contrary persist and create obstacles to family support that is crucial to the proper care and treatment of people experiencing a crisis situation, such as an opioid overdose.

HIPAA 1-2-3

- 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)

https://www.hhs.gov/sites/default/files/hipaa-opioid-crisis.pdf

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.
- Enforcement Office for Civil Rights.

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.
- Enforcement Department of Justice.

Both laws address the confidentiality and security of health information

Enforcement and Penalties

HIPAA

- OCR
- Civil Penalties of $112 to $55,910 per violation.
- Mandatory penalties of $11,182 to $55,910 if act with willful neglect. (possible patient gets %)
- Criminal Penalties $50,000 to $250,000. Up to 10 years in prison.

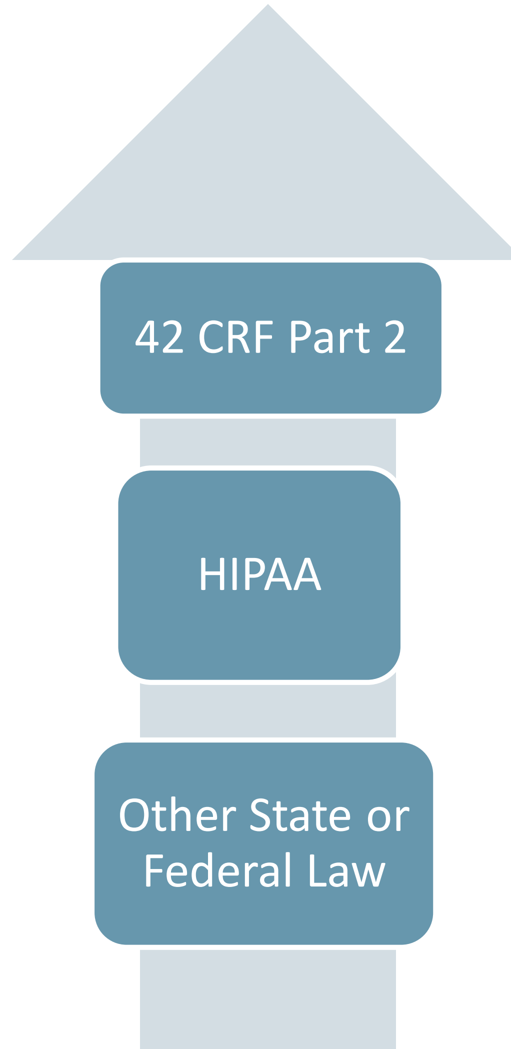
42 CRF Part 2

- DOJ
- Criminal fines of $500 for first offense, $5,000 for subsequent offenses.

Note: Might be used as basis for private lawsuit

Comply with Most Restrictive Law

Privacy Protection



42 CRF, Part 2

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.

Part 2 Rule 1-2-3

Part 2 protects patients from any unintended bias associated with substance use disorders. These regulations protect the confidentiality of SUD treatment records.

-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.

When did Part 2 Change?

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."

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).

- 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

“Holds itself out as …”

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

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.
- 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.").*

How 2018 Rule Revised **Prohibition on Redisclosure Notice**

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*."

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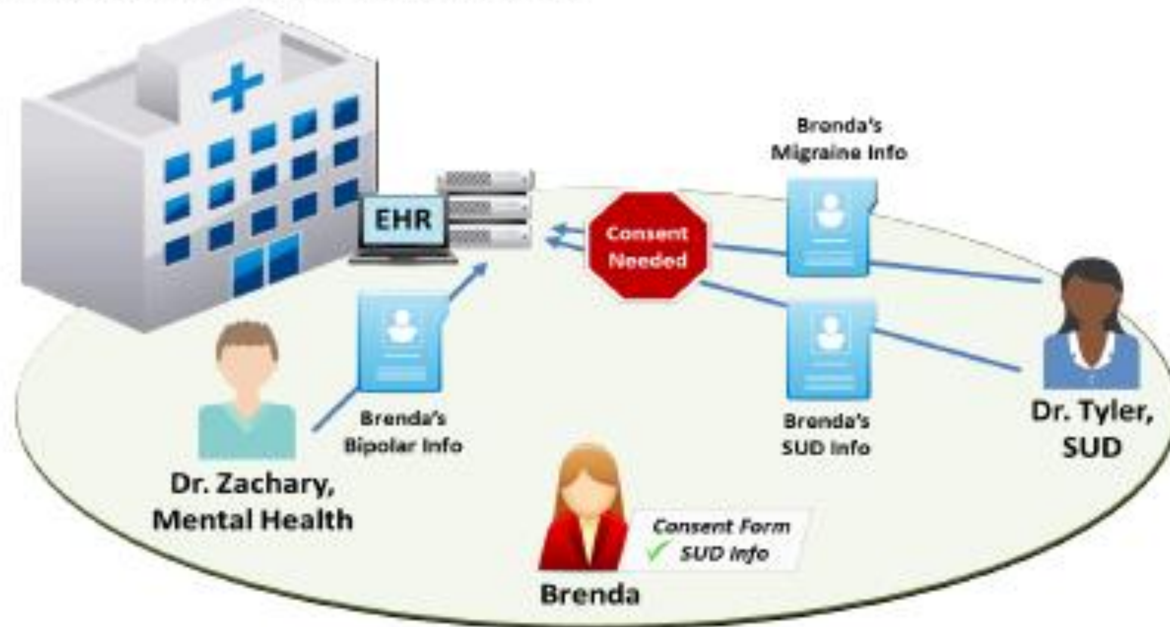
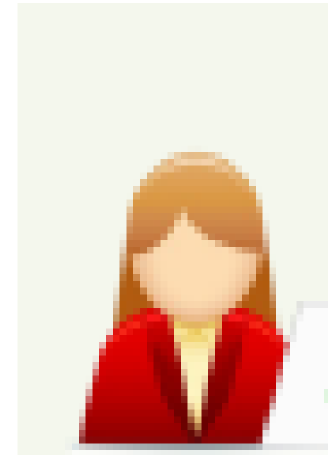
SAMHSA FAQ--Scenario 2



SAMHSA FAQ--Scenario 4

Blue Mountain Integrated Care



Brooke

Dr Pierce is a provider at Blue Mountain, Integrated Care Setting

Brooke, patient with respiratory infection, previous treatment for an Opioid Use Disorder.

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Delivery 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) Many believe, to improve care coordination we need to have statutory change to align with HIPAA.

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

https://www.healthit.gov/sites/default/files/State%20Mental%20Health%20Laws%20Map%201%20Minimum%20Necessary%20-%20revised%202-23-17.pdf

Minimum Necessary Disclosures

State	Citation of Statute or Regulation	Narrative Description of State Law	Definition or Scope of Information/Material Covered by Application of Minimum Necessary Requirement
MT	Mont. Code. Ann. § 53-21-166	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.	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.).
WY	W.S.1977 § 9-2-125	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.	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).

https://www.healthit.gov/sites/default/files/State%20Mental%20Health%20Laws%20Map%201%20Minimum%20Necessary%20-%20revised%202-23-17.pdf

Part 2 Program Next Steps…

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.**

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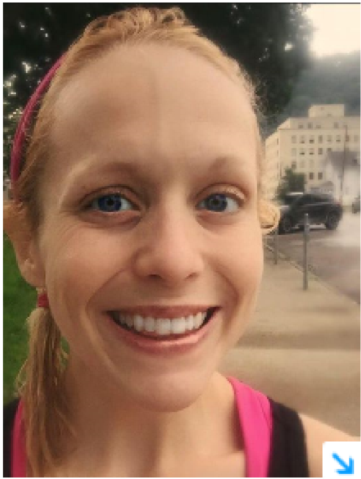
The Overdose Prevention and Patient Safety Act and the Protecting Jessica Grubb's Legacy Act would allow clinicians access to the information they need to ensure patient safety and the highest quality of care.

U.S. House passes bill named for Ann Arbor woman

Melissa Nann Burke, The Detroit News   Published 4:50 p.m. ET June 12, 2018 | Updated 9:27 p



(Photo: Facebook)

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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 ... response to the 2016 overdose ... Jessica Grubb. Since the ... the legislation will n... consideration...

Gr... ...en months after treatment in Michigan for her heroin addi... ...hip surgery for a running injury at St. Joseph Mercy Ho...

Her parents h... ...ir about her condition, but that message allegedly never r... ...ischarged her. He prescribed her 50 Oxycodone pills, a... ...sed that night in March 2016, according to her family.

"... ...aking tragedy is that Jessie's addiction history was recorded eight times in ... 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."

Provider, health IT groups praise proposed bills to change patient privacy regulations

by Heather Landi | Apr 10, 2019 8:10am

March 2016

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"Today, patients suffering with addiction are often caught within a siloed system where – depending on where they receive care – doctors may lack critical patient information — creating life-threatening blind spots. As currently written, Part 2 – which applies only to substance use disorder treatment in select healthcare settings – endangers the very lives it intends to protect. ASAM applauds the introduction of the Overdose Prevention and Patient Safety Act and the efforts of Congressional leaders to bring Part 2 into the 21st Century. Allowing patient information related to substance use disorder to be safely integrated into the rest of the health care system will save lives." -- R. Corey Waller, MD, Chair of the Legislative Advocacy Committee, American Society of Addiction Medicine (ASAM)

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.

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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.

https://www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health

Part of Proposed Rule

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

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Supporting Material

- 42 CFR part 2
- SAMSHA Fact Sheet: Does Part 2 Apply to Me?
- SAMSHA Fact Sheet: How Do I Exchange Part 2 Data?
- SAMSHA FAQ: Applying the Substance Abuse Confidentiality Regulations

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Please let me know how I can help?

For assistance please contact:

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

Questions

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