Substance Use Disorder Privacy Laws

Navigating Federal and State Requirements

Foley & Lardner, LLP
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Adam Hepworth

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Agenda

1. **42 CFR Part 2 Nuts and Bolts**
2. Recent Federal Changes
3. California SUD Privacy Laws
4. Challenges for Integrated Models of Care
5. Questions

42 CFR Part 2

- Protects records of the "identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any [federally assisted] program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research." 42 U.S.C. § 290dd-2.
- Limited statutory exceptions:
  - Bona fide medical emergency
  - Qualified personnel for research, audits, or program evaluation
  - Court order

Who is covered by Part 2?

- Part 2 applies to ***federally assisted programs***
- The definition of "***federally assisted***" is broad, but the definition of "***program***" is limited

"Federally Assisted"

- Any program "carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States"
- Includes Medicare and Medicaid participants, tax-exempt organizations, and physicians registered to prescribe controlled substances

"Program"

1. 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
2. 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
3. ***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

"Holds itself out"

- The phrase "holds itself out" could mean:
  - State licensing procedures
  - Advertising or the posting of notices in offices
  - Certifications in addiction medicine
  - Listings in registries
  - Internet statements
  - Consultation activities for non-"program" practitioners
  - Information presented to patients or their families
  - Any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment or referral for treatments

  Applying the Substance Abuse Confidentiality Regulations (last updated 9/15/2017); *see also* 82 Fed. Reg. 6052, 6066 (Jan. 18, 2017).

"General medical facility"

- SAMHSA guidance explains that "hospitals, trauma centers, or federally qualified health centers would generally be considered 'general medical care' facilities." *Applying the Substance Abuse Confidentiality Regulations* (last updated 9/15/2017).
- One state-court decision appears to have concluded that a state psychiatric hospital was not a "program." *Hurt v. State of Indiana*, 694 N.E.2d 1212, 1216 (Ind. Ct. App. 1998).

Emergency Departments

- Part 2 explicitly does not apply to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose unless the "primary function" of such personnel is the provision of substance-use-disorder services and they are "identified" as providing such services.

Summary Checklist of Part 2 Applicability

- Is there a Part 2 program?
- Is the program federally assisted?
- Does the information at issue identify a patient of the Part 2 program as having or having had a substance use disorder?
- Was the information obtained by the program for the purpose of treatment, diagnosis, or referral for treatment?

How Does Part 2 Restrict Disclosure?

- The patient records subject to the regulations "may be disclosed or used only as permitted by the regulations in this part . . . ."
- "Any disclosure made under the regulations in this part must be limited to that information which is necessary to carry out the purpose of the disclosure."

Enforcement and Penalties

- Criminal fines available for violations of Part 2
- Reports may be directed to the United States Attorney or SAMHSA
- No private right of action

Common Types of Disclosure without Consent

- To patients to access their own records. 42 C.F.R. § 2.23(a).
- Within a Part 2 program or between a Part 2 program and an entity having direct administrative control over the program. 42 C.F.R. § 2.12(c)(3).
- To a qualified service organization (QSO) that provides services to the Part 2 program. 42 C.F.R. § 2.12(c)(4).
- To law enforcement in connection with crimes on program premises or against program personnel. 42 C.F.R. § 2.12(c)(5).
- To a central registry or nearby withdrawal management or maintenance treatment programs to prevent multiple enrollment. 42 C.F.R. § 2.34.
- To medical personnel when necessary to meet a bona fide medical emergency. 42 C.F.R. § 2.51.
- To an individual for scientific research when HIPAA or Common Rule requirements are met. 42 C.F.R. § 2.52.
- To individuals performing audits or evaluations. 42 C.F.R. § 2.53.
- With a valid court order that authorizes disclosure. 42 C.F.R. § 2.61.

Consent Requirements

- Written consent requires:
  - Name of the patient
  - Specific name or general designation of entities permitted to make the disclosure
  - How much and what kind of information is to be disclosed
  - Name of the individual to whom a disclosure is to be made*
  - Purpose of the disclosure
  - A statement that consent is subject to revocation at any time
  - The date, event, or condition upon which the consent will expire
  - Signature of the patient and any other required signatures
  - Date of signature

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General Designations

- The 2017 Final Rule allows Part 2 consent forms to authorize disclosure pursuant to a ***general designation***
- General designations may be used when authorizing disclosure to an entity or class of individuals with a "***treating provider relationship***"

What is a "treating provider relationship"?

- The million-dollar question SAMHSA has been reluctant to answer
- SAMHSA "respectfully declines to provide more specificity" because "[t]he arrangements between treating providers and other entities evolve too rapidly to be comprehensively addressed in regulations." 82 Fed. Reg. 6052, 6082 (Jan. 18, 2017).
- Yet, SAMHSA also says that "[t]he definition of 'treating provider relationship' is sufficiently broad to cover the necessary components of a patient's care team." 82 Fed. Reg. 6079.

Who verifies the "treating provider relationship"?

- Before a non-treating recipient entity like an HIE makes a disclosure to a treating provider pursuant to a general designation, it must have a mechanism in place to determine whether a "treating provider relationship" exists. *See* 82 Fed. Reg. 6052, 6081 (Jan. 18, 2017).
- For example, "an HIE could have a policy in place requiring their participant providers to attest to have a treating provider relationship with a patient, or provide a patient portal where patients designate their treating providers." 82 Fed. Reg. 6082.

Written Disclosure List for General Designations

- This is an additional requirement added in connection with the new option to disclose pursuant to a general designation
- When disclosures are made pursuant to a general designation, the patient has the right to request a list of entities to which their information has been disclosed in the last two years.

Other Changes in Jan. 18, 2017 Rule

- Patient consent forms must include an explicit description of the substance use disorder information that may be disclosed
- Clarification that qualified service organizations may provide population health management services (42 C.F.R. § 2.11)
- Clarification that providing Screening, Brief Intervention, or Referral to Treatment (SBIRT) does not make a provider a Part 2 "program"
- Clarification that prohibitions on re-disclosure apply only to information that would identify an individual as having been diagnosed, treated, or referred for treatment for a substance-use disorder (42 C.F.R. § 2.32(a))
- Security requirements now apply to electronic and paper records (42 C.F.R. §§ 2.16, 2.31, 2.53)
  - All Part 2 programs and other lawful holders of patient identifying information are required to have in place formal security policies and procedures.
- Revisions to authority for disclosures for scientific research (42 C.F.R. § 2.52)

Follow Up 2018 Rule: "Lawful Holders"

- New regulation addresses "lawful holders" who have received records with patient consent for payment or health care operations.
- A lawful holder "may further disclose [records] as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or health care operations on behalf of such lawful holder."
- Lawful holders must have in place "a written contract or comparable legal instrument with the contractor or voluntary legal representative" that provides that the recipient is fully bound by the Part 2 regulations.

Defining "payment and health care operations"

- SAMHSA does not define the term, but offers a list of examples in the 2018 Final Rule, which includes activities such as:
  - Billing, claims management, and collections activities
  - Clinical professional support services
  - Patient safety activities
  - Trainings and assessments
  - Accreditation and licensing
  - Underwriting and premium rating
  - Legal services and auditing functions
  - Business planning and development
  - Business management and general administrative activities
  - Customer services
  - Resolution of internal grievances
  - Sale or transfer of an organization
  - Eligibility or coverage determinations
  - Risk adjusting
  - Medical necessity and coverage reviews

83 Fed. Reg. 239, 243 (Jan. 3, 2018)

Comparison with Qualified Service Organizations

Lawful Holders

- Receive information pursuant to a consent for payment and/or health care operations purposes
- Lawful holder may re-disclose if they have a legal instrument by which the recipient agrees to comply with Part 2
- Lawful holder must also furnish recipients with notice accompanying disclosure
- Disclosures must be limited to what is necessary to carry out the payment or operations purpose
- Re-disclosures are limited to "contractors, subcontractors, or legal representatives" assisting in same payment and/or health care operations purposes

QSOs

- Receive information needed for QSO to provide services*
- QSO must enter written agreement by which it agrees to comply with Part 2 and resist efforts to obtain access to patient identifying information
- No requirement for notice accompanying disclosure (b/c not made with patient consent)
- SAMHSA guidance recognizes one-level QSO redisclosures to their contract agents when necessary to provide the QSO services.

Abbreviated Notice

- The January 3, 2018 Final Rule also authorizes an abbreviated notice to accompany disclosure that reads:

"42 CFR part 2 prohibits unauthorized disclosure of these records."

- Simplified language accommodates electronic systems with character limitations in free text fields

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Health & Safety Code § 11845.5

- Makes confidential "[t]he identity and **records of the identity, diagnosis, prognosis, or treatment of any patient**," which are "maintained in connection with the performance of any alcohol and other drug abuse treatment or prevention effort or function **conducted, regulated, or directly or indirectly assisted by the department**."

Health & Safety Code § 11845.5

- Extremely limited exceptions to the requirement for written consent:
  - ***Treatment within the program***: "In communications between qualified professional persons employed by the treatment or prevention program in the provision of service"
  - ***Emergencies:*** "To qualified medical persons not employed by the treatment program to the extent necessary to meet a bona fide medical emergency"
  - ***Scientific research, management audits, financial and compliance audits, or program evaluation,*** **if the information is de-identified in any report**
  - ***Authorized by appropriate court order***

County Alcohol and Drug Funds

- County funds for "alcohol and other drug problems" are separately regulated by Health and Safety Code § 11812
- Makes confidential personal information and records obtained by county-fund supported programs
- Allows disclosure only "in those instances designated in Section 5328 of the Welfare and Institutions Code"
- Private right of action and fines for violators

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Pressure for Integrated Models of Care

- CMS continues to push alternative payment models
- It is increasingly common for health system providers to take on significant financial risk under managed care contracts
- Succeeding in this environment can mean focusing on more than hospital costs
  - Integration with other health care settings
  - Integration with service providers addressing the social determinants of health

Common Challenges

- Developing a uniform consent that meets HIPAA authorization requirements while also meeting the requirements of Part 2 and other privacy laws
- Identifying the entities in an integrated care context that are subject to Part 2 and State laws
  - How to think about the "general medical facility" carve out in nontraditional contexts

Additional Concerns

- Who on an integrated patient care team qualifies as a "treating provider" for purposes of a Part 2 general designation?
  - Care coordinators?
  - Social workers?
  - Affiliated social service providers (housing support, legal services, financial assistance)?

Additional Concerns

- Are there ways to share with individuals or entities when consent is impractical?
  - QSOs?
  - Within a Part 2 program?
- Be especially mindful of State law when disclosing without a consent

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Contact Information

Adam Hepworth, Esq.
Foley & Lardner LLP
555 South Flower Street
Suite 3300
Los Angeles, CA 90071
Phone: (213) 972-4604
Email: AHepworth@foley.com