42 CFR, Part 2: How does it apply to BH/SUD integrated care and what is the impact of the proposed changes?

Webinar Presentation to the Blue Shield of California Foundation Advancing Behavioral Health Integration Learning Community Care Coordination Cluster

April 20, 2017
Today’s Webinar Agenda

Welcome and Introductions:
  Karen Linkins, Project Director

Opening Remarks and Introduction of Speakers:
  Becky Vaughn. Principle Consultant and SUD Expert, DIR Consulting Group

Presentations:
  Deborah A Reid, Sr. Health Policy Attorney, Legal Action Center
  Jim Sorg, Ph.D., Dir. Of Information Technology, Tarzana Treatment Centers
  Denise Williams, V.P. of Contract & Compliance HealthRIGHT 360

Question and Answers:
  Becky Vaughn
Thank you for what you do!
Applying the Substance Use Disorder Confidentiality Law ("42 CFR part 2")’s Final Rule in Today’s Integrated Care Environment

Blue Shield of California Foundation
April 20, 2017

Deborah A. Reid, Esq.
Who is the Legal Action Center?

- Non-profit law and policy organization

- Anti-discrimination and privacy work in:
  - Substance use disorder ("SUD")
  - HIV/AIDS
  - Criminal record histories

- Legal services, litigation, technical assistance, policy
Today’s Presentation will Cover:

1. History/Background of Confidentiality Regulations:
   • Purpose of 42 CFR part 2 (“part 2”)
   • Who must follow part 2?
   • How can information be disclosed?
   • What is the prohibition on re-disclosure?

2. 42 CFR part 2 – Final Rule:
   • What information has not changed?
   • What has changed? (overall areas)
Today’s Presentation will Cover:
(con’t.)

3. Additional Information/Issues:
   • Supplemental Notice of Proposed Rulemaking ("SNPRM")
   • Prescription Drug Monitoring Programs ("PDMPs")
   • Securing part 2 information when transitioning from one level of care to another.
1. History/Background of Confidentiality Regulations

Purpose of part 2:
Enacted in the 1970s -

• To protect the privacy of people receiving SUD care;

• to guard against the negative consequences of unauthorized release of drug/alcohol patient information, e.g.,
  ▪ loss of child custody and parental rights,
  ▪ loss of jobs,
The Purpose of part 2 (con’t.)

- arrest and/or prosecution,
- denial of health care, and
- exclusion from public housing or insurance;

• to encourage individuals to enter drug/alcohol treatment; and

• to guard against the *stigma and discrimination* associated with having a SUD and/or receiving treatment.
General Rule

- **Part 2 protects patient identifying SUD information** (any direct or indirect information that would identify a patient as a SUD patient).

- **No disclosure of protected SUD information**: even to other health care providers, insurers, or parents -- *unless* there is written consent or another exception applies.

- **Requires a prohibition on re-disclosure of protected SUD information**.

  [Note: Part 2 is more protective of SUD info than HIPAA].
1. History/Background of Confidentiality Regulations:
Who must follow part 2?

Drug/alcohol prevention & treatment programs

that are

Federally assisted

must follow 42 CFR part 2

Definitions
Who must follow part 2?

What is a “program?” - 3 definitions...

**FIRST DEFINITION:**

- Individual *or* entity
- *other than* a general medical facility
- that **holds itself out** as providing, and **does provide,**
- drug/alcohol diagnosis, treatment, or referral for treatment...

**OR...**

Con’t....
Who must follow part 2?

What is a “program?” (con’t.)

SECOND DEFINITION:

- An identified unit
- within a general medical facility
- which holds itself out as providing, and does provide,
- Drug/alcohol diagnosis, treatment, or referral for treatment...

OR...

Con’t....
Who must follow part 2?

What is a “program?” (con’t.)

**THIRD DEFINITION:**

- Medical personnel or other staff
- *in* a general medical care facility
- whose primary function is
- the provision of drug/alcohol diagnosis, treatment, or referral for treatment, and
- who are identified as such.
Who must follow part 2?

What is a “program?” (con’t.)

Additional Key Point:

• For a general medical facility...
  • it is the unit or medical personnel
  • that is the “program,”
• NOT the whole general medical facility.
How can information be disclosed:

*Exceptions to General Rule*

**Part 2’s Permitted Disclosures**

- **Internal Communications**
- **No patient identifying information**
- **Proper Consent**
- **Qualified Service Organization/ Business Associate Agreement**
- **Medical Emergency**
- **Crime on program premises or against program personnel**
- **Research/ Audit**
- **Special Court Order**
- **Reporting suspected child abuse and neglect**
How can information be disclosed: (con’t.)

In addition to the permitted disclosures/exceptions –
• Part 2 information can be disclosed by “lawful holders”* (who disclose the information for the specified purpose via consent).

*New term in the Final Rule’s preamble.
What is the prohibition on re-disclosure?

- 42 CFR § 2.32 – A written notice must accompany the patient’s consent of disclosure of his/her patient identifying information that says:
  - the information is protected by federal law, and
  - the recipient cannot make any further disclosures of the information unless permitted by the part 2 regulations.
2. 42 CFR Part 2 — Final Rule

What has **Not** Changed?

- Who must follow part 2.
- What information is protected by part 2.
- How part 2 information can be disclosed through the exceptions.
- The requirement for the prohibition on re-disclosure.
2. 42 CFR PART 2 – FINAL RULE

WHAT HAS CHANGED?

- Consent Options: § 2.31
  - New form of consent in the “To Whom” section:
    - The name of the individual;
    - The name of the entity which has “treating provider relationship” with the patient;
    - The name of an entity with which the patient does not have a treating provider relationship and which is a 3rd party payer; and/or
2. 42 CFR Part 2 – Final Rule

What has Changed? (con’t.)

- The name of an entity with which the patient does not have a treating provider relationship and which is NOT a 3rd party payer [“Apex HIE”], AND either:
  - The name(s) of specific individual participants - [“Dr. No and Dr. Yes of Apex HIE”], or
  - The name(s) of an entity participant(s) with which the patient has a treating provider relationship - [“my treating providers at New Hospital and Big FQHC”], or
  - A general designation of participants with which the patient has a treating provider relationship – [e.g., “all of my treating providers in Apex HIE”].
2. 42 CFR Part 2 – Final Rule

**What has Changed?**

- **Amount and Kind - § 2.31(a)(3):**
  - Requires the consent form to *explicitly describe* the SUD information to be disclosed.
  - The description of the disclosed information *must be specific enough* to allow the part 2 program or other entity to comply with the disclosure.
  - Examples:
    - ✓ “all of my SUD records”
    - ✓ “all of my prescribed medications after May 2016”
    - X NOT – “all of my records”
2. 42 CFR PART 2 — FINAL RULE

**WHAT HAS CHANGED?**

- **Qualified Service Organization (“QSO”) - § 2.12(c)(4):**
  - Now includes population health management in the list of the types of services a QSO may provide.
  - Clarified that QSO Agreements may be used for “medical staffing services” [a service to get on-call coverage providers], but NOT for “medical services” [treatment by a primary care doctor].
  - QSOAs cannot be used to avoid getting patient consent!
2. 42 CFR Part 2 – Final Rule

What Has Changed?

- Security for Records - § 2.16:
  - Part 2 programs and other lawful holders must now have established formal policies and procedures for the security of both paper and electronic records.
  - Security requirements are now aligned more closely with HIPAA’s Security Rule.
2. 42 CFR PART 2 – FINAL RULE

**WHAT HAS CHANGED?**

- **Revised and New Definitions - § 2.11:**
  
  1. **Treating Provider Relationship**
     
     - An actual in-person encounter is not needed.
     
     - A patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation, for any condition by an individual, or entity, and;
     
     - The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, for any condition.
Revised and New Definitions - § 2.11:

2. **Lawful Holder**: [As described in the Final Rule’s Preamble]

- An individual or entity who has patient identifying part 2 information because of a part 2-compliant patient consent (with a prohibition on re-disclosure notice), or as a result of one of part 2’s exceptions to disclosure.
- Bound by part 2’s requirements.
- Examples of lawful holders - patient’s treating providers, hospital emergency rooms, an individual/entity performing audits or evaluations, researchers, insurance companies.
2. 42 CFR Part 2 – Final Rule

**WHAT HAS CHANGED? (con’t.)**

- **List of Disclosures Requirement - § 2.13(d):**
  - Patients who use a general designation in the “To Whom” section of their consent forms, must be provided (upon written request), a list of entities to which their information has been disclosed through that general designation.
  - The intermediary must provide the list of disclosures:
    
    **General designation example:** “to the HIE and all of my treating providers in the HIE” → as intermediary, the HIE must provide the list of disclosures of the recipients (the treating providers).
2. 42 CFR Part 2 – Final Rule

What has Changed? (con’t.)

Research - § 2.52: Among other provisions -

- The retention and disposal requirements for part 2 data used in research are largely consistent with HIPAA’s Privacy Rule.

- Researchers holding part 2 data can now link to federal and non-federal data repositories if certain conditions are met.

- Part 2 data can be included in research reports in aggregate form, where patient-identifiable information is non-identifiable.

- The prohibition on re-disclosure still applies.
2. 42 CFR Part 2 – Final Rule

**What has Changed?** (con’t.)

- Notice to Patients of Federal Confidentiality Requirements - Contact Information for Complaints of Violations - § 2.22(b)2:

  - This written notice must also include contact information for the authorities to whom patients can report violations of part 2.
2. 42 CFR Part 2 – Final Rule

What has Changed? (con’t.)

- Medical Emergency - § 2.51:
  - A patient’s SUD info can be disclosed w/o consent to medical personnel to meet a “bona fide medical emergency” in which the patient’s prior consent cannot be obtained.
  
  - Note: [Prior consent]“cannot be obtained” = Patient was incapable of providing consent, not that the patient refused consent.
3. ADDITIONAL INFORMATION/ISSUES
SUPPLEMENTAL NOTICE OF PROPOSED RULEMAKING ("SNPRM")

Jan. 2017- SAMHSA issued a SNPRM to get comments on additional proposed changes to the Final Rule:

• Payment and health care operations-related disclosures that can be made to contractors, subcontractors, and legal representatives by lawful holders under the consent provisions.

• Audit and evaluation-related disclosures that can be made to contractors, subcontractors, and legal representatives.

• The appropriate safeguards for lawful holders (and their contractors, subcontractors, and legal representatives’) use and disclosure of patient-identifying part 2 information.
3. ADDITIONAL INFORMATION/ISSUES

Prescription Drug Monitoring Programs ("PDMPs")

- State-run electronic databases used to track the prescribing and dispensing of controlled Rx drugs to patients. (CDC’s definition):
  - SAMHSA did not address e-prescribing and PDMPs in the Final Rule, since these issues were not ripe for rulemaking at the time -- due to the state of existing technology, and because most part 2 programs are not using e-prescribing for controlled substances.
3. ADDITIONAL INFORMATION/ISSUES

Securing Part 2 information Between Different Levels of Care

- Remember, SUD information can be disclosed to lawful holders via patient consent, or through one of the other exceptions to disclosure (e.g., medical emergency, internal communications, QSOAs, etc.):

  • **Question:** Jack, a patient in a part 2 program, needs to disclose his SUD treatment information to a HIE and his treating providers at New Hospital for inpatient care. He is advised that he might also need skilled nursing care at an area Critical Access Hospital (“CAH”) after being hospitalized at New Hospital. Both New Hospital and the CAH are members of a HIE. How can Jack disclose his SUD information to his providers at New Hospital? What if Jack isn’t sure he should disclose his SUD information to the providers at the CAH?
3. **ADDITIONAL INFORMATION/ISSUES**

Securing Part 2 information Between Different Levels of Care (con’t.)

- **Answer:** Jack has choices.
  - He could sign a part 2-compliant consent form to disclose “all of his SUD records” to the HIE and his treating providers of New Hospital who participate in the HIE, *with a re-disclosure* to his treating providers of CAH, who participate in the HIE.

  OR
3. ADDITIONAL INFORMATION/ISSUES

Securing Part 2 information Between Different Levels of Care (con’t.)

- He can sign a part-2 compliant consent form to just disclose “all of his SUD records” to the HIE and his treating providers of New Hospital who participate in the HIE. Because Jack doesn’t consent to a re-disclosure of his SUD information in this consent form, part 2’s prohibition on re-disclosure prevents the treating providers at New Hospital from automatically sending Jack’s SUD information to the CAH.

If Jack needs skilled nursing care, he can decide to sign a second consent form for the HIE to release whatever amount and kind of his SUD information he wishes (e.g., “all of my SUD information after June 2016,” “all of my prescribed SUD medications,” etc.) to some or all of his treating providers at the CAH who participate in the HIE (“Dr. Yes, my treating provider at the CAH,” “all of my treating providers at the CAH”).
For Additional Information:


• Go to our website: www.lac.org for more resources: https://lac.org/resources/substance-use-resources/confidentiality-resources/.

• Subscribe to receive LAC’s updates: at https://lac.org/subscribe/.

• Follow the Legal Action Center on social media: ➢ @lac_news
THANK YOU
Overcoming 42 CFR Part 2 Challenges

TARZANA TREATMENT CENTERS
Outline of Presentation

1. Tarzana Treatment Centers (TTC): Background / Context

2. Overcoming the Challenges of CFR 32 Part 2
TTC Background / Context

• Founded in 1972 - 501 (c) (3) Non-profit Corporation

• 650+ Employees and Contract Staff

• 15 locations in Los Angeles County

• Persons served in Calendar 2016

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<td>Substance Use Disorder</td>
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<tr>
<td>HIV/AIDS</td>
<td>1024</td>
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TTC Behavioral Healthcare Services

- Substance Use Disorder Treatment
- Mental Health Disorder Treatment
- Housing
- Assessment and Referral Services in Co-Located Sites
- In Home Services
- Telehealth
Integrated Primary and Specialty Care

• 6 Primary Care Clinics - first clinic opened in 1995
• 5 Primary Care Clinics integrated with Other TTC Services
• 1 Clinic integrated with BH services provided by LA County Department of Mental Health’s San Fernando Mental Health Center
• 3 of 7 Clinics provide specialty HIV/AIDS and Hep C Care
Revenue Sources

• County and City Contracts
• Federal, State, Foundation Grants
• Medicare and Medi-Cal fee-for-service
• Managed Care Contracts – Private Insurance
• Medi-Cal Managed Care
  ◦ Behavioral Health Care
  ◦ Primary Care
• Private Pay
• Sliding Fee and Charity Care
Overcoming Challenges of Part 2

- Challenge – Providing Needed Care
- Challenge – Resisting disclosure
- Challenge – Limiting disclosure
- Challenge – Managing disclosure
Part 2 Challenge – Providing Care

FIGURE 1. Age-adjusted rate* of drug overdose deaths† and drug overdose deaths involving opioids‡,§,¶ — United States, 2000–2014

Part 2 Challenge – Providing Care

WHEN CHRONIC ILLNESS & MENTAL/BEHAVIORAL ILLNESS COMBINE, UTILIZATION & COSTS RISE

Of the 5% costliest enrollees, 45% have a serious mental illness.

DIABETES

0.7 ER VISITS
3.2 INPATIENT DAYS

DIABETES + ALCOHOL/DRUGS + MENTAL ILLNESS

5.6 ER VISITS
9.5 INPATIENT DAYS

ANNUAL SPENDING PER MEMBER

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<th>Condition</th>
<th>Annual Spending ($)</th>
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Annual per member

Source: California Department of Health Care Services
www.chcf.org/medi-cal-matters
© 2015 California HealthCare Foundation
Part 2 Challenge – Resisting Disclosure

§2.13 Confidentiality restrictions and safeguards.

(a) General. ...

(b) *Unconditional compliance required.* The restrictions on disclosure and use in the regulations in this part apply whether or not the part 2 program or other lawful holder of the patient identifying information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement agency official or other government official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by the regulations in this part.
Part 2 Challenge – Resisting Disclosure

Responding to Subpoenas

◦ Subpoenas of records

◦ Subpoenas of staff

Responding to Law Enforcement at your door
Part 2 Challenge – Limiting Disclosure

§2.13 Confidentiality restrictions and safeguards.

(a) General. The patient records subject to the regulations in this part may be disclosed or used only as permitted by the regulations in this part and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any federal, state, or local authority. 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.
Part 2 Challenge – Limiting Disclosure

- Consent Requirements
- Business Associates
- Redisclosure
Part 2 Challenge – Managing Disclosure

• Who may disclose

• Tracking disclosure

• Challenges of Integrated Care
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HealthRIGHT 360 is a family of integrated health programs that provides compassionate care and treatment to over 38,000 individuals a year through more than 70 distinct and culturally competent programs in 13 California counties.

We provide services, regardless of one's ability to pay, inspired by our belief that healthcare is a right, not a privilege.
HealthRIGHT 360 gives hope, builds health, and changes lives for people in need. We do this by providing compassionate, integrated care that includes primary medical, mental health, substance use disorder treatment and re-entry services.

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- We have over 1100 employees
- Our annual operating budget is $115 million
Questions?

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