

# **42 CFR Part 2 Compliance Disclosures Permitted Without Patient Consent**

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- Partner and Compliance Counsel at Feldesman Tucker Leifer Fidell LLP, specializing in, among other things, assisting health centers with the implementation of effective Compliance Programs.
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- Well-versed in the compliance issues facing health centers because of her experience as Chief Compliance Officer and Manager of Government Grants for Boston Health Care for the Homeless Program, one of the largest health center programs in the country.

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- An Associate with Feldesman Tucker Leifer Fidell LLP, David assists clients in understanding and resolving various legal issues at the intersection of federal grants and health law, both through litigation, as well as corporate compliance.
- David's practice focuses on the legal implications of numerous matters affecting federal grantees, including those relating to the False Claims Act, the Federal Tort Claims Act, Medicare and Medicaid overpayments, and adherence to applicable cost principles.
- In addition, David regularly counsels clients on compliance with health privacy laws, including HIPAA, 42 CFR Part 2 and FERPA.

# AGENDA

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## 42 CFR Part 2: Webinar #3

1. Exceptions to Part 2 Applicability
2. Disclosures without Patient Consent
3. Court Orders Authorizing Disclosure and Use
4. Resources

# Exceptions to Part 2 Applicability



# APPLICABILITY: EXCEPTIONS

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## **“Exceptions” to Applicability: 42 CFR § 2.12(c)**

- Department of Veteran Affairs
- Armed Forces
- **Communication within a Part 2 program or between a Part 2 program and an entity having direct administrative control over that Part 2 program**
- **Qualified service organizations**
- Crimes on Part 2 program premises or against Part 2 program personnel
- Reports of suspected child abuse and neglect

# WITHIN A PART 2 PROGRAM

## Communication within a part 2 program – 42 CFR § 2.12(c)(3)(i)

The restrictions on disclosure in the regulations in this part **do not apply** to communications of information **between or among personnel** having a **need for the information in connection with their duties that arise out of** the provision of **diagnosis, treatment, or referral for treatment of patients with substance use disorders** if the communications are:

- ***(i) Within a part 2 program***; or...



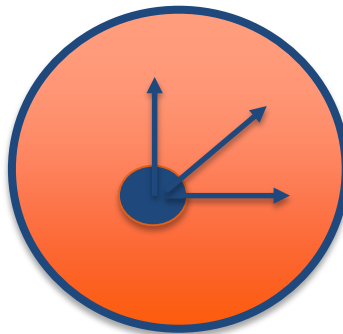


# ENTITIES WITH DIRECT ADMINISTRATIVE CONTROL

## Communication between a part 2 program and an entity that has direct administrative control over the program – 42 CFR § 2.12(c)(3)(ii)

The restrictions on disclosure in the regulations in this part **do not apply** to communications of information **between or among personnel** having a **need for the information in connection with their duties that arise out of** the provision of **diagnosis, treatment, or referral for treatment of patients with substance use disorders** if the communications are:

- *...(ii) Between a part 2 program and an entity that has direct administrative control over the program.*



# APPLICATION OF THE EXCEPTION

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## Case Study – back to Fairview...

ABC Health Center has six sites, including Fairview Clinic which is a Part 2 program specializing in MAT services. Because of the needs of the community, the Fairview Clinic now exclusively provides MAT services.

Debi receives primary care from Dr. Jones at another ABC Health Center site and receives MAT services at Fairview Clinic.

- Can Fairview Clinic communicate information about Debi's SUD treatment at Fairview Clinic to Dr. Jones without Debi's consent in advance of Debi's next primary care visit?
- What factors would inform the analysis?

# QUALIFIED SERVICE ORGANIZATIONS

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## Qualified service organizations – 42 CFR § 2.12(c)(4)

The restrictions on disclosure do not apply to communications **between a Part 2 program and a qualified service organization** of **information needed** by the qualified service organization to **provide services** to the program.

# QUALIFIED SERVICE ORGANIZATIONS

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## Qualified service organization - 42 CFR § 2.11

A qualified services organization is an individual or entity who:

1. Provides **services to a Part 2 program**, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy; and

# QUALIFIED SERVICE ORGANIZATIONS

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## Qualified service organization - 42 CFR § 2.11

2. Has entered into **a written agreement** with a part 2 program under which that individual or entity:
  - i. Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the part 2 program, it is **fully bound by the regulations** in this part; and
  - ii. If necessary, **will resist in judicial proceedings** any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.

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# Disclosures without Patient Consent

# DISCLOSURES WITHOUT PATIENT CONSENT

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- **Medical emergencies: 42 CFR § 2.51**
- Research: 42 CFR § 2.52
- **Audit and evaluation: 42 CFR § 2.53**
- Court authorization: 42 CFR § 2.61

# MEDICAL EMERGENCIES

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## Medical Emergencies - 42 CFR § 2.51(a)

General rule: Part 2-protected information “may be disclosed to **medical personnel** to the extent necessary to meet a **bona fide medical emergency** in which the patient’s prior informed **consent cannot be obtained.**”



# MEDICAL EMERGENCIES

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## Medical Emergencies - 42 CFR § 2.51(c)

Immediately following the disclosure, the Part 2 program shall document, **in writing, the disclosure in the patient's records**, including:

1. Name of medical personnel to whom disclosure was made and their affiliation with any health care facility
2. Name of individual making the disclosure
3. Date and time of the disclosure
4. Nature of the emergency

# AUDIT AND EVALUATION

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## Audit and evaluation: 42 CFR § 2.53

- Records not copied or removed – 42 CFR § 2.53(a)
  - Written agreement to comply with limitations on re-disclosure and use at 42 CFR § 2.53(d)
- Records copied, removed, downloaded, or forwarded – 42 CFR § 2.53(b)
  - Written agreement to:
    - Maintain and destroy Part 2-protected records in a manner consistent with the policies and procedures under § 2.16
    - Retain records in compliance with applicable federal, state, and local record retention laws; and
    - Comply with limitations on re-disclosure and use at 42 CFR § 2.53(d)

# AUDIT AND EVALUATION

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## Audit and evaluation: 42 CFR § 2.53

- Limitations on Disclosure and Use – 42 CFR § 2.53(d)

Patient identifying information disclosed under this section may be disclosed **only back to the part 2 program or other lawful holder from which it was obtained** and **may be used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order** entered under § 2.66.

# AUDIT AND EVALUATION

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## Case Study:

ABC Health Center's Director of Behavioral Health has heard that the State Medicaid Office is conducting billing audits of other health centers that provide SUD services. She recommends hiring Triple Plus Auditing to review all SUD claims submitted by the Fairview Clinic since it became a Part 2 program. Triple Plus Auditing will be on-site for two days and will download any files they cannot review during the site visit. How can ABC Health Center share the Fairview Clinic files with Triple Plus Auditing?

- A. Require Triple Plus Auditing to enter into a QSOA
- B. Require Triple Plus Auditing to complete all claims review on-site
- C. Require Triple Plus Auditing to sign an agreement that addresses the security of the records, including their maintenance and destruction, as well as the record retention requirements

# AUDIT AND EVALUATION

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## Case Study:

Auditors from the State Medicaid Office arrive at the Fairview Clinic and request access to all patient records for the audit. How can ABC Health Center share the Fairview Clinic files with the auditors from the State Medicaid Office?

- A. Require the State Medicaid Office to sign a QSOA
- B. Require the State Medicaid Office to complete all claims review on-site
- C. Require the State Medicaid Office to sign an agreement to comply with the limitations on non-disclosure
- D. Require the State Medicaid Office to sign an agreement to comply with the limitations on non-disclosure and that addresses the security of the records, including their maintenance and destruction, and record retention requirements

# AUDIT AND EVALUATION

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## Case Study:

Auditors from the State Medicaid Office arrive at ABC Health Center. The auditors request access to patient records from three sites, including records from the Fairview Clinic. The auditors provide a list of patient names, which includes Debi. Remember that Debi receives SUD services at the Fairview Clinic and primary care services at another site. The auditors inform ABC Health Center that HIPAA's operations exception allows them access to all patient records. How should ABC Health Center respond?

- A. Tell the auditors that Debi's records are protected by 42 CFR Part 2 and her consent is required to disclose her records
- B. Tell the auditors that ABC Health Center's policy requires additional protections for the records of certain patients, like Debi (because she is a patient of Fairview Clinic)
- C. Tell the auditors that ABC Health Center requires auditors to sign a written agreement before disclosing any records

# AUDIT AND EVALUATION

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## **Audit and evaluation: 42 CFR § 2.53**

Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation – 42 CFR § 2.53(c)

- Includes audits and evaluations to meet requirements for a CMS regulated accountable care organization (ACO) or similar CMS-regulated organization (include a CMS-regulated Qualified Entity)
- The Part 2 program, federal, state or local government agency or any other individual or entity may not disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation

# AUDIT AND EVALUATION

## **Audit and evaluation: 42 CFR § 2.53**

Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation – 42 CFR § 2.53(c)

- Written agreement to:
  - Maintain and destroy Part 2-protected records in a manner consistent with the policies and procedures under § 2.16
  - Retain records in compliance with applicable federal, state, and local record retention laws; and
  - Comply with limitations on re-disclosure and use at 42 CFR § 2.53(d)
- Must be conducted in accordance with 42 CFR § 2.53(c)(3)(i) which requires certain administrative and clinical systems, leadership and management structure, and a signed Participation Agreement as described in 42 CFR § 2.53(c)(3)(ii).



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# Court Orders Authorizing Disclosure and Use

# INITIAL NOTE

## Unconditional compliance required – 42 CFR § 2.13(b)

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 or 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.



# COURT ORDERS AUTHORIZING DISCLOSURE AND USE

## Legal effect of order – 42 CFR § 2.61(a)

*Effect.* An order of a court of competent jurisdiction entered under this subpart is a **unique kind of court order**. Its **only purpose** is to **authorize a disclosure or use of patient information** which would otherwise be prohibited by 42 U.S.C. 290dd-2 and the regulations in this part. Such an order **does not compel disclosure**. A **subpoena** or a **similar legal mandate must be issued** in order to compel disclosure. This mandate may be entered at the same time as and accompany an authorizing court order entered under the regulations in this part.



# COURT ORDERS AUTHORIZING DISCLOSURE AND USE

## Legal effect of order – 42 CFR § 2.61(b)

*Examples.*

(1) A person holding records subject to the regulations in this part receives a **subpoena** for those records. The person **may not disclose** the records in response to the subpoena **unless a court of competent jurisdiction enters an authorizing order** under the regulations in this part.

(2) An **authorizing court order** is entered under the regulations in this part, but the person holding the records does not want to make the disclosure. **If there is no subpoena or other compulsory process or a subpoena for the records has expired or been quashed**, that person **may refuse** to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person holding the records must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of the regulations in this part.

# COURT ORDERS AUTHORIZING DISCLOSURE AND USE

## Confidential communications – 42 CFR § 2.63(a)

(a) A court order under the regulations in this part may authorize disclosure of confidential communications made by a patient to a part 2 program in the course of diagnosis, treatment, or referral for treatment only if:

- (1) The disclosure is necessary to protect against an existing threat to life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect and verbal threats against third parties;
- (2) The disclosure is necessary in connection with investigation or prosecution of an extremely serious crime allegedly committed by the patient, such as one which directly threatens loss of life or serious bodily injury, including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or
- (3) The disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony or other evidence pertaining to the content of the confidential communications.

# COURT ORDERS AUTHORIZING DISCLOSURE AND USE

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## Procedures and criteria for orders authorizing disclosures for noncriminal purposes – 42 CFR § 2.64

...(e) *Content of order.* An order authorizing a disclosure must:

- (1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;
- (2) Limit disclosure to those persons whose need for information is the basis for the order; and
- (3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

# COURT ORDERS AUTHORIZING DISCLOSURE AND USE

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## **Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients – 42 CFR § 2.65**

...(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

- (1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;
- (2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of the extremely serious crime or suspected crime specified in the application; and
- (3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

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# Available Resources



# RESOURCES

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- **42 CFR Part 2 – Current text**

<https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:1.0.1.1.2>

- **SAMHSA's Website**

<https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines>

Includes:

- FAQ from 2010 and 2011
- Two Fact Sheets from 2018
- Promise to provide updated guidance to reflect changes from the 2017 and 2018 rules

# QUESTIONS?

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# OTHER UPCOMING TRAINING EVENTS

## Live Trainings

|   |   |                |
|---|---|----------------|
| September 25 <sup>th</sup> – 26 <sup>th</sup> | HIPAA: Fundamentals   | Washington, DC |
| October 1 <sup>st</sup> – 2 <sup>nd</sup>     | Health Center Compliance Intensive: Fundamentals  | Washington, DC |
| October 3 <sup>rd</sup> – 4 <sup>th</sup>     | Health Center Compliance Intensive: Advanced Concepts   | Washington, DC |
| November 7 <sup>th</sup> – 8 <sup>th</sup>    | Managing Risks Related to Providing Opioid Services: Protecting Patients, Providers and the Health Center | Washington, DC |
| December 3 <sup>rd</sup> – 4 <sup>th</sup>    | Federal Grant Management for Health Centers   | Washington, DC |
| December 4 <sup>th</sup> – 5 <sup>th</sup>    | De-Mystifying the Compliance Manual & Its Impact on the Program Requirements                              | Orlando, FL    |
| December 5 <sup>th</sup> – 6 <sup>th</sup>    | In-Depth Look at FTCA   | Orlando, FL    |

## Webinars

|  |   |
|--|---|
| September 6 <sup>th</sup> , 13 <sup>th</sup> , 20 <sup>th</sup> and 27 <sup>th</sup> @ 1 PM ET | CMS Emergency Preparedness Rule Webinar Series (Live Series)  |
| September 26 <sup>th</sup> @ 1 PM ET   | HRSA Program Compliance: Latest Developments and "Hot" Issues |
| October 11 <sup>th</sup> @ 1 PM ET   | FTCA: Key Elements  |
| November 15 <sup>th</sup> @ 1 PM ET  | Ensuring Access Under the ADA                                 |

For more information and to register:

Email [learning@ftlf.com](mailto:learning@ftlf.com) or go to <https://learning.ftlf.com>