Welcome!

The Nevada Opioid Center of Excellence (NOCE) is dedicated to developing and sharing evidence-based training and offering technical assistance to professionals and community members alike. Whether you're a care provider or a concerned community member, NOCE provides resources to support those affected by opioid use.

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Nevada Opioid Center of Excellence
CASAT | School of Public Health

Privacy and Confidentiality in Opioid Treatment

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A Note on References

- This training has primarily been based on Confidentiality and Communication 2020 & 2021 Edition Revised, Legal Action Center of New York City, Inc.
- Special Thanks to the Legal Action Center for this exceptional work, this training would not be possible without these publications.
- All References will be provided on last slide of this Power Point Presentation

Disclaimer Statement

Disclaimer: I'm not a lawyer, it is important to seek legal counsel in areas needing further clarification or application.

Learning Topics for this training

- 42 CFR, Part 8 – New Rule & Regulations Governing MOUD
- 42 CFR, Part 2 Final Rule (Changes)
- Navigating Conflicts between Part 2 and HIPAA & State Privacy Laws
- Who Must Comply with Part 2 and HIPAA
- How and What Information is Protected

Learning Topics Continued

- Consent Forms
- Exceptions to the General Rule (Disclosures without Consent)
- Subpoenas, Court Orders, Criminal Investigations and Prosecutions
- Duty to Warn Decision Tree
- Prescription Drug Monitoring Program 42 CFR Part 2 & PDMPs
- Patient Privacy Rights HIPAA & Part 2

42 CFR PART 8 - New Rule and Regulations Governing MOUD

Title and Terminology:

The title of the rule has been updated to "Medications for the Treatment of Opioid Use Disorder." The final rule replaces outdated terms such as "detoxification" and adds new definitions.

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

42 CFR PART 8 - New Rule and Regulations Governing MOUD Continued

Admissions:

The final rule eliminates the 1-year opioid addiction history requirement and promotes priority treatment for pregnant individuals. It also removes the requirement for two documented instances of unsuccessful treatment for people under age 18. Allows consent to be obtained electronically. In addition, medication access is no longer contingent on receipt of counseling. The final rule also allows screening examinations to be performed by practitioners external to the OTP under certain conditions.

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

42 CFR PART 8 - New Rule and Regulations Governing MOUD Continued

Treatment Standards:

The final rule adds patient-provider "shared decision making" considerations to all care plans and incorporates harm reduction principles into treatment.

Take-Home Doses:

The final rule updates criteria for consideration of take-home doses of methadone and allows patients to receive take-home doses from the first week of treatment under certain conditions. Safeguards like diversion control procedures remain.

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

42 CFR PART 8 - New Rule and Regulations Governing MOUD Continued

Telehealth:

The final rule allows screening patients for initiation of buprenorphine via audio-only or audio-visual telehealth technology if certain providers determine that an adequate evaluation of the patient can, or has been, completed via telehealth. The final rule also allows for screening patients for the initiation of methadone via audio-visual telehealth under certain conditions.

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

42 CFR PART 8 - New Rule and Regulations Governing MOUD Continued

OTP Compliance and Accreditation

The final rule sets forth time frames and follow-up of OTPs on corrective measures. The time for OTPs to take corrective action is extended to 180 days following receipt of the survey report. Removes an expired type of accreditation, clarifies the category of "provisional" certification and authorizes "conditional" certification. The final rule sets forth time frames and follow-up of OTPs on corrective measures. The time for OTPs to take corrective action is extended to 180 days following receipt of the survey report. Removes an expired type of accreditation, clarifies the category of "provisional" certification and authorizes "conditional" certification.

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

42 CFR PART 8 - New Rule and Regulations Governing MOUD Continued

Scope of Practice Expansion

Allows nurse practitioners and physician assistants to order MOUD for dispensing at the OTP if consistent with state law. The final rule also clarifies medication unit rules and defines the range of services that they may offer.

https://www.samhsa.gov/substance-use/treatment/opioid-treatment-program/42-cfr-part-8/changes

Final Rule 42 CFR, Part 2
Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024. **Link for Updated Regulations: https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2**

Patient Consent

- Allows a single consent for all future uses and disclosures for treatment, payment, and health care operations.
- Allows HIPAA covered entities and business associates that receive records under this consent to redisclose the records in accordance with the HIPAA regulations.[1]

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2 Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

Other Uses and Disclosures

- Permits disclosure of records without patient consent to public health authorities, provided that the records disclosed are de-identified according to the standards established in the HIPAA Privacy Rule.
- Restricts the use of records and testimony in civil, criminal, administrative, and legislative proceedings against patients, absent patient consent or a court order.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2
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Penalties:

- Aligns Part 2 penalties with HIPAA by replacing criminal penalties currently in Part 2 with civil and criminal enforcement authorities that also apply to HIPAA violations.[2]

Breach Notification:

- Applies the same requirements of the HIPAA Breach Notification Rule3 to breaches of records under Part 2.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2
Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

Patient Notice:

- Aligns Part 2 Patient Notice requirements with the requirements of the HIPAA Notice of Privacy Practices.

Safe Harbor:

- Creates a limit on civil or criminal liability for investigative agencies that act with reasonable diligence to determine whether a provider is subject to Part 2 before making a demand for records in the course of an investigation. The safe harbor requires investigative agencies to take certain steps in the event they discover they received Part 2 records without having first obtained the requisite court order.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2
Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

Safe Harbor:

- Clarifies and strengthens the reasonable diligence steps that investigative agencies must follow to be eligible for the safe harbor: before requesting records, an investigative agency must look for a provider in SAMHSA's online treatment facility locator and check a provider's Patient Notice or HIPAA Notice of Privacy Practices to determine whether the provider is subject to Part 2.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2
Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

Segregation of Part 2 Data:

- Adds an express statement that segregating or segmenting Part 2 records is not required.

Complaints:

- Adds a right to file a complaint directly with the Secretary for an alleged violation of Part 2. Patients may also concurrently file a complaint with the Part 2 program.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2 Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

SUD Counseling Notes:

- Creates a new definition for an SUD clinician's notes analyzing the conversation in an SUD counseling session that the clinician voluntarily maintains separately from the rest of the patient's SUD treatment and medical record and that require specific consent from an individual and cannot be used or disclosed based on a broad TPO consent. This is analogous to protections in HIPAA for psychotherapy notes.[4]

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2
Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

Patient Consent:

- Prohibits combining patient consent for the use and disclosure of records for civil, criminal, administrative, or legislative proceedings with patient consent for any other use or disclosure.
- Requires a separate patient consent for the use and disclosure of SUD counseling notes.
- Requires that each disclosure made with patient consent include a copy of the consent or a clear explanation of the scope of the consent.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Final Rule 42 CFR, Part 2 Overview of Updates: Major Changes

Those affected by the new rule must comply two years after its official publication, which was February. 16, 2024.

What has not changed in Part 2?

- As has always been the case under Part 2, patients' SUD treatment records cannot be used to investigate or prosecute the patient without written patient consent or a court order.
- Records obtained in an audit or evaluation of a Part 2 program cannot be used to investigate or prosecute patients, absent written consent of the patients or a court order that meets Part 2 requirements.

https://www.hhs.gov/hipaa/for-professionals/regulatory-initiatives/fact-sheet-42-cfr-part-2-final-rule/index.html#:~:text=Major%20Changes%20in%20the%20New%20Part%202%20Rule&text=Allows%20a%20single%20consent%20for,accordance%20with%20the%20HIPAA%20regulations

Navigating Conflict Between Part 2 and HIPAA

- In Most Cases HIPAA does not impact compliance with 42 C.F.R. Part 2, but there are some important areas in which a provider must develop policies to address differences and conflicts.
- Per the Summary above on changes, both laws are more congruent now.

The following are some examples where there is conflict

Four Examples of Conflicts

- HIPAA allows disclosures without patient consent for the purpose of payment. Part 2 prohibits these disclosures without patient consent. If both programs are covered entities, patient consent to make this disclosure is required meeting Part 2 Requirements. (Note Changes in Final Rule)
- HIPPA requires providers to allow a person to access their health information, Part 2 permits patients to access their own records. Providers must comply with the mandatory HIPAA disclosure provisions. (To be reviewed for changes?)

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Continued

Four Examples of Conflicts

- HIPAA imposes administrative requirements that are not included in Part 2, such as designating a privacy officer. Since these are required, and Part 2 is silent, Part 2 programs must implement them. (Note Changes in Final Rule)
- Both HIPAA and Part 2 require providing patients with notice of privacy protections. While these requirements are not exactly the same, providers that must comply with both laws can use patient notices that comply with both laws by including elements from both. (Note Changes in Final Rule)

General Rule: What to do when the conflicts seem irreconcilable?

- More recent law usually overrules older laws
- If an earlier law is more stringent, the older law overrules the new rules
- If an older law is silent on a matter and the new law address something new, the newer law overrules the older law

Continued

State Law Differences

- Part 2 generally preempts or overrule state laws unless the state law provides greater protections. Note on NRS 629.550.
- HIPAA preempts any contrary state law provision. That is, if a program would "find it impossible" with both the state and federal requirements, or if the state law "stands as an obstacle" to achieving HIPAA's purposes and objectives, then the state law is preempted by HIPAA.
- There are some exceptions related to this. It is important to seek legal council when this happens to assure you are following all applicable laws.

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Continued

- HIPPA does not preempt a state law providing for public health reporting or reporting of disease, injury, child abuse, birth or death. **42 C.F.R Part 2 is more restrictive related to this and will be discussed later. (Note changes in Final Rule)**
- Conclusion: Program's privacy practices should incorporate state law requirements that are more protective of patient privacy than HIPAA and Part 2. It's critical to write policies that describe this dynamic in your organization or if you are in private practice and both laws apply.

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Who Must Comply: Part 2 Programs, HIPAA Covered Entities, and More?

- Most SUD Treatment Programs must comply with HIPAA and Part 2
- HIPAA generally covers healthcare industry, including most treatment providers
- Part 2 applies only to certain SUD programs; this would include COD programs.
- It is possible for a provider to be covered by one, both or neither

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Who Must Comply with Part? (Page 319)

There are specific groups by definition that must comply with Part 2

- Part 2 Programs: Applies to SUD providers that meet the definition of a "Program" and are federally assisted.
- Just because a program provides treatment services, doesn't mean that the program is covered. Understanding the 2 groups is critical.

Step 1: Defining a "Program"

Programs **outside a General Medical Facility** include

- Providing SUD diagnosis, treatment, or referral for treatment and holding themselves out as providing such services.

Programs in **Medical Facilities** are not covered by Part 2 unless one of the following applies

- The provider works in an identified unit that provides SUD diagnosis, treatment or referral for treatment, and holds itself out as providing those services; or
- The provider has medical personnel or other staff whose primary function is to provide SUD diagnosis, treatment or referral and provider is identified as a SUD treatment provider.

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Step 1 Continued

School Based programs, Employee Assistance Programs and SBIRT

- Part 2 applies when
  - School-based programs provide SUD/COD treatment services and hold themselves out as providing those services.
  - Also, may be considered a program if it admits students based on actual or suspected substance use.
  - Additionally includes employee assistance programs that provide SUD treatment or hold themselves out and
  - SBIRT only applies if provided by a Part 2 program.

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Step 2: Determining whether the program receives "Federal Assistance"

A program is federally assisted, and therefore covered by Part 2 if any of the following applies

- Receives federal funds in any form
- Assisted by the IRS (Non-Profit)
- Authorized to conduct business by the federal government
  - Certified as a Medicare/Medicaid provider
  - Licensed DEA to provide controlled substances such as methadone and and/or
  - Conducted directly by the federal government

If programs meet these 2 definitions, it must comply with Part 2

Who Must Comply with HIPAA?

Two Groups

- Healthcare Providers, Insurance Companies and Healthcare Clearing Houses

  And

- Business Associates that Receive Protected Health Information

https://www.brickergraydon.com/insights/resources/key/HIPAA-Regulations-General-Provisions-Definitions-Health-Care-Clearinghouse-160-103#:~:text=In%20the%20NPRM%2C%20we%20defined,information%20into%20standard%20data%20elements

Continued (HIPAA)

Covered Entities Definition

- Health Care Provider: preventive, diagnostic, therapeutic, counseling, and assessment services with respect to the physical or mental condition of the patient (45 CFR 160.103)
- A health care provider is any person or entity that furnishes, bills, or is paid for healthcare in the normal course of business

Providers that treat, diagnose, assess or refer individuals with substance use disorders, as well as SUD prevention programs, are healthcare providers

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Continued (HIPAA)

Additional information and clarity:

- If a Part 2 programs meets HIPAA definition, it is covered by HIPAA only if it transmits health information electronically in connection with a covered transaction (45 CFR 160.103)
- Transactions include processing claims, payment and remittance, coordination of benefits, checking claims status, enrollment or dis-enrollment in a health plan, health plan eligibility, health plan premium payments, referrals, certification and authorization, first report of injury, health claim attachments and other transactions that HHS may prescribe (45 CFR 160.103)

In summary, only providers that electronically transmit information to carry out these financial or administrative activities are required to abide by HIPAA.

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Continued (HIPAA)

Business Associates

- HIPAA applies to "business associate" of covered entities.
- Business Associates are outside contractors and companies that provide services such as legal, actuarial, accounting, consulting, data aggregation etc….
- Under HITECH Act of 2009, business associates became liable for certain elements of compliance with HIPAA.

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Defining the Scope of Confidentiality: What Information is Protected (Part 2/HIPAA)

- Both Part 2 and HIPAA protect information that identifies an individual and relates to healthcare services
- HIPAA applies broadly and protects "protected health information"
- Part 2 applies to "patient identifying information" in records maintained by Part 2 providers.

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Continued

- HIPAA protects any health information that reasonably identifies an individual, while Part 2 only protects information that identifies an individual as applying for or receiving services from a Part 2 program.
- Implicit and explicit disclosures are prohibited under both HIPAA and Part 2.
- If a Part 2 program receives an unauthorized request, it must refuse to make the disclosure. Legal Action Center recommends the following response in light of changes to Part 2 in 2017.
    - "Federal law prohibits me from disclosing any information" Then provide a copy of Part 2 to the person/entity requesting information.

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Proper Format for Consent to Release Information (Part 2/HIPAA)

Required Elements of Written Consent to Satisfy both Part 2 and HIPAA

1. Name of the patient who is the subject of the disclosure
2. Name of general designation of the Part 2 program or other individual/entity making the disclosure
3. The name of the individual or entity authorized to receive the information
4. Description of how much and what kind of information will be disclosed, including explicit description of the SUD information that may be disclosed
5. Purpose of the disclosure

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Continued: Elements of Consent Form

6. Date, event, or condition upon which the consent expires, if not revoked
7. Signature of the patient and/or authorized person
8. Date on which the consent is signed
9. Statement of the patient's right to revoke the consent in writing, the exceptions to the right to revoke, and a description of how patients may seek to revoke their consent
10. A statement of a Part 2 program's ability to condition treatment, payment, enrollment or eligibility of benefits on the patient agreeing to sign the consent, by stating either that the program may not condition these services on the patient signing the consent, or the consequences for the patient refusing to sign the consent

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CONTINUED: Elements of Consent Form

- HIPAA also requires covered entities to provide patients with copies of all consents which the patient signs (45 CFR 164.508(c)(4)) This element can be documented in the release form. (Updated to include Part 2 documents)
- Exception: Re-Disclosures for Payment and Healthcare Operations (updated) amendments introduced a major new exception to the prohibition on re-redisclosure. Under this change a patient consents to a disclosure for the purpose of payment or healthcare operations, the recipient of the information may re-disclose the records as necessary to their contractors, subcontractors or legal representatives, in order to perform payment. There are still limits related to diagnosis, treatment, or referral. (Note Changes in Final Rule, HIPAA and Part 2 are congruent on this matter)

Exceptions to the General Rule: Disclosures without Consent: (page 84)

The General Rule is that patient-identifying information may not be disclosed without written patient consent, in certain circumstances both HIPAA and Part 2 permit disclosure without consent. Before making a disclosure without patient consent, Part 2 programs that are HIPAA-covered programs must be able to identify the HIPAA and Part 2 exceptions that permit disclosure. Unless each law permits the disclosure, written consent must be obtained. Even if there is an exception, obtaining consent is best practice and in line with a solid Risk Management Plan.

Continued: Exceptions

The following questions must be answered when applicable. It is important to have a staff person that acts as the Privacy Officer overseeing these processes. Some decisions may need to be reviewed by legal counsel.

- Has The patient executed a proper consent form? (General Rule)
- Can the proposed communication be made without revealing an individual's status as a patient at a Part 2 program?

Continued: Exceptions

- Is the proposed communication necessary for staff within the Part 2 program to perform their duties, or for staff within an entity with direct administrative control over the program to perform their duties related to SUD services?
- Is the proposed communication necessary to respond to a medical emergency?
- Will the proposed communication be made pursuant to a Qualified Service Organization Agreement or Business Associate?
- Is the proposed communication for research purposes?

Continued: Exceptions

- Does state law mandate the communication for reporting child abuse or neglect?
- Does state law mandate vital statistics report for a deceased patient?
- Does the proposed communication concern a crime, or a threatened crime, on the program premises or against program personnel?
- Is the proposed communication authorized by a valid court order?

If any of the answers to the above questions are no, then communication cannot be made. If any of the questions were yes, communication is allowed under the law. You also need to determine that HIPAA permits the disclosure.

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Communications that do not Disclose Patient-Identifying Information

While not specifically an "exception" to the general rule, Part 2 does not protect information that does not identify an individual as seeking or receiving services from a Part 2 provider, Part 2 only protects "patient-identifying information"

Part 2 defines "patient identifying information" as an individual's name, address, social security number, fingerprints, photograph, or similar information from which a patient's identity can be determined with reasonable accuracy either directly or by reference to other information 42 CFR 2.11.

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Continued

HIPAA, protects any “individual identifiable health information, “which is defined broadly to include any information related to an individual's past, present, or future physical or mental health condition, any healthcare offered to the individual, and any past, present or future healthcare related payment for the individual. (Note Changes in Final Rule)

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Continued

HIPAA impacts Part 2 programs' ability to disclose non-patient identifying information when a Part 2 program seeks to make an anonymous communication about a patient without identifying the name of the program or otherwise revealing the individual's status as a patient in SUD treatment. HIPAA programs must be sure that an anonymous disclosure does not reveal any health-related information, not just information related to the individual's substance use disorder, unless another HIPAA exception permits the disclosure.

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Internal Program Communications

Part 2 programs permit program staff to disclose information to other staff within the Part 2 program or to an entity having direct administrative control over that Part 2 program. This is the case with HIPAA as well. Part 2 specifies if the recipient needs the information in connection with duties that arise out of diagnosis, treatment or referral for SUD treatment.

Internal communication between program and entity that has direct administrative control. The rule above is the same. With this said, safeguards must be put in place to assure privacy of the patient.

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Medical Emergencies (Updated)

If patient consent cannot be obtained, Part 2 allows disclosures to medical personnel in order to treat a bona fide medical emergency (42 CFR 2.51). 2020 amendments to Part 2 also introduced a way to share information for medical emergencies during a temporary state of emergency.

HIPAA permits disclosures to other medical personal for any treatment purpose, Part 2 is more restrictive of patient privacy than HIPAA so programs must continue to follow Part 2's narrower provisions.

Continued: Medical Emergencies

Only medical personnel can receive Part 2 records pursuant to the medical emergency exception. Records cannot be shared with anyone else even family without consent. The best way to address family notification is have the patient sign a consent before treatment starts to be able to communicate with family.

Medical emergencies must be bona fide in order to trigger this exception. The language is more flexible than prior to 2017, but the exception must be followed carefully. Suicide attempt and serious drug overdose would fit within the definition of bona fide.

Continued: Medical Emergencies

Part 2 programs may now report a positive test for sexually transmitted infections to public health authorities.

(Note Changes in Final Rule)

How much information can be disclosed?

Use the minimum necessary rule here. For example, you would only release the portion of the record that is needed to treat the patient.

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Continued: Medical Emergencies

Documenting the disclosure 42 CFR 2.51 (c) (1)-(4).

- Name and affiliation of the recipient of the information
- Name of the individual making the disclosure
- Date and time of the disclosure
- Nature of the emergency

Continued: Medical Emergencies

Once patient-identifying information is disclosed to medical personnel during a medical emergency, medical personnel may re-disclose this information as necessary. This is the case with HIPAA as well.

Natural and Major Disasters (New)

Special Rule for Reporting to the Food and Drug Administration

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Qualified Service Organizations (QSO) & Business Associates (BA)

Both HIPAA and Part 2 allow programs to disclose information without the patient's consent to an outside organization that provides certain services. HIPAA refers to these providers as Business Associates (BAs) while Part 2 using the term Qualified Service Organization (QSO's)

HIPAA allows covered entities to use BAs for payment and health care operations, Part 2 is more restricted. (Note Changes in Final Rule)

Once the QSO/BA receives the patient information, it is required to comply with HIPAA's privacy and security provisions. QSO/BA are subject to HIPAA's penalties.

Continued: (QSO's)

Examples of QSO's: **(Note Changes in Final Rule)**

- Accounting
- Bill collecting
- Data processing
- Dosage preparation
- Laboratory analysis
- Legal services
- Medical staffing services
- Population health management
- Professional services
- Service to prevent or treat child abuse and neglect, including training on nutrition and childcare and individual and group therapy

Continued (QSO's)

Before 2017, the Part 2 regulations permitted QSO's to provide medical services to Part 2 programs. This change emphasizes that QSO's should not be used to avoid obtaining patient consent for let's say, Primary Care Provider. (To be reviewed further under New Rule)

Audit and Evaluation (Updated)

2017 and 2018 amendments to Part 2 introduced major changes to how Part 2 information may be disclosed without patient consent for audit and evaluation. 2020, SAMHSA amended the Audit/Evaluation exception to permit disclosures to a wider range of government entities and for a greater variety of purposes. (Note Changes in Final Rule, Safe Harbor)

State Regulatory Audits (Signing a Privacy Agreement)

Third Party Payers

Medicare, Medicaid, CHIP, and related audits and evaluations

Research (Updated)

Part 2 allows a provider or lawful holder of Part 2 records to disclose patient-identifying information without patient consent for the purpose of scientific research. (42 CFR 2.52)

HIPAA was in conflict with Part 2, but 2017 and 2020 modifications were made to make both laws more congruent.

It is critical that HIPAA and Part regulations related to research be considered prior to allowing any research to take place in your organization.

Mandated Reports of Child Abuse and Neglect

Part 2 and HIPAA allows programs to comply with state mandatory reporting laws. (42 CFR 2.12 (c)(6), 45 CFR 164.512(b)(1)(ii))

Part 2's exception only applies to initial reports of child abuse or neglect, and to a written confirmation of that initial report.

The exception does not apply to requests even when there is a subpoena for additional records. This applies to civil and criminal investigations.

Information can only be released if the patient signs a release or there is a court ordered issued.

Reporting Vital Statistics of Deceased Patients

HIPAA and Part 2 continue to protect the confidentiality of patients after death, both laws permit programs to make limited reports to comply with vital statistics reporting to their state.

Part 2 permits programs to disclose patient-identifying information relating to the cause of death of the patient, in order to comply with a law requiring the collection of death or other vital statistics or permitting inquiry into the cause of death. (42 CFR 2.15 (b)(1))

Continued: Vital Statistics

HIPAA more broadly permits public health reporting of protected health information, including of deceased patients. (45 CFR 164.512 (b)) Part 2 is more restrictive and should be followed if the provider is a covered entity. **(Note Changes in Final Rule)**

Legal counsel should be sought related to local state laws.

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Crimes on Program Premises or Against Program Personnel

When a patient has committed a crime on Part 2 premises or against Part 2 program personnel, or threatened such a crime, both regulations allow provider to report the threat or crime.

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Continued: Crimes

Crimes on Program Premises

HIPAA permits disclosure of PHI that the program believes in good faith to be evidence of criminal conduct. (45 CRF 164.512(f)(5))

Part 2 allows providers to disclose information regarding the circumstances of the incident, including the persons name, address, last know whereabouts, and status as a patient in a program. (42 CFR 2.12(c)(5)(ii))

Part 2 allows a program to provide information about a suspected person who committed a crime but can't provide a list of several clients. This relates to the narrow instances listed above.

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Continued: Crimes

Threats of Crimes on Program Premises or Against Program Personnel (Continued)

If the provider hears about a serious or imminent threat to commit a crime on program premises or against program personnel, it may report the threat. Note that even though Part 2 permits programs to report a threat on program premises, HIPAA only allows reporting when it will prevent or lesson a serious or imminent threat to the health or safety of a person or to the public. **(There are no changes related to this in the Final Rule)**

Continued: Crimes

Follow up after the Initial Report

If a staff person of a Part 2 program is later asked to testify in a criminal proceeding against the patient, they can only do so if a court order is issued or the client signs a consent.

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Court-Ordered Disclosures

A state or federal court may issue an order that authorizes a Part 2 program to disclose patient-identifying information under both Part 2 and HIPPA. (42 CFR 2.63-2.67; 45 CFR 164.512(e)) Part 2 has several requirements for a court order and thus when applicable, Part 2 must be followed.

A court order related to a criminal investigation or to prosecute a patient has stricter requirements than those of a civil case.

Continued: Court-Ordered

Under Part 2, a subpoena, search warrant or arrest warrant, even when signed by a judge and labeled a court order, is not sufficient, when standing alone. (42 CFR 2.61) A subpoena may be used, however, to compel a program to attend a hearing to see whether a court order should be issued.

Before a court order can be issued under Part 2, the patient must be given notice that the records are being requested. Additionally, the patient shall be given the opportunity to give an oral or written statement to the court. This does not apply if the information is sought to investigate or prosecute the client, only the program must be notified in this case. If the information being sought is to investigate a program, no notice is required in either case.

Continued: Court-Ordered

The initial application and any court order must use fictitious names for any known patient, and all court proceedings in connection with the application must remain confidential unless the patient requests otherwise. (42 CFR 2.64(a)-(b), 2.65(a)-(b), 2.66(a))

Before a court can issue an order, the court must find good cause. This is only if it is determined that the public interest and the need for the disclosure outweighs any adverse effect to the patient.

Continued: Court-Ordered

If the information is available elsewhere, the court should not issue the order. If not, the judge can view the record in private prior to making a decision.

Only the information that is essential to fulfill the purpose of the order and only the persons who need the information should view it.

The judge should further seek to protect information post review such as sealing the record. (42 CFR 2.64(e))

A court may not authorize disclosure of confidential communications by the patient unless it is necessary due to safety.

Criminal Investigation or Prosecutions

Related to Part 2, an investigation, law enforcement, or prosecutorial agency seeking an order to authorize disclosure for purposes of investigating or prosecuting a patient for a crime must establish five stringent criteria:

- Extremely serious crime
- Information significant to investigation or prosecution
- No other practical way to obtain information
- Public interest in disclosure outweighs potential harm to patient
- Program has an opportunity to be represented by legal counsel

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Duty to Warn Summary

3 Laws at Play in Nevada:

- State law requires duty to warn when a threat is made. This applies to most credentialed counselors. The statute for duty to warn is NRS 629.550.
- Part 2 has limitations to reporting when threat is made.
- HIPAA has limitations to what information is reported when threat is made.

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Duty to Warn Decision Tree

Part 2 Programs

- Is the threat being made to a staff member of the Part 2 program?
    - If yes, the Part 2 program may contact law enforcement/person being threatened.
- Is the threat against staff, client's or the public on the premises of the Part 2 program?
    - If yes, the Part 2 program may contact law enforcement.
- Is the program part of a general hospital, community mental health center or other organization that offers services other than substance use treatment services. (remember earlier definition)
    - If yes, information can be shared utilizing the minimum necessary rule.

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Duty to Warn Decision Tree Continued

- Related to the Part 2 exception, how should a program notify law enforcement/person being threatened and assure compliance with state law when the Part 2 exception doesn't apply.
    - Legal Action Center recommends making an anonymous call that cannot be traced back to the Part 2 program. Information cannot contain the status of the client receiving treatment or any Patient Identifying Information other than the threat, name of client and last known whereabouts.

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Duty to Warn Decision Tree Continued

- What kinds of threats are reportable?
    - Is the crime extremely serious, i.e., directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect (Legal Action Center) This is allowed under HIPAA as well though there are some restrictions related to types of information.

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Prescription Drug Monitoring Program 42 CFR Part 2 and PDMPs

Q: Does 42 CFR Part 2 permit Part 2 programs to report data to PDMPs?

A: Yes. A Part 2 program or lawful holder is permitted to report protected records (e.g., SUD medication prescribed or dispensed) to the applicable PDMP if required by state law, and if the patient consents. The Part 2 program or lawful holder must obtain patient consent to disclose records to a PDMP under § 2.31 prior to reporting of such information. 42 CFR §2.36.

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Prescription Drug Monitoring Program 42 CFR Part 2 and PDMPs (Continued)

Q: According to Part 2, how must PDMPs protect Part 2 data?

A: As a lawful holder of Part 2 data, the PDMP must:

1. Protect security of records (42 CFR § 2.16), and
2. Only release records to law enforcement with a Part 2-compliant court order (42 CFR § 2.65).

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Prescription Drug Monitoring Program 42 CFR Part 2 and PDMPs (Continued)

Q: If a patient consents to a disclosure of his or her Part 2 records to the state's PDMP, does that allow the PDMP to share the patient's data with another state?

A: No. The PDMP may not redisclose Part 2-protected records without patient consent.

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Prescription Drug Monitoring Program 42 CFR Part 2 and PDMPs (Continued)

Q: Does it violate 42 CFR Part 2 for an OTP to share ALL its patient records with the PDMP, including records of patients who did not consent?

A: Yes. This violates Part 2 because the OTP must have written patient consent from each individual patient before sharing records with the PDMP (42 CFR § 2.36). Even if state law does not require written patient consent, 42 CFR Part 2 does. Even if state law requires a disclosure prohibited by 42 CFR Part 2, Part 2 takes precedent because it is the federal law and a stricter standard. 42 CFR §2.20.

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Patient Privacy Rights

Notice of Privacy Rights

- HIPAA and Part 2 require programs to notify patients of their privacy rights and provide a written summary of each law's protections and exceptions. (Note updates per Final Rule)
- Part 2 requires this notice be provided at admission, but, if the patient lacks capacity to understand their medical status, "as soon thereafter as the patient has the capacity." (42 CFR 2.22(a))
- HIPAA requires programs to provide notice upon initial contact with the patient, in either paper or electronic format. (45 CFR 164.520(c)(2)(i))

To comply with HIPAA, Part 2 programs should provide notice upon first contact. If there is an emergency, HIPAA allows programs to provide notice as soon as possible. (45 CFR 164.520(c)(2)(i)(B))

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Continued: Patient Rights

A single notice of privacy can be used for both HIPAA and Part 2. The notice must include:

Header: This notice describes how medical/Behavioral Health and substance and alcohol related information about you may be used and disclosed and how the client can get access to this information. Please review it carefully: (Note updated Final Rule)

Citation of both federal laws

Detailed description, including one example, of the types of uses and disclosures that program is permitted to make.

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Continued: Patient Rights

Detailed description, including one example, for each of the other purposes for which the program is allowed to disclose without consent. This should include those uses and disclosures that Part 2 permits, and include a summary of the information that is allowable without consent;

- Qualified Service Agreement and/or Business Associate Agreement
- Research, audit and evaluation
- Patient's commission of a crime against program personnel or on program premises
- Program statements regarding suspected child abuse or neglect pursuant to state law
- Medical Emergency
- Court Order

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Continued: Patient Rights

A statement of the individual's right to the following: HIPAA Specific:

- Request restriction on certain uses and disclosures of PHI (e.g.) health provider statements must note that individual's who have paid out-of-pocket and in full for healthcare or service may restrict disclosures of this information to health plans
- Receive confidential communications of PHI
- Inspect and copy this information
- Right to receive an accounting of disclosures
- Amend information

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Administrative Privacy & Security Requirements

HIPAA requires that Part 2 programs comply with the following if defined as a covered entity.

Designate Privacy Officer

- Deliver or oversee ongoing employee privacy training, conduct risk assessments and develop HIPAA-compliant procedures where necessary.
- A HIPAA Privacy Officer will have to monitor compliance with the privacy program, investigate incidents in which a breach of PHI may have occurred, report breaches as necessary, and ensure patients´ rights in accordance with state and federal laws.
- In order to fulfil the duties of a HIPAA Privacy Officer, the appointed person will have to keep up-to-date with relevant state and federal laws.

https://www.hipaajournal.com/duties-of-a-hipaa-compliance-officer/

Administrative Privacy & Security Requirements

Designate Security Officer

- Responsible for the development of security polices, the implementation of procedures, training, risk assessments and monitoring compliance.
- However, the focus of a Security Officer is compliance with the Administrative, Physical and Technical Safeguards of the Security Rule.
- In this respect, the duties of a HIPAA Security Officer can include such diverse topics as the development of a Disaster Recovery Plan, the mechanisms in place to prevent unauthorized access to PHI, and how electronic PHI (ePHI) is transmitted and stored. Due to the similarity in duties, the roles of a HIPAA Privacy Officer and HIPAA Security Officer are performed by the same person in smaller organizations.

https://www.hipaajournal.com/duties-of-a-hipaa-compliance-officer/

Thank you for your participation

Question/Feedback

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