42 CFR Part 2 and HIPAA: Sharing Behavioral Health Information in Compliance with the Law

Substance Abuse and Mental Health Services Administration U.S. Department of Health and Human Services

American Bar Association Health Law Section July 11, 2018





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Overview of Continuing Legal Education Presentation

Section I: Introduction

• Ashley Thomas, JD, Baker Donelson, Washington, DC

Section II: 42 CFR part 2

• Mitchell Berger, MPH, Substance Abuse and Mental Health Services Administration

Section III: HIPAA Privacy Rule

• Peyton Isaac, JD, Program Analyst, HHS Office for Civil Rights

Section IV: Examples from the Field

• Jennifer Lohse, JD, CHC, Hazelden Betty Ford Foundation

Section V: Conclusion / Question and Answer



Section I: Introduction

Ashley Thomas, JD, of Baker Donelson, Washington, DC



Course Objectives

As a result of this course, participants will be able to identify federal privacy rules that HHS governs, including:

- 42 CFR part 2: applicability, exceptions and exclusions (disclosures with patient consent), and consent requirements.
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA): privacy and security rules, state laws and minors, and opioid guidance



Federal Privacy and Confidentiality Laws and Regulations Governed by HHS



42 CFR Part 2 Brief Overview

- 42 CFR part 2 is a regulation that implements statutory provisions (42 USC § 290 dd-2) enacted in 1970s at a time when individuals seeking treatment for substance use disorders faced significant consequences, even legal problems, because they sought help
- Since that time, part 2 has been instrumental in supporting individuals seeking help for substance use disorders by ensuring that substance use disorder diagnosis, treatment and referral information will be safeguarded and shared only for certain reasons specified in statute or with their written consent
- SAMHSA substantially revised the regulations in 2017 and 2018. While patient privacy is a critical concern, equally important is the need for individuals with substance use disorders to get the safest and most effective treatment possible when they experience medical illnesses



HIPAA Brief Overview

- HIPAA, also known as Public Law 104-191, improved the efficiency and effectiveness of the health care system and required national standards for privacy and security of individuals' health information
- The HIPAA Privacy, Security, and Breach Notification Rules, at 45 Code of Federal Regulation Parts 160 and 164, set standards for the use and disclosure of individuals' protected health information (PHI) and for protecting the confidentiality, integrity and availability of PHI
- HIPAA is carefully balanced to protect privacy and avoid unnecessary barriers so that health information is available for treatment and other important purposes, including to protect the health and safety of others in certain exceptional instances



State Behavioral Health Privacy Laws

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- State behavioral health privacy laws may be more restrictive
- 42 CFR part 2 does not preempt more stringent state laws (See § 2.20)
- A compilation of state laws may be found at: <u>https://www.nasmhpd.org/content/tac-assessment-working-paper-</u> <u>2016-compilation-state-behavioral-health-patient-treatment</u>

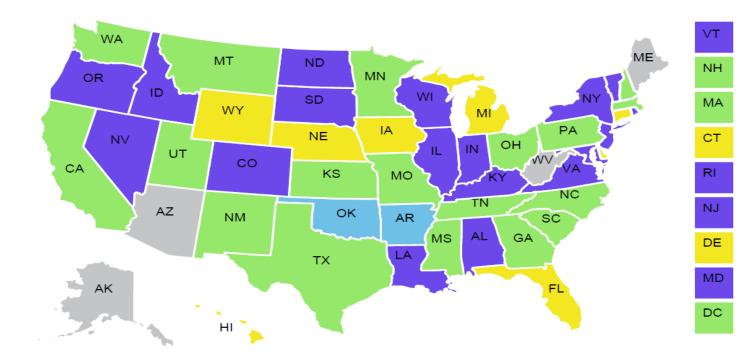


Medical Privacy-HIPAA, Part 2, State Laws

- Part 2 currently aligns with Health Insurance Portability and Accountability Act (HIPAA) as feasible given the governing statute
- Substance use disorder patient records and information may concurrently be subject to HIPAA, part 2, *and* state laws
- Other laws also may apply in select settings (e.g., Family Educational Rights and Privacy Act)



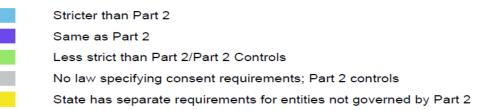
State laws and Substance Use Disorder Records-Disclosure with Patient Consent



Source: Healthinfolaw.org

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State Consent Requirements for Disclosure of Records as Compared with Part 2



SAMHSA Substance Abuse and Mental Health Services Administration

Section II: 42 CFR Part 2

Mitchell Berger, MPH, Substance Abuse and Mental Health Services Administration



What Will be Covered?

- ✓ Background
- ✓ Applicability
- Exceptions and Exclusions (Disclosures without patient consent)
- Consent Requirements (Disclosures with patient consent)
- \checkmark Where things stand now



Confidentiality of SUD Records: Statute and Regulation

- Congress noted in 1970s discrimination associated with substance use disorders (SUDs) and fear of prosecution deterring people from entering treatment
- At that time most SUD treatment was provided by specialty providers
- Authorizing statute for confidentiality of SUD patient records regulations intended to ensure an individual's right to privacy and confidentiality.
 - Persons with SUDs continue to need appropriate protections to prevent misuse of medical information related to substance use



Statute: 42 U.S.C. § 290dd-2

42 U.S.C. § 290dd-2 is the basis for 42 CFR Part 2 regulations, and <u>can only be</u> <u>changed by Congress:</u>

- "Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States" **shall be confidential**
- May be disclosed as permitted by prior written consent of the patient
- Statute does not apply to exchange of records within the Department of Veterans Affairs (VA) or between the VA and the Uniformed Services. VA to issue regulations and coordinate with HHS
- o Reports under state law of suspected child abuse or neglect



Statute: 42 U.S.C. § 290dd-2:Exceptions

Exceptions to disclosures with written consent requirement:

- To medical personnel to the extent necessary to meet a bona fide medical emergency
- To qualified personnel for the purpose of conducting scientific research, management or financial audits, or program evaluation but individual patients cannot be identified by those personnel in any report or otherwise disclosed
- If authorized by a court order showing good cause (e.g., need to avert a substantial risk of death or serious bodily harm)



Penalty & Violations

- Purpose and Effect (§2.2): Because there is a criminal penalty for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute
- Penalty: Statute establishes that violations to be fined under Title 18 of US Code (Crimes and Criminal Procedure) (§2.3)
 - Reports of alleged violations may be made to US Attorney in district where (alleged) violation occurs (§2.4) or to the US Attorney and SAMHSA's Division of Pharmacologic Therapies if the violation was committed by an opioid treatment program (OTP)



A Framework for Understanding Part 2

Applicability: Is information covered/protected by Part 2 (§§2.11-2.23)? Exceptions: If so covered, does information fall under one of the exceptions to consent/exclusions (§2.12, §2.23, §§2.51-2.53)?

Consent: Will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?

Court orders: If no exception/exclusion to Part 2 applies and patient does not consent to disclosure or situation is such that consent cannot be requested, can a court order be obtained (§§2.61-2.67)?

Approach adapted from: Dennis Helms, A Guide to the New Federal Rules Governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 4 Contemp. Drug Probs. 259 (1975)



Definitions

Substance Use Disorder: replaced Alcohol abuse and Drug abuse (Final 2017 Rule) (§2.11)

• A cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal. For this regulation, does not include tobacco or caffeine use



Definitions

- ✓ Diagnosis: "any reference to an individual's substance use disorder or to a condition which is identified as having been caused by that substance use disorder which is made for the purpose of treatment or referral for treatment." (§2.11))
- ✓ A diagnosis prepared for the purpose of treatment or referral for treatment *even if it is not used* for those purposes is covered by the regulations
- ✓ *These regulations do not cover:*
 - (i) A diagnosis which is made solely for the purpose of providing evidence for use by law enforcement agencies or officials; or
 - (ii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved does not have a SUD. (§2.12)



• These regulations impose restrictions upon the disclosure and use of substance use disorder patient records which are maintained in connection with the performance of **any part 2 program** (§2.2)

• Regulations apply to any information, whether or not recorded, which "[w]ould identify a patient as having or having had a **substance use disorder** either directly, by reference to publicly available information, or through verification of such identification by another person" (§§2.11, 2.12)



Applicability is fact-specific so is hard to categorically state whether a given type of program is or is not a Part 2 program but key questions include:

A. Is the program *federally assisted*? Program carried out under license, certification or registration by federal department or agency

Ex. Participating provider in Medicare

Ex. being authorized to conduct maintenance treatment or withdrawal management (42 CFR Part 8);

Ex. registration under Controlled Substances Act to extent controlled substance used in treatment of substance use disorders (e.g., medication-assisted treatment)

✓ What is a Part 2 Program?

Programs also are considered to be federally assisted (§ 2.12(b)) if they:

- Are conducted in whole or in part, whether directly or by contract or otherwise by any department or agency of the US. This includes receiving federal funds and/or through states or local governments, including for purposes other than SUD activities;
- Are supported by funding provided by any department or agency of the US;
- Are assisted by the IRS of the Department of the Treasury, e.g., tax deductions for contributions to programs or tax exempt status



B. Is a unit/entity/individual *other than a general medical facility* a Part 2 Program

1. Do they "hold themselves out" as providing and provide diagnosis/treatment/referral for SUD?

Ex. Licensed/certified/registered to provide and provides these services

Ex. Advertisements, notices or statements about such services

Ex. Consultation activities about such services



For services provided by staff in general medical facilities:

2. Are services provided by an identified unit within the general medical facility that *holds itself out* as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment?

3. For medical personnel or other staff in a general medical facility or practice, is their *primary function* to provide SUD diagnosis/treatment/referral and *are they identified* as providers of such services by the facility/practice?



LAWFUL HOLDER

"[A]n individual or entity who has received such information as the result of a part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as permitted under the part 2 statute, regulations, or guidance" and therefore is bound by part 2. (2017 Final Rule, p. 6997)

• Examples: May include patient's treating provider, a hospital emergency room, an insurance company, an individual or entity performing an audit or evaluation, or an individual or entity conducting scientific research



• These regulations do not prohibit a part 2 program from giving a patient access to his/her SUD records (§2.23)

• The patient is not considered a lawful holder or a part 2 program and therefore the regulations do not prohibit self-disclosures



If information is covered by part 2, does it fall under one of the exceptions or exclusions(§2.12, §§2.51-2.53)?

(i.e., Disclosures without patient consent)



What does it mean to <u>disclose</u> Part 2 info?

- Disclose (§2.11): Many ways to 'disclose' such as providing testimony, sharing written records, sharing patient identifying information in a way that the patient to be re-identified, verbal discussions with staff or others outside the SUD treatment program, submitting claims information to a payer (e.g., Medicare)
- Applies whether or not information has been recorded (§2.12(a))
- Even when disclosures are permitted, what is shared should be limited to that information which is necessary to carry out the purpose of the disclosure (§2.13)
- Consider data segmentation to ensure that records that originate from part 2 programs are appropriately protected



- Even when exceptions to Part 2 exist or a patient consents to disclosure, absent a court order/legal mandate disclosures by program are not compulsory (§ 2.2)
- When disclosure is permitted, that permission acts to remove the prohibition on disclosure but it does not compel disclosure



Some exceptions to written consent requirements, <u>each of which has</u> <u>caveats, qualifications and limitations</u>, include:

- Bona-fide medical emergencies (§2.51)
- Research (§2.52)
- Audit and Evaluation (§2.53)
- Disclosures to central registry or maintenance or withdrawal treatment to prevent multiple enrollments in programs within 200-mile radius (§2.34)

Some additional exceptions to written consent requirements, *each of which has caveats, qualifications and limitations, include:*

- Communication within a part 2 program or between a part 2 program and an entity having direct administrative control over that part 2 program (§2.12)
- Qualified Service Organization Agreements (QSOAs) (§§2.11; 2.12)
- Reports of suspected child abuse and neglect (§2.12)-note: for elder abuse, domestic violence can make anonymous report
- Reporting of crime on program premises or against program personnel or threat of such activity (§ 2.12)
- Disclosures to elements of the criminal justice system which have referred patients (§2.35)***



- The Final 2017 Rule revised the <u>medical emergency</u> exception to make it consistent with the statutory language and to give providers more discretion to determine when a "bona fide medical emergency" exists. See §2.51
- Information can be shared by Part 2 program in these circumstances when consent *cannot* be obtained.
- Treating provider makes determination of what constitutes a bona fide medical emergency
- Following the disclosure, part 2 program must document date/time, medical personnel information shared with, nature of emergency



QSOAs (§2.11; § 2.12(c)(4))

- A QSOA is a "two-way agreement between a part 2 program and the entity providing the part 2 program and an individual or entity providing a service to a part 2 program"
- QSOs provide services to a part 2 program under a written agreement (QSOA). Such services include 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
 - "A QSOA cannot be used to avoid obtaining patient consent in the treatment context."



Research (§2.52)

- The Final 2017 Rule allows a part 2 program or other lawful holder of patient identifying information to disclose part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule)
- Data in reports must be aggregated/de-identified
- Researchers must agree to resist in judicial proceedings any efforts to obtain access to patient records except as permitted by the regulations in this part



A Framework for Understanding Part 2-Exceptions and Exclusions

Audit and Evaluation (§2.53)

- Audit and evaluation not defined but can include financial and quality purposes (see statute)
- Part 2 program may determine who is qualified to conduct an audit or evaluation
- Patient-identifying information may not be used to prosecute/investigate patients
- Covers both paper and electronic patient records
- Discusses requirements if records forwarded/removed versus viewed on premises
- Final 2017 Rule-Specifies inclusion of audit or evaluation necessary to meet the requirements (under certain conditions) of Centers for Medicare & Medicaid (CMS)-regulated accountable care organizations or similar CMS-regulated organizations (e.g., Qualified Entities)
- Final 2018 Rule- Revised to address further disclosures to contractors/subcontractors/legal representatives to carry out audits and evaluations



Consent requirements: Will the patient consent in writing to disclosure (§§2.13, 2.31-2.35)?

Disclosures with patient consent



- ✓ Consent must be in writing (paper or electronic) and requires 9 elements (§§ 2.13; 2.31-2.35):
- 1. Name of patient;
- 2. Name or general designation of the part 2 program, entity, or individual permitted to make the disclosure ("from whom");
- 3. A description of the amount and kind of information, including an explicit description of the substance use disorder information, to be disclosed;
- 4. Name(s) of individual(s) or entity(ies) to whom the disclosure is to be made;
- 5. Purpose of the disclosure;



Amount and Kind of Information to Disclose

 It is permissible to include on consent form 'all my substance use disorder information' as long as more granular options are also included

Examples of Part 2 Categories

Diagnostic Information

Medications and Dosages

Lab Tests

Allergies

Substance Use History

Trauma History Summary

Clinical Notes

Discharge Summary

Employment Information

Living Situation and Social Supports

Claims/encounter Data



Treating Provider Relationship

- 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, or consultation with the patient, for any condition

It exists whether or not there is an actual in-person encounter.



- Allows a patient to include a general designation in the 'to whom' section of the consent form
- Ex. Current treating providers, past treating providers, all my current and future treating providers
- List of disclosures



Individual or Entity To Whom	Treating Relationship	Primary designation	Required Additional Designation
Individual	Yes	Name of individual(s) (e.g., Jane Doe, MD)	None
Individual	No	Name of individual(s) (e.g., John Doe)	None
Entity	Yes	Name of entity (e.g. Lakeview County Hospital)	None
Entity	No	Name of entity that is a third-party payer as specified under § 2.31(a)(4)(iii)(A) (e.g., Medicare)	None
Entity	No	Name of entity that is not covered by § 2.31(a)(4)(iii)(A) (e.g., HIE, or research institution)	 At least one of the following: <u>The name(s) of an individual participant(s)</u> (e.g., Jane Doe, MD, or John Doe) <u>The name(s) of an entity participant(s) with a treating provider relationship with the patient whose information is being disclosed (e.g., Lakeview County Hospital)</u> A general designation of an individual or entity participant(s) or a class of participants limited to those participants who have a treating provider relationship with the patient whose information is being disclosed Notes: Patient may choose all providers with a relationship; patient may designate further to include "past", "current," or "future" treating providers; patient may specific one or more individuals on health care team whom they do not have a treating provider relationship.



Consent forms must also contain:

- 6. Revocation notice indicating that consent can be revoked at any time (except to the extent a Part 2 program or lawful holder already has relied on it);
- 7. Date, event, or condition upon which consent will expire;
- 8. Signature of patient or person authorized to give consent; and
- 9. Date when signed.



A Framework for Understanding Part 2: Re-Disclosure

Prohibition on Redisclosure (§2.32)

- Notice is required to accompany the disclosure of patient identifying information with consent
- Notice that information should not be further re-disclosed without written consent
- Such information should not be used for criminal investigation or prosecution
- General authorization for the release of medical or other information is *NOT* sufficient to permit re-disclosure of part 2 information
- 2018 final rule permits an abbreviated Notice of Prohibition on Redisclosure



A Framework for Understanding Part 2

- An individual or entity not covered by part 2 (such as many primary care providers) who receives patient identifying information from a part 2 program or other lawful holder via a part 2-compliant consent (along with a prohibition on re-disclosure notice) must comply with part 2 requirements (e.g., re-disclosure/§2.32)
 - Compliance could involve maintaining the part 2 patient identifying information separately from other information in the patient's medical record to prevent unauthorized disclosures
- SUD diagnosis or treatment information disclosed by a patient while providing health history to a provider that is not a part 2 program is not covered by part 2 and may be recorded in the same manner as other medical history information
 This information, however, may be subject to HIPAA and state law requirements



2018- Disclosures for Payment and Healthcare Operations (§2.33) Revised to permit:

- 1. Additional disclosures of patient identifying information, with patient consent, to facilitate payment and healthcare operations such as claims management, quality assessment, and patient safety activities
- 2. Lawful holders to disclose or re-disclose patient identifying information to their contractors, subcontractors and legal representatives for purposes of carrying out the lawful holder's payment and health care operations activities, when patient consents to disclosure for those activities
- If such disclosures made, contract/comparable legal instrument should be updated to reflect part 2 requirements



Concluding Thoughts

Where things stand as of July 2018?



Part 2 Listening Session, Jan. 31, 2018

- 86 in-person participants at SAMHSA building in Rockville, MD, and roughly 1200 online (phone/Web conference). Comments accepted in-person, via phone and in writing to PrivacyRegulations@samhsa.hhs.gov through Feb. 28, 2018.
- Comments emphasized aligning Part 2 and HIPAA, further steps to foster care coordination and integrated care, need to respect stigma of SUD and impact on patients of privacy and confidentiality violations, need for more subregulatory guidance/technical assistance, electronic health records and consent implementation challenges.
- Sample comment: "Anything that you can do to better align Part 2 specifically with HIPAA is very much appreciated, and we urge administration to implement regulations that can bring us to that and really allow us to integrate care in the way that we would love to for the benefit of our patients."-American Psychiatric Association
- Sample comment: "We specifically want to acknowledge the clarifications [...] regarding the ability for lawful holders to disclose part 2 information with Medicaid agencies and other contracted managed care entities in the performance of Healthcare operations. We also wish to applaud the clarifications permitting part 2 data disclosures for Medicaid and shift audits and evaluations.... National Association of Medicaid Directors

Balancing Privacy & Integrated Patient Care

- In 2018, patient privacy remains a critical concern. However, equally important is the need for:
 - Providers to be able to share information to improve SUD patient treatment
 - SUD patients to benefit from integrated care
 - Patients, providers, and the overall health system to benefit from use of new technologies and approaches (e.g., Health Information Exchanges, Electronic Health Records, and Multi-payer Claims Databases)
 - Further consideration of the benefits of aligning Part 2 with HIPAA. See Final 2018 Rule: "SAMHSA plans to explore additional alignment with HIPAA and is considering additional rulemaking"



Section III: HIPAA

Peyton Isaac, JD, Program Analyst, HHS Office for Civil Rights



The Health Insurance Portability and Accountability Act of 1996 (HIPAA)



The HIPAA Privacy Rule establishes a floor (minimum) of safeguards to protect privacy of PHI.

Covered entities may only use or disclose PHI as permitted or required by the Privacy Rule.

Covered entities must put in place administrative, technical, and physical safeguards to protect against intentional or unintentional use or disclosure of PHI that violates the Rule and reasonably safeguard PHI to limit incidental uses or disclosures.

The HIPAA Security Rule applies to electronic PHI (ePHI).



HIPAA Mental Health and Opioid Use Guidance

On February 20, 2014, HHS Office for Civil Rights published guidance designed to address a number of frequently asked questions surrounding the appropriateness of health care providers sharing the protected health information of patients who are being treated for mental health conditions. OCR updated the guidance in 2017, and released additional guidance to help address opioid overdose situations.

This guidance provides clarification on communications with family members and caregivers of adults and minors, in light of the patient's capacity to agree or object to the sharing of their information as well as in certain exigent circumstances.

https://www.hhs.gov/hipaa/for-professionals/special-topics/mentalhealth/index.html



Individually Identifiable Health Information (IIHI)

As defined in HIPAA & the Privacy Rule, IIHI is:

Health information (including demographic information collected from an individual) if it is created or received by a health care provider, health plan, employer, or health care clearinghouse and relates to the:

- Past, present, or future physical or mental health or condition of an individual
- Provision of health care to an individual
- Past, present, or future payment for the provision of health care to an individual



Protected Health Information (PHI)

Protected health information generally includes individually identifiable health information that is:

- (i) Transmitted by electronic media;
- (ii) Maintained in any medium described in the definition of electronic media at 45 CFR § 160.103 of this subchapter; or(iii) Transmitted or maintained in any other form or medium.



Protected Health Information

Protected Health Information (PHI)

Protected health information excludes individually identifiable health information:

- In education records covered by the Family Educational Rights and Privacy Act (FERPA)
- In employment records held by covered entities in their role as employer;
- About a person who has been deceased for more than 50 years.



HIPAA: Compassionate Communications

With whom can treatment professionals share health care information?

Individuals Who are Present and Have Decision Making Capacity

HIPAA permits treatment professionals to share relevant health information with individuals involved in the patient's care, such as a patient's family, friends, personal representative, and health care power of attorney.

Unless the other person is a personal representative, professionals generally must give patient opportunity to agree or object:

- Ask patient's permission
- Inform patient of intent to inform family or friends and give opportunity to object
- Infer from circumstances, using professional judgment, that patient does not object



HIPAA: Compassionate Communications

With whom can treatment professionals share health care information?

Individuals Not Present or Without Decision Making Capacity

HIPAA permits treatment professionals to share health information with someone involved in the patient's care, such as a patient's family, friends, personal representative, and health care power of attorney. Unless the person is the patient's personal representative, conditions must be met:

- The patient is not available due to an emergency or the health care provider determines that the patient is incapacitated
- Health care provider determines, based on professional judgment, that sharing information is in best interests of the patient
- May disclose only the PHI directly relevant to person's involvement in patient's care/payment for care



HIPAA: Compassionate Communications

What information may a health care professional share?

Professionals who provide treatment to patients with a mental health condition or opioid addiction may share protected information, including mental health information and information about the substance use disorder with family, friends and others involved in the patient's care:

- HIPAA doesn't require written permission or authorization by patient or personal representative (can be verbal or implied, based on circumstances)
- Share only information that is directly related to the person's involvement with the patient's health care or payment for care

Note: Providers subject to both Part 2 and HIPAA are responsible for complying with the more stringent Part 2 rules, as well as with HIPAA.



Health & Mental Conditions, Including Substance Intoxication or Overdose, May Constitute Incapacity:

- Decision-making incapacity may be temporary and situational, and does not have to rise to the level where another decision maker has been or will be appointed by law.
- For example, a patient who arrives at an emergency room severely intoxicated or unconscious will be unable to meaningfully agree or object to information-sharing upon admission, but may have sufficient capacity several hours later.
- Once patient regains capacity, provider should offer patient opportunity to agree or object to any future sharing of information.



Communicating with Patient's Friends and Family

Patient's State	Family Member or Friend
Patient is present and has the capacity to make health care decisions	 Provider may disclose relevant information if the provider does one of the following: (1) Obtains the patient's agreement (2) Give the patient an opportunity to object and the patient does not object (3) Decided from the circumstances, based on professional judgment, that the patient does not object Disclosure may be made in person, over the phone or in writing.
Patient is not present or is incapacitated	Provider may disclosure relevant information if, based on professional judgment, the disclosure is in the patient's best interest. Disclosure may be made in person, over the phone, or in writing.



Serious and Imminent Threat

If a health provider believes that a patient might hurt himself or someone else, may the provider notify the family or law enforcement?

- A covered health care provider may share information and notify a patient's family members, law enforcement or others who are in a position to lessen a serious and imminent threat to the health and safety of the patient or others when the disclosure of information is necessary to prevent or lessen the serious and imminent threat.
- Disclosures must be consistent with applicable law and standards of ethical conduct.
- Opioid overdose may constitute imminent threat to self.



What constitutes a "serious and imminent" threat?

HIPAA expressly defers to the professional judgment of health care providers when they make determinations about the nature and severity of the threat to health or safety. Specifically, HIPAA presumes the health care provider is acting in good faith in making this determination, if the provider relies on his or her actual knowledge or on credible information from another person who has knowledge or authority.

OCR would not second guess a health provider's good faith belief that a patient poses a serious and imminent threat to the health or safety of the patient or others and that the situation requires the disclosure of patient information to prevent or lessen the threat.



HIPAA and State Laws and Minors



Parents and Minors

- Generally, parents are the personal representatives of their minor children for HIPAA purposes, and providers may share patient information with a patient's personal representative.
- However, there are certain exceptions, e.g., where a minor may obtain certain health care services without parental consent under State or other law.
- HIPAA defers to state law to determine age of majority.
- See OCR Guidance on Personal Representatives, <u>http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/p</u> <u>ersonalreps.html</u>



Exceptions: Parents and Minors

A parent is not treated as a minor child's personal representative when:

- 1) State or other law does not require the consent of the parent or other person before a minor can obtain a particular health care service, the minor consents to the service, and the minor has not requested that the parent be treated as a personal representative
- 2) Someone other than the parent is authorized by law to consent to the provision of a particular health service to the minor and provides such consent, or
- 3) A parent agrees to a confidential relationship between the minor and the health care provider with respect to the health care service.



HIPAA and The Opioid Crisis



If a person presents at a hospital distressed from opioid and/or a mental health crisis, can the health care provider contact a family member or caregiver?

Example: If the patient has capacity to agree or object, the health care provider must ask the patient if he/she wants to share the information with the family member/caregiver.



HIPAA: Opioid Emergency Guidance

If a person presents at a hospital distressed from opioid and/or a mental health crisis, can the health care provider contact a family member or caregiver?

Example: A provider may use professional judgment to talk to the parents of <u>someone incapacitated</u> by an opioid overdose about the overdose and related medical information, but generally could not share medical information unrelated to the overdose without permission.

Example: A doctor whose patient has overdosed on opioids is presumed to have complied with HIPAA if the doctor informs family, friends, or caregivers of the opioid abuse after determining, based on the facts and circumstances, that the patient poses <u>a serious and imminent threat</u> to his or her health through continued opioid abuse upon discharge.



Section IV: Examples from the Field

SAMHSA Substance Abuse and Mental Health Services Administration

Jennifer Lohse, JD, CHC, Hazelden Betty Ford Foundation

Caveats and Assumptions

Caveats:

- Not intended to constitute (and should not be considered) legal advice
- People and places in scenarios are not real and are illustrative only
- Only federal privacy statutes are being analyzed in the foregoing scenarios. State laws may be more stringent than the federal laws discussed and legal counsel should be consulted.

Scenario Assumptions: all health care facility and providers in the scenario are:

- "covered entities" as defined under HIPAA
- "federally assisted" as defined under 42 CFR Part 2s



- Patient is being treated in Hospital ER due to a drug overdose and suicidal ideation
 - Receives medical services by ER medical staff
 - Receives screening, brief intervention evaluation for possible referral to drug treatment by Hospital social worker while being stabilized in the ER
 - Receives a psych consult by Hospital Psychiatrist while in ER
- Family Member calls to inquire if Patient is at Hospital.

What can Hospital say?



- The Privacy Rule generally permits an ER to maintain directory information and release information related general condition of Patient
 - Name, location within facility, general health condition (expressed in a way that does not communicate specific medical information)
 - Examples of health condition: "stable", "critical," "unconscious", "treated and released"
- Patient must be informed of being included in directory Patient can opt out of being included in directory
 - Preferences binding whether given orally or in writing
 - In emergencies or lack of capacity, provider must decide based upon patient's best interests
 - Must inform patient as soon as practicable after capacity restored
 - Patient must be given opportunity to express preference



- Does 42 CFR Part apply?
 - Does the Hospital ER holds itself out as provide <u>and</u> provide substance use disorder diagnosis, treatment or referral for treatment?
 - ER is likely not holding itself out as providing substance use disorder diagnosis, treatment, or referral for treatment therefore 42 CFR Part 2 would not apply to the ER
 - What if ER provides screening, brief intervention, and referral for treatment (SBIRT) services?
 - SBIRT services alone not enough (fact-based analysis); and still not "holds itself out".

CONCLUSION: Unless Patient has opted out of directory services, ER staff may provide directory information and general condition of Patient to Family Member



- At some point, Patient becomes unconscious. ER staff need to make decisions related to care of the Patient.
- Family Member is present in the Hospital with Patient.

How may Family Member and Hospital communicate to make decisions?



• <u>Assumption</u>: 42 CFR Part 2 does not apply.

• What does HIPAA allow?

- Permits ER staff to communicate with persons that are involved with the Patient's health care or payment for care with necessary and relevant information.
- ER staff must first determine whether Patient agrees to share information with Family Member (or Patient's personal representative)
 - If unable to make decision (e.g. unconscious, severely intoxicated), ER staff will need to make a professional determination to contact Family Member without Patient's permission <u>in</u> <u>Patient's best interest</u>.
 - As soon as Patient has capacity, then Patient's wishes must be honored.
- ER staff can imply consent if Patient does not object to ER staff discussing condition and treatment plan while Family Member is present.



• ER Staff want to access Patient's prior records, including prior mental health and substance use disorder records from Hospital's Behavioral Health Clinic ("BHC").

Does staff need Patient consent to access these records?



- The Privacy Rule permits covered entities to use and disclose protected health information for treatment, payment and health care operations ("TPO") without an individual's authorization.
- No consent/authorization from Patient needed.

BUT ...

- What does 42 CFR Part 2 allow?
 - <u>Assumption</u>: BHC holds itself out as providing <u>and</u> provides substance use disorder diagnosis, treatment, or referral for treatment.
 - No TPO exception
 - Possible to use bone fide medical emergency exception prior informed consent cannot be obtained & necessary for the medical emergency
 - If able to use, no re-disclosure prohibition attaches to information / records.
 - If cannot use emergency exception, patient written consent for ER staff
 - Re-disclosure prohibition attaches to all release of information through consent



CONCLUSION: Likely yes, but it a fact-specific analysis on whether or not the medical emergency exception can be utilized.

ALSO NOTE:

- 42 CFR applies to any records maintained by BHC that identifies Patient as receiving a diagnosis, treatment, referral for treatment for a substance use disorder.
- Mental health records otherwise excluded from Part 2 regulations may become Part 2 records if contain information about Patient substance use disorder



- Patient is released from ER and receives referrals to Hospital outpatient services:
 - Behavioral health clinic ("BHC") for Patient's substance use and mental health conditions
 - Doctor Davis (primary care clinic) for Patient's chronic pain
- Patient begins to receive services from Dr. Davis and the BHC. As part of treatment planning, both Dr. Davis and BHC want access to Patient records.

What consents from Patient (if any) are required to coordinate care?



- No consent/authorization from Patient needed for TPO.
- For the purposes of treatment, both BHC and Dr. Davis could consult and share information.

BUT ...

What does 42 CFR Part 2 allow?

• No TPO exception; patient written consent required.

CONCLUSION: BHC may access Patient's records from Dr. Davis without prior authorization, but BHC must receive valid Part 2 compliant consent from Patient to disclose information or records to Dr. Davis

- Re-disclosure prohibition attaches to all release of information through consent
- Any reference to SUD services at BHC in Dr. Davis' notes will attach Part 2



New Information

• Dr. Davis holds a Data 2000 waiver and regularly prescribes buprenorphine to patients as part of his practice.

Does that make Dr. Davis a Part 2 program and change the requirement to get consent to coordinate care with BHC?



CONCLUSION: It depends; more information is needed.

- Does Dr. Davis hold himself out as providing <u>and</u> provides substance use disorder diagnosis, treatment, or referral for treatment?
 - If yes, then he is likely a Part 2 program and further analysis need to be done to see if he would qualify to be part of the same Part 2 program as BHC.
 - If no, then he is likely not a Part 2 program. Prescribing buprenorphine alone is likely not enough to be a Part 2 program.



- During a one-to-one session with Therapist at BHC, Patient reveals that he has an intention to physically harm his ex-girlfriend, including how he intends to harm her.
- Therapist is treating Patient for both mental health and substance use disorders.
- <u>Assumption</u>: Therapist is a mandated reporter under state law. Duty of warn has been appropriately triggered by this admission and state law has an exception to privacy laws.

What are the privacy considerations for Therapist?



- Exception exists for disclosures required by other law, such as for mandatory reporting of abuse.
- Mandatory "duty to warn" situations regarding threats of serious and imminent harm made by the Patient would qualify for disclosures required by the law.
- Minimum necessary should be disclosed in order to meet disclosure obligations.

• What does 42 CFR Part 2 allow?

- No state law preemption.
- No duty to warn exception under Part 2.
- Only mandated reporting exception is child abuse or neglect (as defined by the state in which the Part 2 program is located).

CONCLUSION: Under HIPAA, a disclosure can be made under state laws for mandated reporting. However, BHC and Therapist are a Part 2 program, and therefore cannot reveal Patient's substance use disorder treatment without prior consent. Consider if report can reasonably and practically be made without revealing Patient's substance use disorder.



- Hospital America receives a subpoena for "any and all records" within its possession for Patient.
- Subpoena is validly served according to state subpoena statute.
- <u>Assumption</u>: subpoena request is broad enough to cover all billing, medical, laboratory, pharmacy, mental health, and substance use disorder records

How should Hospital America respond?



Records Request: the Analysis

- Is the subpoena compliant with both HIPAA and Part 2?
 - HIPAA
 - Common subpoena mistakes: Has the Patient been given a reasonable opportunity to object? Has the requesting party submitted evidence of giving Patient such opportunity?
 - 42 CFR Part 2
 - Common subpoena mistakes: Is the subpoena accompanied by a 42 CFR Part 2 compliant court order? Both are needed to release Part 2 records.
 - NOTE: there are separate procedures and criteria for court orders in civil and criminal actions.

• Which law applies to which records?

- HIPAA applies to all records of Hospital
 - Consider if subpoena is broad enough to attach to psychotherapy notes, which are generally excluded from the medical record.
- 42 CFR Part 2:
 - All records that would identify Patient as receiving a diagnosis, treatment, referral for treatment for a substance use disorder.
 - All records that reference information obtained by Patient consent and are protected by the re-disclosure prohibition.
 - Consider reach of Part 2 to other records, such billing records with SUD diagnosis and billing codes.



 While receiving services at the BHC, Patient verbally revokes all consents obtained by BHC for the purposes of communicating with 3rd parties, including Patient's insurer, Family Member and Dr. Davis.

What are the potential ramifications for such revocations?



- Revocations of authorization must be in writing and is not effective until Hospital receives it.
- TPO purposes do not require authorization or consent.
- Patient has the right to request restrictions on how Hospital will use and disclose for TPO. Hospital does not have to agree to Patient's request for a restriction, but is bound by any restrictions to which it agrees.

• What does 42 CFR Part 2 allow?

- Consents may be revoked verbally or in writing, and are effective when the BHC receives it.
- TPO require valid consent.
 - BHC will not be able to bill Patient's insurance for services for services without a valid consent. Prior billings while consent was active may be processed, but utilization review or peer review may be affected.
 - BHC will not be able to communicate with Dr. Davis for care coordination.
- Part 2 program may not communicate with any 3rd party without valid consent.
 - BHC will not be able to communicate with Family Member.
 - Cannot "confirm or deny" that Patient is a current or former patient, or if Patient was ever a patient at all.



Section V: Conclusion/ Q&A

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Materials available through SAMHSA and OCR

The materials used to prepare this presentation are available through SAMHSA and OCR:

- <u>SAMHSA part 2 Information Web site: https://www.samhsa.gov/health-information-technology/laws-regulations-guidelines</u>
- <u>42 CFR part 2 Confidentiality of Substance Use Disorder Patient Records FAQs</u>
- <u>Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?</u>
- <u>Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?</u>
- <u>HHS Health Information Privacy Web site: https://www.hhs.gov/hipaa/index.html</u>
- <u>HIPAA FAQs for Professionals</u>
- <u>HIPAA FAQs for Professionals Related to Mental Health</u>
- <u>HIPAA Privacy Rules and Sharing Information Related to Mental Health</u>
- Information Related to Mental and Behavioral Health, including Opioid Overdose
- How HIPAA Allows Doctors to Respond to the Opioid Crisis



Question and Answer



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