

# HIPAA and 42 CFR part 2

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(8/18)

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# Written Materials

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- 42 CFR part 2
- SAMHSA Fact Sheet: *Does Part 2 Apply to Me?*
- SAMHSA Fact Sheet: *How Do I Exchange Part 2 Data?*
- SAMHSA FAQs: *Applying the Substance Abuse Confidentiality Regulations*

# Additional Info

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- If you have questions, please use the chat feature or e-mail me at [kcstanger@hollandhart.com](mailto:kcstanger@hollandhart.com).
- This presentation will be recorded and available for download at <https://www.hhhealthlawblog.com/webinar-recordings-and-presentations>.

# HIPAA and 42 CFR part 2



# The Laws

**Health Insurance Portability and Accountability Act (“HIPAA”), 42 CFR part 164**

- **Privacy Rule**
  - Privacy of protected health information (“PHI”)
  - Patient rights re PHI
  - Administrative requirements
- **Security Rule**
  - Protection of ePHI
- **Breach Notification Rule**

**Confidentiality of Substance Use Disorder Patient Records, 42 CFR part 2 (“Part 2”)**

*(rev’d 1/18/17 and 1/3/18)*

- **General rules**
- **Disclosures with patient consent**
- **Disclosures without patient consent**
- **Court orders authorizing disclosures**

# Confidentiality

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- Both laws address the confidentiality and security of health information.
- For purposes of our discussion, “consent” =
  - consent to disclose info.
  - not consent for treatment (although the two may be related).

# Comply with Most Restrictive Law



Privacy Protection

**42 CFR part 2**

**HIPAA**

**Other state  
or federal  
law**

- Most healthcare providers engaged in substance use treatment must comply with both laws.
- Where the laws conflict with each other or state law, comply with the most restrictive state law, i.e.,
  - The law that gives greater protection to patient info, or
  - The law that gives greater control of their info to the patient.



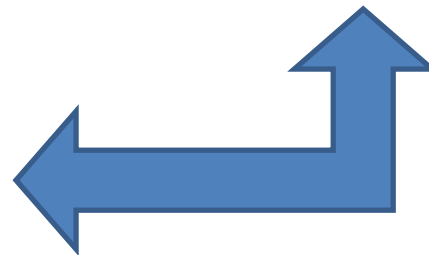
# Enforcement and Penalties

## HIPAA

- Office for Civil Rights (“OCR”)
- Civil penalties
  - \$112 to \$55,910 per violation
  - Mandatory penalties of \$11,182 to \$55,910 if act with willful neglect
  - Patients get %
- Criminal penalties
  - \$50,000 to \$250,000
  - Up to 10 years in prison

## 42 CFR part 2

- Dept. of Justice (“DOJ”)
- Criminal fines
  - \$500 for first offense
  - \$5000 for subsequent offenses



**These statutes might be used as basis for private lawsuit.**

# Covered Entities

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## HIPAA

- Healthcare providers that engage in certain electronic transactions.
- Health plans, including group health plans if:
  - 50 or more participants, or
  - Administered by third party.
- Business associates of covered entity.

## 42 CFR part 2

- Federally assisted program that holds itself out as providing and provides alcohol or drug abuse diagnosis, treatment or referral.
- Third party payers who receive info from Part 2 programs.
- Entities having direct administrative control.
- “Lawful holders”, i.e., persons who receive info + notice from Part 2 programs.

# Covered Entities

## 42 CFR part 2

- “Program” =
  - Individual or entity who holds itself out as providing substance use disorder diagnosis, treatment or referral.
  - Identified unit in a general medical facility that holds itself out as providing substance use disorder diagnosis, treatment or referral.
  - Medical personnel in a general medical facility whose primary function is providing substance use disorder diagnosis, treatment or referral and who are identified as such providers.
- “Hold self out” = activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder, diagnosis, treatment, or referral for treatment, e.g., through advertising or marketing.
- Not ER physician who refers person to ICU for overdose unless hold the physician or ER out as providing substance use disorder diagnosis, treatment, or referral.

# Covered Entities

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## 42 CFR part 2

- “Federally assisted” =
  - Carried out under license or authorization granted by U.S. department or agency (e.g., Medicare, DEA registration, etc.);
  - Supported by funds provided by a U.S. department or agency (Medicare, Medicaid, grants, etc.);
  - Program is tax-exempt or claims tax deductions relating to program; or
  - Conducted directly or by contract or otherwise by any dept or agency of the United States (but see rules re VA or armed forces).

# Covered Information

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## HIPAA

### Protected health info (“PHI”)

- Individually identifiable health info,
- Concerns physical or mental health, health care, or payment,
- Created or received by covered entity in its capacity as a healthcare provider,
- Maintained in any form or medium, e.g., oral, paper, electronic, images, etc.

## 42 CFR Part 2

### Patient identifying info re substance use disorder

- Info identifying patient as having, diagnosed with, or referred for treatment of a substance use disorder, either directly or indirectly.
- Identifying info includes name, address, SSN, fingerprints, photos, or similar info by which identity of patient can be determined.

# Prohibited Disclosures

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## HIPAA

- May not access, use or disclose PHI without the patient's authorization or consent unless a HIPAA exception applies.

## 42 CFR part 2

- May not disclose info that identifies person as having, having had, or referred for a substance use disorder without the patient's consent unless a Part 2 exception applies.
- May not acknowledge that a person is a patient in a substance use program, including in response to record requests.

# Permitted Disclosure Without Patient Authorization

## HIPAA

- Treatment
- Payment
- Some healthcare operations
- Some info to family, friends involved in care or payment
- Some info for facility directory
- Required by law
- Substantial risk of harm
- Public health
- Health oversight
- Court proceedings
- Some law enforcement purposes
- Others

## 42 CFR Part 2

- Communications within Part 2 program for those who have need to know.
- Medical emergency where patient cannot consent; document disclosure.
- Report crime or threats on Part 2 premises or against Part 2 personnel to law enforcement; limit info.
- Report child abuse or neglect per state.
- Research; subject to conditions.
- Audit of Part 2 program by govt, payer, or other lawful holder; subject to conditions.

# Use to Initiate Criminal Proceedings

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## 42 CFR part 2

- **No one can use any program info to:**
  - Initiate or substantiate criminal charges against a patient, or
  - Conduct a criminal investigation of patient.unless have qualifying court order.
- **Cannot place undercover agents or informants in program.**
  - Cannot use info obtained from undercover agent or informant to investigate or prosecute criminal actions against the patient.



# Consent for Disclosure

## HIPAA

- **Third party request:** formal written authorization.
  - Required elements.
  - Required statements, e.g.,
    - Re-disclosure not protected.
  - May be revoked.
  - Expiration date or event.
  - Signed by patient or personal representative.
- **Patient request:** informal writing
  - Name of recipient.
  - Address of recipient.
  - Signed by patient.

## 42 CFR part 2

- Patient's name.
- Specific names or general designation of persons authorized to disclose.
  - If general designation, advise of right to get list of disclosures.
- How much and what kind of info may be disclosed.
- Names of recipients of disclosure; rules differ depending on whether recipient is individual or entity.
- Purpose of disclosure.
- May be revoked unless relied on.
- Expiration date, event or condition.
- Signed by patient or surrogate.
- Date of signature.

# Notice of Re-Disclosure

## 42 CFR part 2

- If disclose with written consent, include one of these notices:
  - “This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies 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 unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65”; or
  - “42 CFR part 2 prohibits unauthorized disclosure of these records.”

# Minimum Necessary

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## HIPAA

- Must limit any permitted use or disclosure of PHI to the minimum necessary.
- Exceptions:
  - Disclosure to another provider for treatment purposes.
  - Disclosure to patient.

## 42 CFR part 2

- Must limit disclosure to the info necessary for permitted purpose of disclosure.

# Business Associates, Contractors, Etc.

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## HIPAA

- May disclose to business associates (“BAs”).
  - Create, receive, maintain, transmit PHI on behalf of covered entity.
  - Not other providers.
  - Not members of workforce
- Must have business associate agreement (“BAA”) between covered entity, business associate, and subcontractor.

## 42 CFR part 2

- May disclose to qualified service organizations (“QSOs”)
  - Provides services to Part 2 program, e.g., data processing, collections, dosage prep, lab analyses, legal, accounting, or other professional services.
- Must have written agreements between program and QSO (“QSOA”)

# Agreements with Associates

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## HIPAA

### BA Agreement

- Requires business associate to:
  - Not disclose info in a manner that would violate HIPAA if the covered entity did it.
  - Comply with security rule.
  - Assist the covered entity in complying with certain patient rights.

## 42 CFR part 2

### QSO Agreement

- Acknowledge that it is bound by Part 2 in receiving, storing, processing or dealing with patient records from Part 2.
- If necessary, resist in judicial proceedings any efforts to obtain access to patient identifying info related to substance use disorder unless exception applies.
- Cannot re-disclose except as necessary to its duties.

# Lawful Holders and Agreements

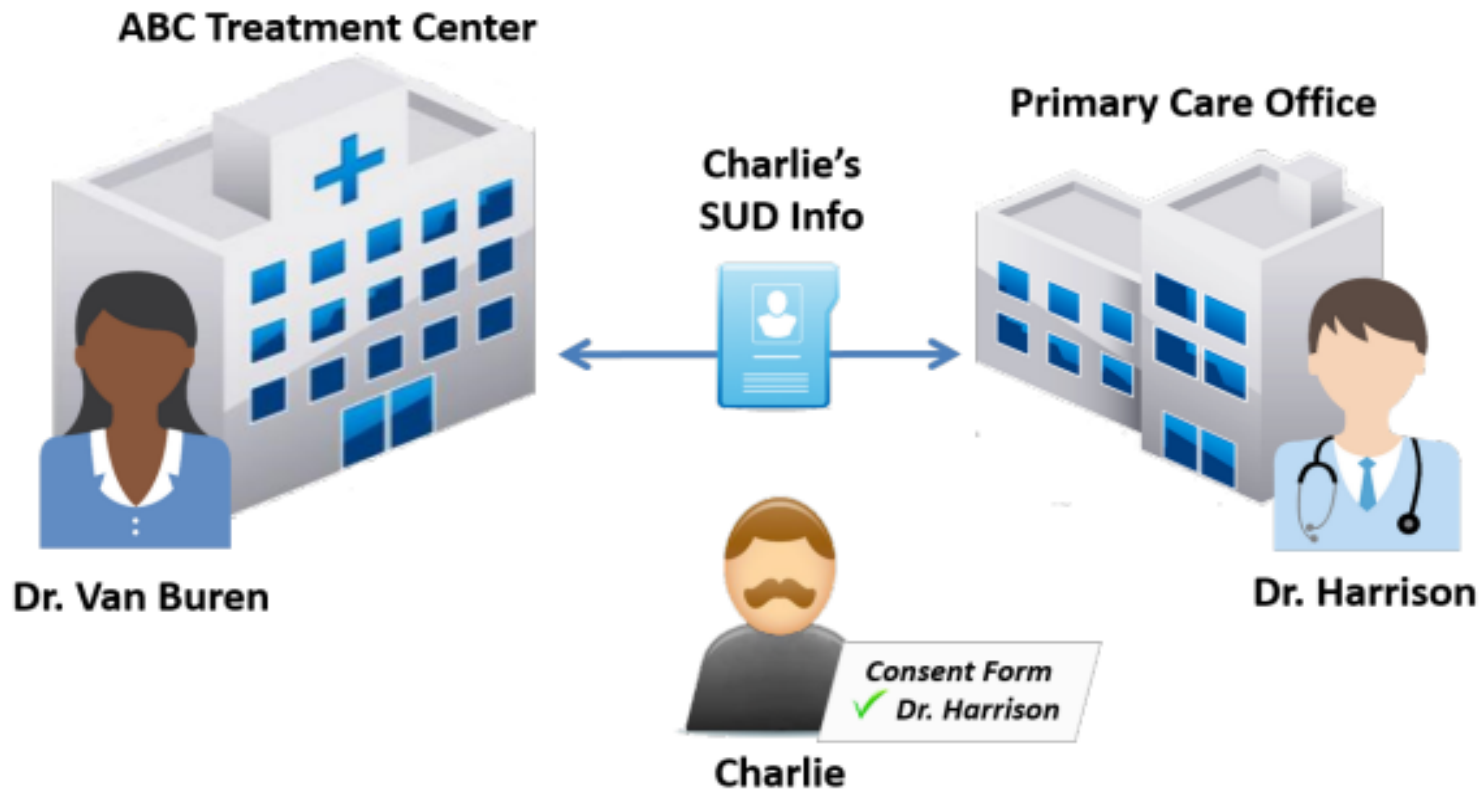
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## 42 CFR part 2

- Lawful holders may disclose info to contractors, subs and legal representatives to carry out purpose of disclosure if have contract with recipient by which they agree to be bound by Part 2.
- Lawful holder must provide notice of re-disclosure, protect info, and report unauthorized uses, disclosures or breaches.

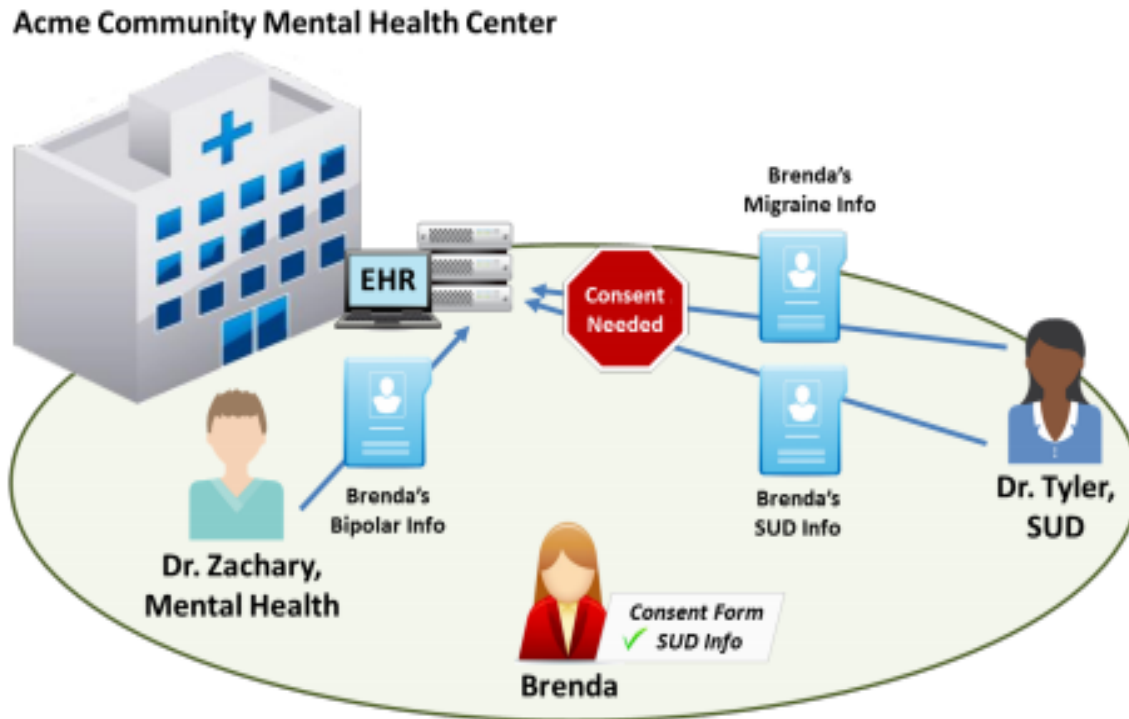
# Scenario: Treatment Program

## SCENARIO 1: OPIOID TREATMENT PROGRAM



# Scenario: Mixed-Use Facility

## SCENARIO 2: MIXED-USE FACILITY





# Scenario: Integrated Care Setting

## SCENARIO 4: INTEGRATED CARE SETTING



### Blue Mountain Physician Group

- Primary care, integrated setting
- Does not advertise SUD treatment



### Dr. Pierce

- DEA registration
- SAMSHA waiver
- SUD not primary function

### Brooke

# Minors

## HIPAA

- If minor may consent to their own care, generally cannot disclose PHI to parents.
- May disclose for purposes of payment unless prohibited by state law.

## 42 CFR part 2

- If minor may consent to care, generally may not disclose info to parent/guardian.
  - May not disclose to obtain payment.
  - May refuse to provide care unless consent is given.
- If minor may not consent to care:
  - Cannot disclose minor's request for treatment to parent/guardian without minor's written consent unless minor not rational.
  - Any consent for disclosure to others must be signed by minor and parent/guardian.
- If minor poses substantial threat and not rational, may disclose to parent/guardian.

# Incompetent Persons Other than Minors

## HIPAA

- Surrogate authorized by state law may make decisions concerning the patient's PHI, e.g.,
  - Guardian
  - Agent in DPOA
  - Spouse
  - Adult child
  - Parent
  - Other family member
  - Other care giver

## 42 CFR Part 2

- If patient has been adjudicated as incompetent, consent for disclosure may be given by surrogate authorized by state law.
- If patient has not been adjudicated as incompetent but suffers from medical condition that prevents knowing or acting, program director may consent for sole purpose of obtaining third party payment.

# Deceased Patients

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## HIPAA

- May disclose to the extent required by state law, e.g., vital statistics, death by suspicious circumstances, etc.
- May disclose to family members unless patient objected prior to death.
- Personal representative may authorize disclosures.

## 42 CFR Part 2

- May disclose for vital statistics relating to cause of death.
- Consent for other disclosures may be given by:
  - Personal representative of estate or, if none:
  - Spouse or, if none:
  - Any responsible family member.

# Subpoenas and Orders

## HIPAA

May disclose if have:

- Order or subpoena signed by judge or magistrate.
- Grand jury subpoena.
- Subpoena signed by attorney or clerk of court, but only if:
  - Patient notified and given chance to object, or
  - Qualified protective order in place.

## 42 CFR part 2

May disclose if have:

- Subpoena + court order authorizing disclosure.
  - Protect life or serious bodily injury.
  - Extremely serious crime committed by patient.
  - Criminal prosecution.
  - Investigate Part 2 program.
- Process for obtaining order, including notice to holder of record.

# Disclosures to Prevent Multiple Enrollments

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## 42 CFR part 2

- Part 2 program may disclose records to central registry or withdrawal management or treatment program < 200 miles to prevent multiple enrollments if:
  - Have patient consent that names registry or programs, except may generally refer to programs < 200 miles.
  - Disclosure is made when patient accepted treatment; drug changed; treatment interrupted, resumed or terminated.
  - Disclosure limited to certain info.
- Registry or withdrawal program may communicate to avoid multiple enrollments.

# Disclosures to Criminal Justice System that Have Referred Patient

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## 42 CFR part 2

- If patient referred by criminal justice system as condition in criminal proceeding or parole, part 2 program may disclose info about patient to the individuals in justice system if:
  - Disclosure limited to those officers with duty to monitor, and
  - Patient signs written consent that satisfies certain elements.
- Person in criminal justice system may only use and re-disclose info to carry out duties regarding patient's conditional release or parole.

# Identification Cards

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## 42 CFR part 2

- May require ID cards within program.
- May not require ID cards away from program.



# Notice of Confidentiality Protections

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## **HIPAA**

### **Notice of Privacy Practices**

- **First date of treatment.**
- **Post on website and in facility**
- **Contains required elements and statements.**
- **Good faith effort to obtain patient's acknowledgment of receipt.**

## **42 CFR part 2**

### **Written Notice**

- **Upon admission.**
- **Summarize federal law re confidentiality, including:**
  - **Limited situations in which program may acknowledge that person is a patient.**
  - **Violation of law is a crime + contact info for making reports.**
  - **Permissible disclosures to police.**
  - **Child abuse reporting permitted.**
  - **Cite federal regs.**

# Patient Access to Records

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## HIPAA

- Patient or personal rep generally has right to access or obtain copy of PHI in designated record set except:
  - Psychotherapy notes.
  - Provider determines that access may endanger patient or others; subject to review.
- Must respond within 30 days.
- May charge reasonable cost-based fee.

## 42 CFR part 2

- May provide records to patient.

# Amendment of Records

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## HIPAA

- Patient or personal rep generally has right to request amendment of records in designated record set.
- May deny if:
  - Did not create the record unless creator not available.
  - Record is accurate and complete.
- Must respond within 60 days.
  - If accept, must amend records and notify others.
  - If deny, must notify patient and allow patient to attach statement of disagreement.

## 42 CFR part 2

- Not addressed

# Accounting of Disclosures

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## HIPAA

- Patient has a right to request accounting of disclosures made in prior 6 years:
  - In violation of HIPAA.
  - Under certain HIPAA exceptions.
  - Not disclosures per authorization.
- May require written request.
- Provider must respond within 60 days.
- Must provide certain info about disclosures.

## 42 CFR part 2

- Patient who has consented to disclosure through general designation has right to list of disclosures for prior 2 years.
- Patient must submit written request.
- Intermediary must respond within 30 days.
- Must list names, dates, and description of disclosures.

# Administrative Requirements

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## HIPAA

- Designate HIPAA privacy and security officers
- Implement policies and safeguards
- Train workforce
- Respond to complaints
- Mitigate violations
- Maintain documents relating to HIPAA compliance for 6 years

## 42 CFR part 2

- Not addressed

# Security

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## HIPAA

- **Privacy Rule:** covered entities must implement reasonable safeguards.
- **Security Rule:** covered entities and business associates must implement specific administrative, technical and physical safeguards for e-PHI.

## 42 CFR part 2

- Programs and entities receiving info must have policies addressing at least:
  - Transfer and removing records
  - Destroying records
  - Maintaining records in secure room or location
  - Using and accessing workstations, secure rooms, etc.
  - De-identification of records

# Disposition of Records

## HIPAA

- Covered entity must protect or destroy records consistent with standards.
- Covered entity may transfer records to successor.
- Business associate must return or destroy records if feasible.

## 42 CFR part 2

- If program discontinues or is taken over, it must de-identify or destroy records unless:
  - Patient consents to transfer; or
  - Applicable law requires records to be retained for period.
    - Requirements concerning how paper or electronic records must be maintained.
    - Destroy records upon expiration of retention period.

# Reporting Violations

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## HIPAA

- Must report breach of unsecured PHI to patient and HHS unless you can demonstrate there is a low probability that the data has been compromised.
- “Breach” = unauthorized access, use or disclosure in violation of the HIPAA Privacy Rule.

## 42 CFR part 2

- No duty to self-report.




# Additional Resources





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# <https://www.hhs.gov/hipaa/for-professionals/index.html>





HHS.gov  
U.S. Department of Health & Human Services  
Health Information Privacy

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## HIPAA for Professionals

To improve the efficiency and effectiveness of the health care system, the [Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#), Public Law 104-191, included Administrative Simplification provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.

- HHS published a final [Privacy Rule](#) in December 2000, which was later modified in August 2002.

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6/28/2018

# <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>

Confidentiality Regulation x

Secure | <https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs>

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Listening Session  
Comments on Substance Abuse Treatment Confidentiality Regulations

Interagency Activities

## Substance Abuse Confidentiality Regulations

Frequently Asked Questions (FAQs) and Fact Sheets regarding the Substance Abuse Confidentiality Regulations.

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### Fact Sheets regarding the Substance Abuse Confidentiality Regulations

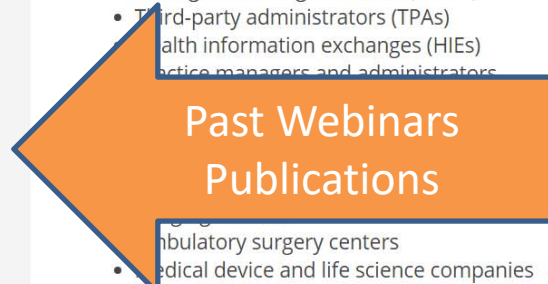
- [Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?](#)
  - This fact sheet explains a 42 CFR Part 2 Program and how healthcare providers can determine how Part 2 applies to them.
- [Disclosure of Substance Use Disorder Patient Records: How Do I Exchange Part 2 Data?](#)
  - This fact sheet describes how 42 CFR Part 2 applies to the electronic exchange of healthcare records with a Part 2 Program.

### Applying the Substance Abuse Confidentiality Regulations

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

<https://www.hollandhart.com/healthcare#overview>

The screenshot shows the top of the Holland & Hart website. The header includes the slogan "EXCELLENCE IN LEGAL SERVICES" and the firm's logo, which features a stylized mountain peak and the text "HOLLAND & HART" along with "70 YEARS EST. 1947". A navigation menu is visible on the left. The main content area is titled "OVERVIEW" and includes sections for "PRACTICES/INDUSTRIES", "NEWS & INSIGHTS", and "CONTACTS". Under "CONTACTS", there are two profile cards for Kim Stanger and Blaine Benard. Below the contact section is a "HEALTH LAW BLOG" section with a sub-headline "Access to previous webinar recordings, publications, and more." The bottom of the page shows a Windows taskbar with various application icons and a system tray with the time "7:34 AM" and date "2/8/2017".





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